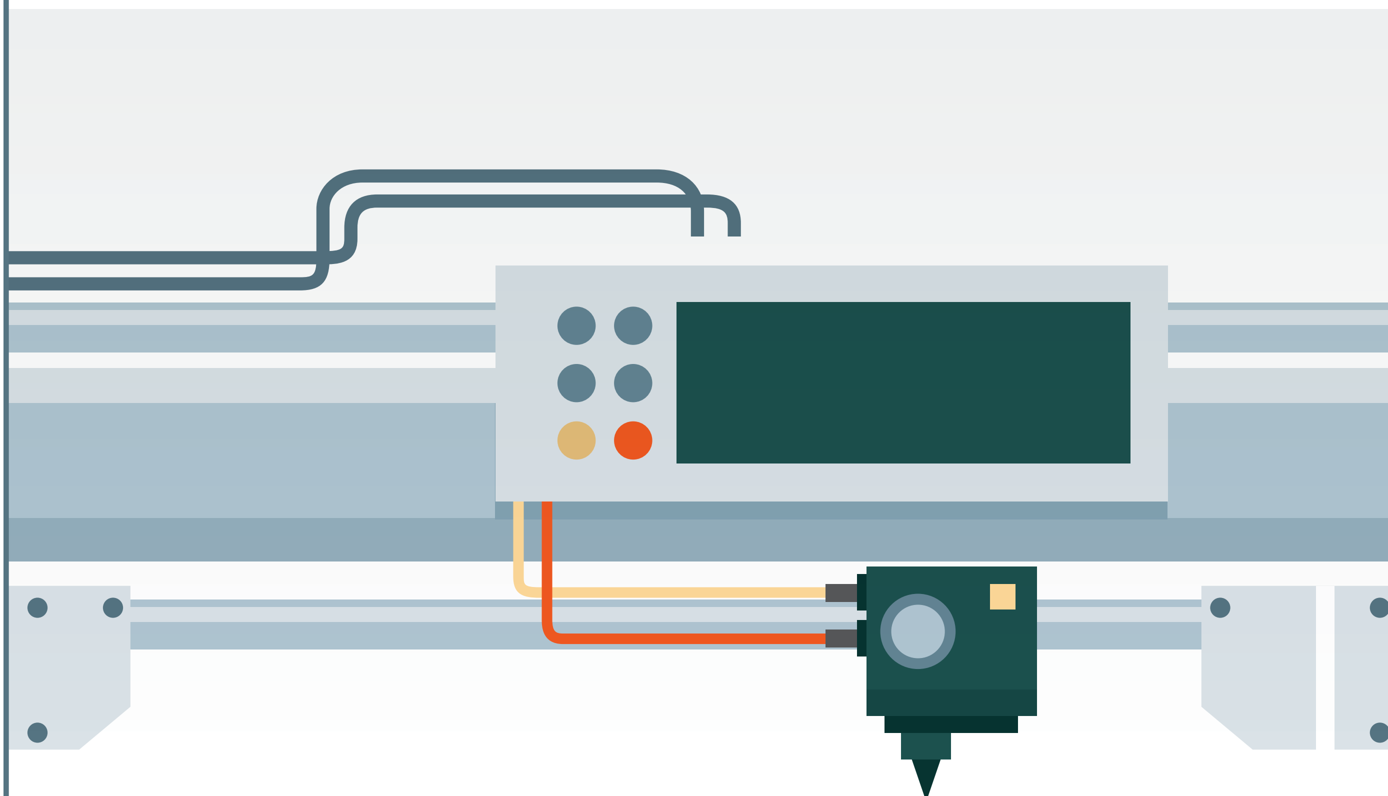

STANDARDIZATION ROADMAP FOR ADDITIVE MANUFACTURING

Version 3.0 | July 2023

Prepared by the America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC)

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The roadmap is based on a consensus of those who actively participated in its development and does not necessarily reflect the views of the individuals or organizations listed below. The employment status and organizational affiliation of participants may have changed during the course of this project.

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Executive Summary

In March, 2016, America Makes and the American National Standards Institute (ANSI) launched the America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC). The AMSC was established to coordinate and accelerate the development of industry-wide additive manufacturing (AM) standards and specifications consistent with stakeholder needs and thereby facilitate the growth of the AM industry.

America Makes is the nation's leading public-private partnership for additive manufacturing technology and education. Its members work together to accelerate the adoption of AM and the nation's global manufacturing competitiveness. Founded in 2012 as the Department of Defense's manufacturing innovation institute for AM, and first of the Manufacturing USA network, America Makes is managed by the National Center for Defense Manufacturing and Machining (NCDMM).

Founded in 1918, ANSI serves as administrator and coordinator of the private-sector led voluntary standardization system in the United States. As a neutral facilitator, the Institute has a successful track record of convening stakeholders from the public and private sectors to define standardization needs for emerging technologies and to address national and global priorities.

The catalyst for the AMSC was the recognition that a number of standards development organizations (SDOs) are engaged in standards-setting for various aspects of additive manufacturing, prompting the need for coordination to maintain a consistent, harmonized, and non-contradictory set of additive manufacturing standards. The AMSC does not develop standards. Rather, it identifies standardization needs and facilitates coordination among SDOs and others.

This *Standardization Roadmap for Additive Manufacturing, Version 3.0* is an update to version 2.0 of this document published in June 2018. It identifies existing standards and standards in development, assesses gaps, and makes recommendations for priority areas where there is a perceived need for additional standardization and/or pre-standardization research and development. The focus is industrial additive manufacturing, across market sectors that are using AM.

The roadmap has identified a total of 141 open gaps and corresponding recommendations across six topical areas: 1) design; 2) process and materials (precursor materials, process control, post-processing, and finished material properties); 3) qualification and certification; 4) nondestructive evaluation; 5) maintenance and repair; and 6) data. Of that total, 54 gaps/recommendations have been identified as high priority, 64 as medium priority, and 23 as low priority. A "gap" means no *published* standard or specification exists that covers the particular issue in question. In 91 cases, additional research and development (R&D) is needed.

As with the earlier versions of this document, the hope is that the roadmap will see broad adoption by the user community and will facilitate a more coherent and coordinated approach to the future development of standards and specifications for additive manufacturing. It is envisioned that the roadmap will be widely promoted and that progress on its implementation will be tracked.

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Highlights of Roadmap Version 3.0

Summary Table of Gaps and Recommendations

Accompanying this roadmap is a ***Summary Table of Gaps and Recommendations*** identified in this document. The table is actually a sortable spreadsheet. Sorting and filtering of gaps can be done on columns that may be of interest such as R&D Needed, Priority, Status of Progress, Lifecycle Area, Sector, Material Type, Process Categories, and Qualification and Certification (Q&C) Categories. In the case of Priority and Status of Progress, there are some instances where more than one value is listed, for example, in relation to different Material Types.

Consult chapter 2 of the roadmap itself for the full discussion of issues and identified published and in-development standards that precede each gap, along with the text of the gaps.

Significant Changes from Version 2.0

The process of developing this roadmap version 3.0 included a comprehensive review of all content in the *Standardization Roadmap for Additive Manufacturing* (version 2.0, June 2018) including all previously identified gaps for ongoing relevancy. Many sections and previously identified gaps were substantially revised, and many new sections and gaps were added. Below are additional changes from version 2.0 that might not otherwise be immediately apparent from a review of the table of contents or the gaps themselves. This is not an exhaustive list of all changes that were made to the document.

High-Level Structural and Content Changes

- Links to relevant published and in-development standards continue to be listed in the roadmap text ahead of the corresponding gaps. There is no longer a separate spreadsheet of standards accompanying the roadmap.
- The introduction has been streamlined. Section 1.4, List of Organizations Covered in this Roadmap, has been added, replacing what was section 1.5 in v2.
- An entire new section, 2.6 on Data across the AM lifecycle, has been added.
- Carryover gaps from version 2.0 retain their original numbering except where noted. Design section gaps are now are renumbered “DE” and “DA” is used for Data section gaps.

Repositioned v2 Roadmap Sections/Subsections

- 2.2.1.4, Precursor Material Handling: Use, Reuse, Mixing, and Recycling Feedstock (was 2.2.2.7 in v2)
- 2.6.7.2, Cybersecurity (was 2.5.7 in v2)

Summary of Open Gaps

- 141 open gaps are identified in version 3.0, including 60 new gaps. Of these

  - 54 are High priority* (should be addressed in 0-2 years)
  - 64 are Medium priority (should be addressed in 2-5 years)
  - 23 are Low priority (should be addressed in 5+ years)
- 91 gaps require research and development

* priority in terms of desired timeframes for having a published standard

Breakdown of Open Gaps by Lifecycle Area

Section	High Priority (0-2 years)	Medium Priority (2-5 years)	Low Priority (5+ years)	Total
Design	8	11	2	21
Precursor Materials	2	9	8	19
Process Control	2	8	3	13
Post-processing	1	4	3	8
Finished Material Properties	9	0	1	10
Qualification & Certification	13	10	3	26
Nondestructive Evaluation	5	6	1	12
Maintenance & Repair	1	4	2	7
Data	13	12	0	25
Total	54	64	23	141

Closed v2 Gaps (4)

- Gap DE1: Decision Support: Additive vs. Traditional
- Gap DE2: Decision Support: Additive Processes
- Gap DE19: Organization Schema Requirement and Design Configuration Control
- Gap DE21: New Terminology in Design Documentation

Withdrawn v2 Gaps (8)

- Gap DE5: Support for Customizable Guidelines
- Gap DE6: Software-encodable/Machine-readable Guidelines
- Gap DE22: In-Process Monitoring
- Gap PM3: Particle Size and Particle Size Distribution
- Gap PC10. Re-use of Material that Has Not Been Processed
- Gap PC11: Re-use of Material that Has Been Processed
- Gap QC12: Resorbable Materials
- Gap M3: AM Level of Repair Analysis

Repositioned v2 Gaps

- Gap PM9: Characterization of Material Extrusion Feedstock (Filaments & Pellets) under 2.2.1.5.3 (was under 2.2.1.4.5 in v2)
- Gap PM13 (was Gap PC9 in v2): Environmental Conditions: Effects on Materials under 2.2.1.2.1 (was under 2.2.2.7 in v2)
- Gap PM18 (was Gap PC7 in v2): Recycle & Reuse of Materials under 2.2.1.4 (was under 2.2.2.7 in v2)
- Gap DA10 (was Gap NDE5 in v2): Data Fusion under 2.6.3.1 (was under 2.4.5 in v2)
- Gap DA21 (formerly M7 in V2): Additive Manufacturing Supply Chain Security under 2.6.7.2 (was under 2.5.7 in v2)

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Breakdown of High, Medium, and Low Priority Gaps

Note: The table below contains navigational hyperlinks to the full text of the gaps as they appear in the roadmap.

Key:

DE – Design (2.1)
PM – Precursor Materials (2.2.1)
PC – Process Control (2.2.2)
P – Post-processing (2.2.3)
FMP – Finished Material Properties (2.2.4)
QC – Qualification & Certification (2.3)
NDE – Nondestructive Evaluation (2.4)
M – Maintenance & Repair (2.5)
DA – Data (2.6)

Section #	Gap #, Title and Description	High	Medium	Low
2.1.2.1	Gap DE1: Decision Support: Additive vs. Traditional (Closed)		X	
2.1.2.1	Gap DE2: Decision Support: Additive Processes (Closed)		X	
2.1.2.2	Gap DE3: Process-Specific Design Guidelines		X	
2.1.2.3	Gap DE4: Design Guides for Specific Applications		X	
2.1.2.4	Gap DE5: Support for Customizable Guidelines (Withdrawn)		X	
2.1.2.5	Gap DE7: Design Guide for Post-processing		X	
2.1.3.1	Gap DE8: Machine Input and Capability Report		X	
2.1.3.2	Gap DE9: AM Simulation Benchmark Model/Part Requirement	X		
2.1.4.1	Gap DE10: Design for As-built Assembly			X
2.1.4.2	Gap DE11: Design for 3D Printed Electronics		X	
2.1.4.3	Gap DE12: Imaging Consistency	X		
2.1.4.3	Gap DE13: Image Processing and 2D to 3D Conversion		X	
2.1.2.6	Gap DE14: Designing to be Cleaned		X	
2.1.2.7	Gap DE15: Design of Test Coupons	X		
2.1.2.7	Gap DE16: Verifying Functionally Graded Materials (FGM)		X	
2.1.5.1	Gap DE17: Contents of a Data Package	X		
2.1.5.3	Gap DE18: New Dimensioning and Tolerancing Requirements	X		
2.1.5.4	Gap DE19: Organization Schema Requirement and Design Configuration Control (Closed)	X		
2.1.5.5	Gap DE20: Neutral Build File Format		X	
2.1.5.6	Gap DE21: New Terminology in Design Documentation (Closed)		X	
2.1.5.8	Gap DE23: Documentation of New Functional and Complex Surface Features			X
2.1.6	Gap DE26: Design for Measurement of AM Features/Verifying the Designs of Features such as Lattices, etc.		X	
2.1.3.3	Gap DE27: Standardized Design for Additive Manufacturing (DFAM) Process Chain		X	

Section #	Gap #, Title and Description	High	Medium	Low
2.1.5.8	Gap DE28: Specification of Surface Finish	X		
2.1.7	New Gap DE29: Best Practices for Design for Anti-counterfeiting		X	
2.1.5.2	New Gap DE30: STEP Based 3D PDF	X		
2.1.5.2	New Gap DE31: Feature-based Support for STEP	X		
2.2.1.3.2	Gap PM1: Flowability		X	
2.2.1.3.3	Gap PM2: Spreadability		X	
2.2.1.3.6	Gap PM4: Particle Morphology		X	
2.2.1.3.7	Gap PM5: Metal Powder Feedstock Sampling		X	
2.2.1.3.8	Gap PM6: Hollow Particles and Hollow Particles with Entrapped Gas			X
2.2.1.3.9	Gap PM7: Metal Powder Specifications for Procurement Activities in Support of AM		X	
2.2.1.3.1	Gap PM8: Use of Recycled Polymer Precursor Materials			X
2.2.1.5.3	Gap PM9: Characterization of Material Extrusion Feedstock (Filaments & Pellets)			X
2.2.1.6.3	Gap PM10: Sampling of Open Liquid Feedstock System			X
2.2.1.2	New Gap PM11: Segregation of Powder		X	
2.2.1.2	New Gap PM12: Requirements for Large Storage and Transport Vessels of Powder Feedstock		X	
2.2.1.2.1	Gap PM13 (was Gap PC9 in v2): Environmental Conditions: Effects on Materials			X
2.2.1.3.1	New Gap PM14: Test Method to Assess Hydrogen Content in Aluminum Powder Feedstocks		X	
2.2.1.3.1	New Gap PM15: Identification and Quantification of Impurities in Chemical Compositions			X
2.2.1.3.5	New Gap PM16: Universal Reference Standard on Size Distribution			X
2.2.1.3.5	New Gap PM17: Error Quantification of PSD Measurement Methods		X	
2.2.1.4	Gap PM18 (was Gap PC7 in v2): Recycle & Reuse of Materials	X		
2.2.1.4.1	New Gap PM19: Terminology Related to Reuse of Feedstock Materials	X		
2.2.1.4	New Gap PM20: Recycling the Polymeric Structures to Fabricate Filaments			X
2.2.2.2	Gap PC1: Digital Format and Digital System Control		X	
2.2.2.3	Gap PC2: Machine Calibration and Preventative Maintenance	X		
2.2.2.3	Gap PC3: Machine Health Monitoring			X
2.2.2.4	Gap PC4: Machine Qualification and Re-Qualification		X	
2.2.2.5	Gap PC5: Parameter Control		X	
2.2.2.6	Gap PC6: Adverse Machine Environmental Conditions: Effect on Component Quality			X
2.2.2.7	Gap PC8: Stratification		X	
2.2.2.9	Gap PC12: Precursor Material Flow Monitoring		X	

Section #	Gap #, Title and Description	High	Medium	Low
2.2.2.9	Gap PC13: Flow Parameters for Material Jetting			X
2.2.2.10	Gap PC14: Environmental Health and Safety: Protection of Machine Operators	X		
2.2.2.11	Gap PC15: Configuration Management		X	
2.2.2.12	Gap PC16: In-Process Monitoring		X	
2.2.2.8	New Gap PC18: Powder Blending and Powder Mixing Terminology		X	
2.2.3.1	Gap P1: Post-processing Qualification, Validation, and Production Builds		X	
2.2.3.2	Gap P2: Heat Treatment (HT)-Metals		X	
2.2.3.3	Gap P3: Hot Isostatic Pressing (HIP)		X	
2.2.3.4	Gap P4: Surface Texture (Surface Finish)		X	
2.2.3.6	Gap P5: Use of Post-cure to Reduce Toxic Gases from Uncured Polymer Feedstock			X
2.2.3.6	Gap P6: Guidelines for Post-curing AM Plastics to Address Outgassing and Offgassing			X
2.2.3.2	Gap P7: Heat Treatment (HT)-Polymers			X
2.2.3.7	New Gap P8: EHS Hazards Related to Post-Processing Tasks	X		
2.2.4.2.2	Gap FMP1: Material Properties (Metals)	X		
2.2.4.5	Gap FMP3: Removal of AM Feedstock from Medical AM Parts	X		
2.2.4.7	Gap FMP4: Material Allowables	X		
2.2.4.8	Gap FMP5: Microstructure	X		
2.2.4.1.1	New Gap FMP6: Finished Material Properties Terminology			X
2.2.4.2.1	New Gap FMP7: Material Properties: Specification Content Requirements	X		
2.2.4.2.3	New Gap FMP8: Material Properties (Non-Metals)	X		
2.2.4.2.4	New Gap FMP9: Material Properties: Test Methods (Metals and Non-Metals)	X		
2.2.4.9	New Gap FMP10: Catalogs of Process Specific Defect Types	X		
2.2.4.9	New Gap FMP11: Assessment of Models Linking Defect Structures and Material Performance	X		
2.3.1	Gap QC1: Harmonization of AM Q&C Terminology	X		
2.3.3.1.2	Gap QC2: AM Part Risk Classification System for Consistent Qualification Standards	X		
2.3.3.4	Gap QC3: Harmonizing Q&C Terminology for Process Parameters		X	
2.3.3.4	Gap QC4: Process Approval for DoD-procured Parts		X	
2.3.3.4	Gap QC5: Machine Operator Training and Qualification			X
2.3.3.7.2	Gap QC6: Importing 3D Source Data to CAD Application for Creation of Design File		X	
2.3.3.7.3	Gap QC7: Imaging Protocols		X	
2.3.3.7.6	Gap QC8 Phantoms		X	
2.3.3.7.5	Gap QC9: Personnel Training for Image Data Set Processing	X		
2.3.3.7.13	Gap QC10: Verification of 3D Model	X		

Section #	Gap #, Title and Description	High	Medium	Low
2.3.3.7.10	Gap QC13: Material Control Data and Procedures			X
2.3.3.7.4	Gap QC14: Segmentation		X	
2.3.3.7.14	Gap QC15: Sterilization of AM Medical Products			X
2.3.3.7.15	Gap QC16: Sterilization of 3D Printed Tissue Engineered Products		X	
2.3.3.1.2	New Gap QC17: AM Part Material Development Timeline	X		
2.3.3.1.2	New Gap QC18: OQ/PQ Process Know-How	X		
2.3.3.1.2	New Gap QC19: Workforce Training		X	
2.3.3.1.2	New Gap QC20: Certifying agency KPV Checklist		X	
2.3.3.1.2	New Gap QC21: Detailed Requirements Integration Document		X	
2.3.3.5	New Gap QC22: Additively Manufactured Electronics (AME)	X		
2.3.3.6.1	New Gap QC23: Production and Incorporation of AM Parts in Nuclear Applications and Facilities	X		
2.3.3.6.1	New Gap QC24: Nuclear AM Component In-service Performance	X		
2.3.3.6.1	New Gap QC25: Nuclear Industry Use of Artificial Intelligence (AI) and Machine/System Learning Technologies to Qualify AM Parts	X		
2.3.3.6.1	New Gap QC26: Nuclear Industry Use of Material and Production Data Combined with Digital Analysis and Diagnostic Informed Qualification of AM Components	X		
2.3.3.6.1	New Gap QC27: Use and Qualification of AM Non-Metallic Advanced Materials in Support of New or Advanced Nuclear Fuel and High-temperature Reactor Applications	X		
2.3.3.6.2	New Gap QC28: Susceptibility of AM Products to Corrosion and Environmental Cracking Mechanisms	X		
2.4.2	Gap NDE1: Terminology for the Identification of AM Anomalies Interrogated by NDE Methods	X		
2.4.2	Gap NDE2: Standard for the Design and Manufacture of Physical Reference Standards, Image Quality Indicators, and Representative Quality Indicators to Demonstrate NDE Capability		X	
2.4.3	Gap NDE3: Standard Guide for the Application of NDE to Objects Produced by AM Processes	X		
2.4.4	Gap NDE4: Dimensional Metrology of Internal Features		X	
2.4.6	Gap NDE6: NDE of Polymers, Ceramics, and Composite Materials		X	
2.4.7	Gap NDE7: NDE of Counterfeit AM Parts			X
2.4.8	Gap NDE8: NDE Acceptance Criteria for Fracture Critical AM Parts	X		
2.4.9	New Gap NDE9: Effect-of-Defect of AM Defects Detectable by NDE		X	
2.4.10	New Gap NDE10: In-service Inspection		X	
2.4.3.1	New Gap NDE11: Reliability of NDT		X	

Section #	Gap #, Title and Description	High	Medium	Low
2.4.3.2	New Gap NDE12: 3D Image Quality Indicator for Determining the Sensitivity of a CT System	X		
2.4.3.3	New Gap NDE13: Reference Radiographic Images and Standards for Additive Manufacturing Anomalies	X		
2.5.2	Gap M1: AM Analyses in RCM and CBM		X	
2.5.4	Gap M4: Physical Inspection of Parts Repaired Using AM		X	
2.5.5	Gap M5: Model-Based Inspection		X	
2.5.6	Gap M6: Tracking Maintenance			X
2.5.7	Gap M8: Surface Preparation for Additive Repair		X	
2.5.3	Gap M9: Laser Based Additive Repair	X		
2.5.7	New Gap M10: Best Practices on Repair using Additive Manufacturing			X
2.6.2.1	New Gap DA1: Standard Data Format for Material Characterization	X		
2.6.2.2	New Gap DA2: Process Specific Common Data Dictionary	X		
2.6.2.3	New Gap DA3: Digital Format for In Process Monitoring Data	X		
2.6.2.4	New Gap DA4: Data Capturing for Machine Logs During a Build	X		
2.6.2.5	New Gap DA5: Extended Design Specifications for Meta-Data Format Standardization	X		
2.6.2.6	New Gap DA6: Specifications and Representations for AM Big Data		X	
2.6.2.7	New Gap DA7: Additively Manufactured Electronics (AME) Data Transfer Format	X		
2.6.2.8	New Gap DA8: Customizable Standard AM Data Collection Templates	X		
2.6.3.1	New Gap DA9: Best Practices and/or Specifications for Registering and Fusing Data Sets During the AM Manufacturing and Inspection Process	X		
2.6.3.1	Gap DA10 (formerly NDE5 in V2): Standard Guideline for NDE Data Fusion		X	
2.6.3.2	New Gap DA11: Best Practices for Anomaly Characterization and Localization for Part Defect Prediction Purpose	X		
2.6.3.3	New Gap DA12: Consistent Part Traceability and Provenance (Digital Twin)		X	
2.6.3.4	New Gap DA13: Data Visualization		X	
2.6.4.1	New Gap DA14: Best Practices and Guidance for AM Data Collection	X		
2.6.4.2	New Gap DA15: Data Aggregation of Time Series and Object Data		X	
2.6.4.3	New Gap DA16: Data Retention Guidelines		X	
2.6.5	New Gap DA17: Assessment and Specifications of AM Data Quality		X	

Section #	Gap #, Title and Description	High	Medium	Low
2.6.6.1	New Gap DA18: Reference Workflow (Digital thread) for AM Part Fabrication		X	
2.6.6.2	New Gap DA19: Context and Scenario-specific Data Selection		X	
2.6.7.1	New Gap DA20: AM-Specific Security Guidance		X	
2.6.7.2	Gap DA21 (formerly M7 in V2): Additive Manufacturing Supply Chain Security		X	
2.6.7.3	New Gap DA22: Technical and IP Authentication and Protection	X		
2.6.8.1	New Gap DA23: AM Machine Data Framework and Guideline for Automated AM Data Integration and Management	X		
2.6.9.1	New Gap DA24: Medical AM Design File Retention		X	
2.6.9.2	New Gap DA25: Quality Management of Medical AM Files	X		
	Total Open Gaps	**54**	**64**	**23**

1. Introduction

Additive Manufacturing (AM), sometimes referred to as three-dimensional printing (3DP), encompasses a variety of processes wherein a 3D object is produced from a digital model by adding successive layers of material to create the object. In name, it stands in contrast to traditional or subtractive manufacturing where material is removed through machining or other means to create an object.

AM as a field has grown significantly over many years, where it offers significant potential cost savings and shortening of the supply chain by allowing parts to be manufactured on-site rather than at a distant supplier. Its use is also driven by AM-enabled designs that provide unique performance characteristics and efficiencies that cannot be achieved through subtractive machining.

The process for making production AM parts may be summarized as follows:

- Design the part for AM
- Specify the materials from which the part will be built
- Establish build parameters
- Control the AM build process to achieve the desired part's dimensions, structure, and performance properties
- Perform post-processing steps
- Final testing
- Certify the part's fitness-for-use
- Maintain/repair machines, parts, and systems

Standards, specifications, and related conformance and training programs, are integral to this process and are a key enabler for the large-scale introduction and growth of AM.

1.1 Background on the AMSC and Catalyst for this Roadmap

The America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC) was established in the first quarter of 2016. America Makes and the American National Standards Institute (ANSI) entered into an agreement to create a roadmap that would identify AM standards and specifications that have been published, or that are in development, or that are otherwise needed.

Federal agencies, including the National Institute of Standards and Technology (NIST), Department of Defense (DoD), Federal Aviation Administration (FAA), and others, as well as several standards development organizations (SDOs), supported the formation of the AMSC.

America Makes, as the nation's leading public-private partnership for additive manufacturing technology and education, engaged ANSI because of the Institute's role as neutral coordinator and administrator of the U.S. private sector system of voluntary standardization, and its past success in producing consensus-based standardization roadmaps when there was a perceived need for such coordination. The AMSC has not undertaken to develop standards, as ANSI's charter expressly prohibits the Institute from doing so.

The establishment of the AMSC complemented America Makes' formulation of a standards strategy for AM. America Makes recognized the need for, and importance of, AM standards and conformance procedures to advance the adoption of AM technologies in the U.S., for example, for use by industry during qualification of AM materials, processes, and systems, and by regulatory bodies during certification of AM parts.

America Makes also recognized that a number of SDOs, both U.S. based and elsewhere, are engaged in producing voluntary consensus standards for AM to meet the needs of different industries. The existence of these parallel standards-setting activities increased the need for U.S. leadership and coordination toward achieving a consistent, harmonized, and non-contradictory set of AM standards for use by the AM community.

Thus, the AMSC project endeavored to bring together the community of stakeholders, including original equipment manufacturers (OEMs), industry, government, academia, and SDOs, to develop a coherent roadmap of existing and needed standards for additive manufacturing. Participation in the effort was open to any AM stakeholder having operations in the United States, regardless of America Makes and/or ANSI membership status.

Version 1.0 of the roadmap was published in February 2017, with a heavy focus on metallic AM and largely informed by interests in the aerospace, defense, and medical sectors. Version 2.0 of the roadmap was published in June 2018 with expanded content on polymer AM across the document and additional input from other sectors such as the electronic and electrical products industry. Building on the earlier efforts, version 3.0 introduces a section on data and again expands the use of AM by other industry sectors such as oil & natural gas, and nuclear.

Over the years, the roadmap has been promoted at various industry events. During 2020-2021, the AMSC held a series of virtual events addressing different aspects of the roadmap, including process control to enable qualification, design for additive manufacturing, feedstock materials, and inspection/monitoring. The AMSC also issued semi-annual progress reports to maintain the roadmap as a "living document," tracking the publication of new standards or the initiation of new standards projects by SDOs to address the gaps and recommendations outlined in the roadmap.

Following a survey about use of the roadmap conducted in early 2022, the AMSC advisory group – a steering committee comprising industry, government, and SDO representatives that provides overall strategic direction – concluded it was time to again update the document to maintain its relevancy and alignment with current practices and stakeholder needs.

1.2 Roadmap Goals, Boundaries, and Target Audience

Ultimately, the goal of this roadmap is to coordinate and accelerate the development of industry-wide AM standards and specifications, consistent with stakeholder needs. The intent is to facilitate the growth of the AM industry.

Building on the prior AMSC efforts, this roadmap seeks to describe the current and desired future standardization landscape that will support and facilitate the widespread adoption of AM. It identifies key issues, notes relevant published and in-development standards, and makes recommendations to address gaps in standards. This includes recommending pre-standardization research and development (R&D) where needed. It also includes identification of prioritized timeframes for when standardization work should occur and SDOs or other organizations that may be able to lead such work. It seeks to facilitate coordination among SDOs to maintain a common framework of AM standards and specifications.

The roadmap's focus is industrial AM, across market sectors that are using AM technologies. In terms of what is out of scope, the consumer desktop 3D printing market is not addressed in this roadmap.

The roadmap is targeted toward a broad audience including OEMs, material producers, government and industry users of AM, SDOs, the R&D community, and others. The roadmap may assist:

- SDOs in identifying opportunities to coordinate and collaborate.
- Government agencies in advancing U.S. policy objectives.
- Industry with deployment of AM technologies and identifying commercial opportunities.
- All stakeholders with focusing standards participation resources.
- Raising awareness and understanding of the issues around AM.

It is assumed that those reading the roadmap are directly affected stakeholders who have some understanding of AM technologies.

1.3 Roadmap Structure

To develop the roadmap, the AMSC took the approach of conducting a life-cycle assessment of producing an AM part, from initial design, through production, and ending with post-production testing, qualification, and maintenance. Thus, it organized itself around nine working groups covering Design, Precursor Materials, Process Control, Post-processing, Finished Materials Properties (FMP), Qualification and Certification (Q&C), Nondestructive Evaluation (NDE), Maintenance and Repair, and Data.

Chapter 2 of the roadmap provides the context and explanation for why specific issues were considered important and subsequently assessed as part of the roadmap. This is the gap analysis evaluation of existing and needed standards, specifications, and conformance programs. A "gap" is defined as meaning that no *published* standard, specification, etc. exists that covers the particular issue in question.

Where gaps are identified and described, they include an indication whether additional pre-standardization R&D is needed, a recommendation for what should be done to fill the gap, the priority for addressing the gap, and an organization(s) – for example, an SDO or research organization – that potentially could carry out the R&D and/or standards development based on its current scope of activity. Where more than one organization is listed, there is no significance to the order in which the organizations are listed.

Carryover gaps from version 2.0 retain their original numbering except where noted, and include a descriptor on the status of progress to address the gap. These are described as: Closed (completed) or, using a traffic light analogy, Green (moving forward), Yellow (delayed), Red (at a standstill), Not Started, Withdrawn, or Unknown. Any significant changes from version 2.0 are also summarized in a narrative update statement. New Gaps for version 3.0 are identified as such, starting with the next number in sequence from version 2.0 for a particular section. In cases where version 2.0 or even 1.0 gaps were withdrawn or closed, there may be “gaps” in the numbering.

Each gap is identified as being high, medium, or low priority. In terms of acting to address the priorities, the desired timeframes for having a published standard available are as follows: high priority (0-2 years), medium (2-5 years), and low (5 + years). In arriving at the priority level, consideration is supposed to be given to the criteria described in Table 1 below.

Table 1: Prioritization Matrix

Criteria (Make the C-A-S-E for the Priority Level)	**Scoring Values**
Criticality (Safety/Quality Implications). How important is the project? How urgently is a standard or guidance needed? What would be the consequences if the project were not completed or undertaken? A high score means the project is more critical.	3 - critical 2 - somewhat critical 1 - not critical
Achievability (Time to Complete). Does it make sense to do this project now, especially when considered in relation to other projects? Is the project already underway or is it a new project? A high score means there's a good probability of completing the project soon.	3 - project near completion 2 - project underway 1 - new project
Scope (Investment of Resources). Will the project require a significant investment of time/work/money? Can it be completed with the information/tools/ resources currently available? Is pre-standardization research required? A high score means the project can be completed without a significant additional investment of resources.	3 - low resource requirement 2 - medium resource requirement 1 - resource intensive

Effect (Return on Investment). What impact will the completed project have on the industry? A high score means there are significant gains for the industry by completing the project.	3 - high return 2 - medium return 1 - low return

Score Rankings
High Priority (a score of 10-12)
Medium Priority (a score of 7-9)
Low Priority (a score of 4-6)

In version 3.0, additional metadata has been added to the gaps. This includes: a description of R&D expectations, the applicable AM lifecycle area(s), relevant sector(s), material type(s), process category(ies), Q&C category(ies), and current alternative being used until an AM standard or specification is available to address the issue. Gaps can be sorted/filtered using the ***Summary Table of Gaps and Recommendations*** sortable spreadsheet. Full text describing the issues and published and in-development standards precede each gap in chapter 2.

Readers are encouraged to take note of gaps and recommendations that may not be specific to their industry sector.

The final chapter briefly describes next steps.

1.4 List of Organizations Covered in this Roadmap

The following organizations identified in this roadmap have standards, specifications, guidance materials or R&D activities that support additive manufacturing.

3MF	3MF Consortium
	Aerospace Corporation, The
AA	The Aluminum Association
AAMI	Association for the Advancement of Medical Instrumentation
AATB	American Association of Tissue Banks
ABS	ABS Group
ACR	American College of Radiology
AFRL	U.S Air Force Research Laboratory
AIA	Aerospace Industries Association
AMCOM	U.S. Army Aviation and Missile Command
AMDC	Additive Manufacturing Data Consortium (SAE-ITC)
America Makes	America Makes
AMMTO	Advanced Materials and Manufacturing Technologies Office
AMO	Advanced Manufacturing Office
AMPP	Association for Materials Protection and Performance

ANSI	American National Standards Institute
API	American Petroleum Institute
ARL	Applied Research Laboratory (Penn State)
ASM	ASM International
ASME	American Society of Mechanical Engineers
ASSP	American Society of Safety Professionals
ASTM	ASTM International
AWS	American Welding Society
BINDT	British Institute of Non-Destructive Testing
CM4QC	Computational Materials for Qualification and Certification Steering Group (NASA)
CMDS	Consortium for Materials Data Standardization (ASTM)
DARPA	Defense Advanced Research Projects Agency
DEVCOM	U.S. Army Combat Capabilities Development Command
DHS	U.S. Department of Homeland Security
DICOM	DICOM
DIN	Deutsches Institut für Normung
DMSC	Dimensional Metrology Standards Consortium (QiF)
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
EASA	European Union Aviation Safety Agency
ECSS	European Cooperation for Space Standardization
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
FAA	U.S. Federal Aviation Administration
FDA	U.S. Food and Drug Administration
GAO	U.S. General Accounting Office
HDF	The HDF Group
HL7	HL7 International
ICNDT	International Committee for Non-Destructive Testing SIG
IEC	International Electrotechnical Commission
IEDO	Industrial Efficiency and Decarbonization Office
IEEE	Institute of Electrical and Electronics Engineers
IETF	Internet Engineering Task Force
IMDRF	International Medical Device Regulators Forum
IPC	Association Connecting Electronics Industries
ISA	International Society of Automation
ISO	International Organization for Standardization
JMADD	Joint Metals Additive Database Definition
LANL	Los Alamos National Laboratory
MASAAG	U.K Military Aircraft Structural Airworthiness Advisory Group

MIT	Massachusetts Institute of Technology
MITA	Medical Imaging & Technology Alliance
MPIF	Metal Powder Industries Federation
MTDA	Montana Digital Academy
NASA	National Aeronautics and Space Administration
NAVSEA	Naval Sea Systems Command
NAWC	Naval Air Warfare Center
NCAMP	National Center for Advanced Materials Performance
NDIA	National Defense Industrial Association
NEI	Nuclear Energy Institute
NEMA	National Electrical Manufacturers Association
NFPA	National Fire Protection Association
NIH	National Institute of Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NNSA	National Nuclear Security Agency (DOE)
NRC	Nuclear Regulatory Commission
OSHA	The Occupational Safety and Health Administration
Phantoms	Phantoms Foundation
PWG	Printer Working Group
RSNA	Radiological Society of North America
SABIC	SABIC
SAE	SAE International
SME	SME
TAPPI	TAPPI
UL	Underwriters Laboratory
USP	United States Pharmacopeia
VDI	The Association of German Engineers

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2. Gap Analysis of Standards and Specifications

This roadmap chapter sets forth a description of key issues; relevant published standards and specifications, as well as those in development; recommendations on the need for additional R&D and/or standards and specs, as well as priorities for their development; and the organization(s) that potentially could perform the work. It is divided into several sections corresponding to the AMSC working groups. These are: Design, Process and Materials, Qualification and Certification, Nondestructive Evaluation, Maintenance and Repair, and Data. The Process and Materials section is further divided into four sections corresponding to the AMSC subgroups on Precursor Materials, Process Control, Post-processing, and Finished Materials Properties.

2.1 Design

2.1.1 Introduction

Additive manufacturing offers unique design opportunities not afforded by traditional manufacturing processes. These opportunities include unique lattice structures and material gradients as well as other novel designs such as the creation of inseparable assemblies or embedded electronics.

This section will assess the currently available and developing industry standards and specifications relevant to the AM design process. Specifically, design guides, design tools, design documentation, anti-counterfeiting, and design verification and validation (V&V) will be discussed as well as design standards relevant to specific applications such as medical and electronics. Gaps in applying these standards and methods to AM shall be identified, and recommendations will be made to address them.

AM designs must ultimately be documented in a product definition data set that includes all of the information necessary to build a part. However, AM presents challenges to designers seeking to apply traditional design methods for part manufacturing. To aid them, the existing design systems, processes, and methodologies must be evaluated for their applicability to AM, and in special cases new ones may be required.

2.1.2 Design Guides

Design guides for AM serve to support users in both design and manufacturing decisions. Guidelines are used to highlight AM process capabilities and inform users on process limitations and requirements. Different AM processes have different design requirements, manufacturing requirements, and manufacturing capabilities. Design guides potentially could also be used to help designers consider other factors such as reliability, cost assessment, logistics, and risk assessment.

As AM has matured as a technology, design guidelines have become more prevalent and more advanced. Guidelines are developed as process-independent, process-specific, manufacturer-specific, and application-specific. Design guides do not necessarily need to be developed by SDOs. They are also available from equipment manufacturers and service providers, though these are not generally identified in this document.

2.1.2.1 General Guides for AM

From the standards perspective, ASTM F42 and ISO TC261 have taken the lead in the development of design guidelines.

Published Standards

- ISO/ASTM 52910-18, Additive manufacturing — Design — Requirements, guidelines and recommendations *(*ASTM F3154-18).
- ASTM F3488-22, Guide for Additive Manufacturing Design - Decision Guide (F42.04, formerly WK64190) discusses advantages and comparisons of different AM processes versus traditional manufacturing as well as a flow chart to aid in decision-making related. The document was approved in 2022 and is targeted for publication in summer 2023[1].

In-Development Standards

- ASTM WK83512, Revision of ISO/ASTM52910-18 Additive manufacturing — Design — Requirements, guidelines and recommendations (F42.04)

Gap DE1: Decision Support: Additive vs. Traditional (CLOSED). Currently there is no standard that helps users understand the advantages/disadvantages of AM processes versus traditional manufacturing processes while also providing decision criteria so informed design/manufacturing decisions can be made.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop a guideline that helps understand trade-offs between AM processes and traditional processes (e.g., sacrifice design freedom for greater certainty of established processes in terms of material properties, reliability, etc.). This gap does not recommend qualification or certification requirements but may help designers consider certification needs and requirements for the parts, equipment, etc.

[1] Once published, it will be located on the ASTM F42.04 subcommittee standards listing website at the URL provided.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/ASTM, AWS, SAE, SME, ASME

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) Not Q&C Related

Current Alternative: Organizational level internal evaluations, traditional manufacturing decision-making processes.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☒Closed; ☐New

V3 Update: See standards activity above. Commercial tools are available.

Gap DE2: Decision Support: Additive Processes (CLOSED). The version 1.0 gap stated that there is no standard that normalizes the characteristics of the general AM process and ranks the pros/cons or strengths/weaknesses of each process, allowing users to make informed decisions about which AM process best suits their need. In 2018, ISO/ASTM published ISO/ASTM 52910-18, Additive manufacturing — Design — Requirements, guidelines and recommendations).The standard briefly addresses AM process selection, providing an example of a high-level diagram and with section 6.8.2, specific process considerations. However, additional standards may be needed to address trade-off criteria between processes. ASTM F3488-22 addresses tradeoffs between processes.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Continue work to complement what has been published in ISO/ASTM 52910. Focus on identification of trade-off criteria between processes. There is still a need to develop a standard for reporting process inputs and capabilities.

Priority: ☐High; ☒Medium; ☐Low

Organization: National labs and government agencies for the R&D. ISO/TC 261 & ASTM F42 for the standards work.

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify) Not Q&C Related

Current Alternative: Organizational level internal evaluations

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☒ Closed; ☐New

V3 Update: ASTM F3488 was approved in 2022, which includes the pros/cons of each process per the gap description above. Revisions currently underway on the ISO/ASTM 52910-18 version do not appear to address the needs identified in this gap. An MIT tool is available to help identify the process (not for design) and inform decision-making based upon user needs.

2.1.2.2 Process-Specific Guides for AM

ASTM and ISO plan to continue to jointly develop guidelines following the standards development framework their PSDO agreement. Accordingly, process-specific design guidelines are beginning to be developed. ISO/TC 261 and ASTM F42 have jointly developed technical design guidelines for laser-based powder bed fusion (PBF-LB) for both metals (ISO/ASTM 52911-1), and polymers (ISO/ASTM 52911-2) These are similar in concept to an existing German standard VDI 3405. Work is ongoing for electron beam. In addition, AWS has developed D20.1 which addressed directed energy deposition (DED) and PBF processes.

Published Standards

- ASME PTB-13 – 2021; Criteria for Pressure Retaining Metallic Components Using Additive Manufacturing provides guidance on the essential elements to be addressed in standards for the construction of metallic pressure retaining equipment using powder bed fusion additive manufacturing.

- ASTM F3413-19e1, Guide for Additive Manufacturing — Design — Directed Energy Deposition (F42.04)
- ASTM F3529-21, Guide for Additive Manufacturing – Design – Material Extrusion of Polymers (F42.04)
- ASTM F3530-22, Standard Guide for Additive Manufacturing — Design — Post-Processing for Metal PBF-LB (F42.04)
- AWS D20.1/D20.1M:2019, Standard for Fabrication of Metal Components using Additive Manufacturing
- ISO/ASTM 52900:2021, Additive manufacturing — General principles — Fundamentals and vocabulary
- ISO/ASTM 52911-1-2019, Additive manufacturing — Design — Part 1: Laser-based powder bed fusion of metals
- ISO/ASTM 52911-2-2019, Additive manufacturing — Design — Part 2: Laser-based powder bed fusion of polymers
- ISO/ASTM 52911-3:2023, Additive manufacturing -- Design -- Part 3: PBF-EB of metallic materials

In-Development Standards

- ASME Pressure Technology Book (PTB) for Additive Manufacturing Criteria Document for Direct Energy Deposition.
- ASTM WK69732, New Guide for Additive Manufacturing -- Wire Arc Additive Manufacturing (F42.05)
- ASTM WK83109, New Guide for Additive manufacturing -- Design -- Vat Photopolymerization (F42.04)

Gap DE3: Process-Specific Design Guidelines. Develop AM process-specific design guidelines for binder jetting (including shrinkage factor in final dimensions), material jetting, sheet lamination, and non-polymer material extrusion as well as complete standards work for vat photopolymerization. The objective is to have AM process-specific design guidelines for the 7 types of AM process identified by ASTM and ISO. Guidance to reduce warpage during sintering for post-processing for metal binder jetting is also needed.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Not yet determined to fill the gaps on the remaining processes and related materials. ASTM to complete WK83109 on vat photopolymerization.

Recommendation: Develop guidelines for the other AM processes defined in ISO/ASTM 52900:2021, Additive manufacturing -- General principles – Fundamentals and vocabulary.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM F42/ISO TC 261 JG 57, AWS

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Organizational level internal practices.

V3 Status of Progress: ☒Green (ISO/ASTM for vat-P); ☐Yellow; ☐Red; ☒Not Started for other processes defined in ISO/ASTM 52900; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Per above, the ISO/ASTM is addressing the PBF, directed energy deposition and material extrusion for polymers. Work is underway on vat photopolymerization.

2.1.2.3 Design Guides for Specific Applications

Following the ASTM/ISO framework , the next generation of design guidelines are expected to be application specific. Candidates for early application-specific guidelines include Design for Aerospace, Design for Medical, Design for Automotive, etc. The current landscape suggests that such standards may be developed by ASTM F42 and ISO/TC 261. ISO/TC 44/SC 14, Welding and brazing in aerospace, also has formed a WG 1, Additive manufacturing in Aerospace. While this group is application-specific, the design implications are unclear. Design guidelines are often manufacturer-specific.

ASTM subcommittee F42.07 on Applications develops sector specific AM standards for ten sectors including aviation, spaceflight, medical/biological, transportation/heavy machinery, maritime, electronics, constructions, oil/gas, consumer, and energy.

Published Standards

- ASME PTB-13 – 2021; Criteria for Pressure Retaining Metallic Components Using Additive Manufacturing, which covers powder bed, but not “traditional” arc welding processes This provides guidance on the essential elements to be addressed in standards for the construction of metallic pressure retaining equipment using powder bed fusion additive manufacturing.

- ASTM F3456-22, Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials (F42.07)
- ASTM F3554-22, Standard Specification for Additive Manufacturing – Finished Part Properties – Grade 4340 (UNS G43400) via Laser Beam Powder Bed Fusion for Transportation Applications (F42.07)
- ASTM F3572-22, Standard Practice for Additive Manufacturing – General Principles – Part Classifications for Additive Manufactured Parts Used in Aviation (F42.07)
- BPVC Code Case 3020, Qualification of Gas Metal Arc Manufacturing (GMAAM) Procedures (approved 05/24/2021)
- ISO/ASTM 52941-2020, Additive manufacturing — System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application
- ISO/ASTM 52942-2020, Additive manufacturing — Qualification principles — Qualifying machine operators of laser metal powder bed fusion machines and equipment used in aerospace applications
- SAE ARP7042, Recommended Practice: Development Planning for Design of Additive Manufactured Components in an Aircraft System (2022-03-02)
- SAE ARP7043, Recommendations for an Additive Manufacturer Designing/Repairing Aircraft Components (2022-08-05)

In-Development Standards

- ASME Pressure Technology Book (PTB) for Additive Manufacturing Criteria Document for Direct Energy Deposition.
- ASTM WK81114, Standard Practice for Additive Manufacturing -- General Principles -- Design Process of Additively Manufactured Building Elements (F42.07)

Gap DE4: Design Guides for Specific Applications. As industry fields mature in particular AM applications, best practices should be recorded.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: N/A

Recommendation: It is recommended that any application-specific design guides extend available process-independent and process-specific design guides. However, application-specific design guidelines may also need to be developed by their respective communities, and in such cases these guidelines may fall under respective societies or SDOs. For instance, a design guideline for printed electronics may be best suited for an organization such as IEEE or IPC.

Priority: ☐High; ☒Medium; ☐ Low

Organization: ASME, SAE, ASTM F42/ISO TC 261, and potentially other SDOs et al. (e.g., manufacturers, industry consortia)

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Each industry sector is leveraging domain specific guidance.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: See text above.

2.1.2.4 Machine Customizable/Adaptive Guides for AM

Producing the same part on different machines from different manufacturers (and often the same manufacturer) will return different results. While process and application guidelines will provide meaningful insight, additional tailoring may be needed for specific instantiations. Many manufacturers, including those of hobbyist machines as well as production machines, have begun to provide guidelines to help in decision-making and process-planning for their specific machines (e.g., EOS, MakerBot documentation). Service providers have begun to provide design guidelines to help customers better understand manufacturing constraints and better prepare designs before sending them to a service provider to be manufactured (e.g., Xometry and documentation). The implications are that guidelines and rules may become machine and implementation specific.

As machines are benchmarked and calibrated (see gap PC2), designers should have mechanisms available to them that will provide operational constraints on their available AM processes. Designers should understand what geometric and process liberties might be taken for their particular implementation. When gap DE8 on Machine Input and Capability Report is closed, it will provide the data necessary to minimize this issue.

No standards gaps have been identified with regards to this issue.

Gap DE5: Support for Customizable Guidelines (WITHDRAWN). Producing the same part on different machines from different manufacturers and often the same manufacturer will return different results. While process and application guidelines will provide meaningful insight, additional tailoring may be needed for specific instantiations. Methods that incorporate machine specific data into guidelines. For example, how to use in-situ monitoring to better inform internal guidelines.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Customizable guidelines require understanding process/machine/design characteristics and subsequent tradeoffs. New monitoring techniques and data being generated which support customizable design guidelines; applicable to various machines.

Recommendation: As machines are benchmarked and calibrated (see gap PC2), designers should have mechanisms available to them that will provide operational constraints on their available AM processes. Designers should understand what geometric and process liberties might be taken for their particular implementation.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/ASTM

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Internal guidelines.

V3 Status of Progress: ☐ Green; ☐Yellow; ☐Red; ☐☒Not Started; ☐Unknown; ☒☐Withdrawn; ☐Closed; ☐New

V3 Update: ASTM WK54856, New Guide for Principles of Design Rules in Additive Manufacturing, has been tabled. No other active standards projects are known at this time.

2.1.2.5 Design Guide for Post-processing

When designing a part for AM, often considerations must be taken for post-processing requirements. These requirements include:

1. **Surface Roughness/Fatigue:** The surface roughness of parts is significantly greater when using AM. This can be of significant concern for fatigue critical parts and gas or fluid flow in internal passages for heat transfer and pressure drop effects. However, there are numerous third-party finishing processes that can enhance this finish. These processes include, but are not limited to: micro-machining, Isotropic Super Finishing, Drag Finishing, and laser micromachining. Since material may be removed, the AM part might have to be designed oversized. However, there are no standard design guides to assist the engineer in designing for this.
2. **Design for Inspection:** Though AM may enable more complex designs, the need for inspecting critical features, including internal surfaces, should be considered in a part and build design. For example, a poorly planned build or design may offset savings in fabrication by increasing the resources needed to verify a part's final dimensions. Including key pieces of geometry to allow for easy datum identification in the printed part can reduce inspection costs.
3. **Design for Post-processing Operations:** Most parts will require some post-processing (such as machining or heat treatment) after AM. This is similar to castings and forging. Traditional post-processing methods may not be applicable or may require tailoring to be suitable for AM parts. However, design considerations to facilitate post processing for AM parts can reduce overall program costs. This may include, a means to fixture or index the part as well as ways to reduce or eliminate the need for supports. As an example (shown in Figure 1), the Penn State Applied Research Laboratory (ARL) and the Naval Air Warfare Center (NAWC) at Lakehurst incorporated a means for indexing a drill into the design of a Hydraulic manifold. Also, incorporating fixture tabs and "soft Jaws" in the printed part can facilitate manufacturing.

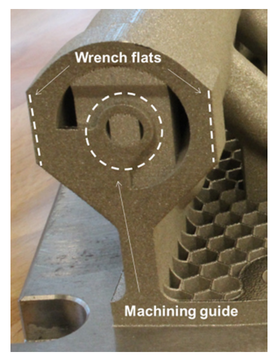

Figure 1: Hydraulic Manifold

   a. Has the design been optimized to reduce the need for support structure?
   b. Has the design been optimized for unreacted liquid or unadhered powder to be able to drain from internal cavities or lattices?
   c. If required for post-machining operations such as drilling, has a means to facilitate indexing been incorporated in the design?
   d. Have considerations for the fixturing of the part during post processing been incorporated in the design?
   e. Has the part's removal from the build platform been considered in the design, which may include potential impacts from localized heating effects, kerf required by each removal operation, clearance for cutting tools, and impacts from vibrations during the cutting process?

    f. Have the mechanical properties used for design of the AM part accounted for stress relief, heat treatment, and HIP effects, such as minimizing part distortion, reducing porosity, healing voids, and improved/controlled mechanical properties? (Depending on the application, design mechanical properties may need to be validated in order to complete qualification and certification of the AM part.)

4. **Design for Heat Treatment:** Designers need to understand how post-processing heat treatments and stress relief can impact the material properties and the intent of the design. For example, thermal post-processing may be used to remove residual stresses that could have resulted in part distortion; heat treatments can be used to tailor and improve mechanical properties; and HIP may reduce defects and porosity. Heat treatment methods that are standardized and validated (through experimentation) need to be developed for AM and may be adapted from "traditional" methods.
5. **Design Parts for Safe AM Processing and Post-Processing:** When designing parts and build plans for fabrication by AM methods, safety must be considered for personnel operating the machines and conducting post-processing tasks.
    a. Parts should avoid trapped volumes which could trap unused liquid or powder build materials (for some AM processes) creating potential safety hazards. Access features, such as holes and slots, may be included to remove excess materials.
    b. Solid supports are encouraged because they may be stronger and safer.
    c. If parts need to be cut from a build platform, the layout should be planned to reduce the risk of breaking tools during the removal process.
    d. Prior to printing, the build file and parameter sets should be reviewed to determine the likelihood of a successful build and to assess the risk to the equipment from the build file and parameters.
6. **Design for Fasteners:** Fused deposition modeling designs in additive manufacturing have challenges interfacing with fasteners. Standards which address the print profile for printed holes, design for countersunk fasteners, design for rivets; and guidance for addressing printed threads, helicoils and heat set inserts are needed. An increased understanding about these areas from stakeholders would help advance discussions about future standards development and print design needs.

Published Standards

- ASTM F3530-22, Standard Guide for Additive Manufacturing — Design — Post-Processing for Metal PBF-LB (F42.04)
- ISO/ASTM 52910-18, Additive manufacturing — Design — Requirements, guidelines and recommendations (ASTM F3154-18)
- ASME B46.1-2019, Surface Texture (Surface Roughness, Waviness, and Lay)

In-Development Standards

- ASME B46 Project Team (PT) 52: Additional work has begun on revisions for the next edition of B46.1-2019 and further revisions are expected based on the work from PT 52.
- ASTM WK66682, Guide for Evaluating Post-processing and Characterization Techniques for AM Part Surfaces (F42.01)

Gap DE7: Design Guide for Post-processing. There is a need for additional design guides for post-processing. Depending on the type of process used for post processing different practices may be used.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: General research about post processing is needed, surface finishing and its correlation to fatigue and fatigue requirements.

Recommendation: Continue work to develop a design guide(s) related to various AM processes, materials, and applications for post processing.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASME B46, ASTM F42/ISO TC 261

Lifecycle Area: ☒ Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Depends on the process used for post-processing.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: See text above. ASTM F3530-22 and ISO/ASTM 52910-18 has been published and includes a high-level discussion of design considerations for post-processing but more detailed design guides addressing specific AM processes, materials, and applications are needed.

ASME B46 Committee is working on measurement and characterization methods for AM surface finish (not a design guide). The measurement and characterization methods that work for relating performance for machined or ground finishes should not be expected to work for relating performance for AM finishes. B46 explains how to find parameters that can describe the topography so they can correlate and discriminate between processing and performance parameters.

2.1.2.6 Design of Lattice Structures

AM allows manufacturing of lattice structures layer-by-layer directly from a CAD model. Lattice structures can be used for a wide range of applications and to integrate multiple functions into a physical part. For example, in the medical sector lattice structures are designed to engineer material properties and enhance biological cellular growth for better functioning of implants and to prevent stress shielding. Off-the-shelf software can allow a designer to create a myriad of periodic cellular structures and stochastic structures that replicate natural tissues. IEEE's paper on Design of Lattice Structure for Additive Manufacturing[2] provides additional context on AM processes, design methods and considerations, mechanical behavior, and applications for lattice structures enabled by this emerging technology. A state-of-the-art review on types, design, optimization, and additive manufacturing of cellular structures was published in 2019.[3]

Published Standards

- ANSI/AAMI/ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ASME Y14.46-2022, Product Definition for Additive Manufacturing
- ASTM F1160-14(2017)e1, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
- ASTM F1854-15, Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants. Definition 4.4 discusses "tissue interface gradients" which would apply to gradients for porous structure sizing. It is currently under revision per WK60654 and WK78770.
- ASTM F2971-13(2021), Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing
- ASTM F3122-14(2022), Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes

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[2] W. Tao and M. C. Leu, "Design of lattice structure for additive manufacturing," *2016 International Symposium on Flexible Automation (ISFA)*, Cleveland, OH, USA, 2016, pp. 325-332, doi: 10.1109/ISFA.2016.7790182. Last accessed April 4, 2023. https://ieeexplore.ieee.org/document/7790182

[3] Nazir, A., Abate, K.M., Kumar, A. *et al.* A state-of-the-art review on types, design, optimization, and additive manufacturing of cellular structures. *Int J Adv Manuf Technol* **104**, 3489–3510 (2019). https://doi.org/10.1007/s00170-019-04085-3

- ASTM F3335-20, Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion
- ISO/ASTM 52901:2017, Standard Guide for Additive Manufacturing – General Principles – Requirements for Purchased AM Parts
- ISO/ASTM TR 52912:2020 Additive manufacturing — Design — Functionally graded additive manufacturing
- ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 19227:2018, Implants for surgery - Cleanliness of orthopedic implants- General requirements
- ISO/TS 19930:2017, Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6
- FDA 21 CFR 820.70, Production and process controls
- FDA's Design Control Guidance for Medical Device Manufacturers (relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001)

In-Development Standards

- ASTM WK76163, Standard Test Method for Additive Manufacturing -- Test Artifacts -- Compression Validation Coupons for Lattice Designs

Gap DE14: Designing to be Cleaned. Currently there are no design guidelines for devices to assure cleanability post-production. When designing a device (including medical), cleanability must be evaluated at different stages for a number of reasons:

1. Manufacturing residues/contact materials encountered during the manufacturing process may need to be removed (see Gap DE7: Design Guide for Post-processing).
2. Unmelted/unsintered AM material from the manufacturing process may need to be removed (see Gap DE7).
3. For devices that are to be sterilized prior to use, a sterilization test soil can be placed at the most difficult location to sterilize so that the validation will accurately show if foreign bodies picked up during the manufacturing process can either be killed or removed from the device prior to sterilization
4. For reusable devices, a device may need to be adequately cleaned and sterilized prior to subsequent uses
5. For reusable devices, the device materials may need to be maintained for the specified number of cleaning cycles

For medical devices, there may be more specific sterilization needs. This is more directly related to post-processing and testing related aspect and less related to AM design. The need identified within this gap is not solely related to medical. Regarding #4 and #5 above, requirements exist for reprocessing medical devices.

Note: While there may be situations where cleaning is not desired, scenarios that do necessitate it, may consider the above.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: In terms of ways to determine what parts are likely to be cleanable before they are made, AM technology and material specific needs exist. Per #3 above, research on sterilization validation for where you place the soil is needed.

Recommendation: Develop design guidance within existing published design guidelines to provide general design limits and recommendations that achieve both needed surface structure and allow adequate cleaning. A separate standard may not be needed. See also gap FMP3 and gap QC15.

Priority: ☐High; ☒Medium; ☐Low

Organization: AAMI, ASTM F04, ASTM F42/ISO TC 261, ISO/TC 198, ASME (surface metrology), FDA

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Vendors will specify the needs and internal design practices will be leveraged.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: AAMI and ASTM have an interest and are meeting. FDA is also looking at this.

2.1.2.7 Design of Test Coupons

Test coupons have very specific uses in manufacturing but are not always the appropriate way to evaluate a part or sample and cannot replace a robust process validation. In specific circumstances when a feature can be effectively isolated and still represent the whole part, they can be useful tools as an over check for the process. For example, the use of test coupons to determine the capability and repeatability of the manufacturing process to make porous structures may be useful. In addition, surface topography including at the nanoscale could impact the testing procedures. It may not be necessary to design test coupons for each production lot.

Published Standards

- ASME Y14.46-2022, Product Definition for Additive Manufacturing
- ISO/ASTM TR 52912:2020 Additive manufacturing — Design — Functionally graded additive manufacturing

In-Development Standards

- ASTM WK76163, Standard Test Method for Additive Manufacturing -- Test Artifacts -- Compression Validation Coupons for Lattice Designs

Gap DE15: Design of Test Coupons. No AM standards are currently available for the design of test coupons for additively-manufactured structures. There may be application specific needs, which would focus on application specific related stresses. While there are many methods, they are not design related and they would need to be revised for this purpose. Test methods may need to be developed first.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Effects on what is in the build and how well can you replicate your feature of interest.

Recommendation: Develop standard application specific test methods and specifications for the design of test coupons for additively-manufactured porous structures.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F04 and F42, ISO TC 261

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Standard coupons are being used

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASTM F42 is working on standards for the compression test and test coupons. Also, ASTM F04 is looking at this. ASME V&V 40 Subcommittee on Verification and Validation in Computational Modeling of Medical Devices is working to form a working group on this item.

Gap DE16: Verifying Functionally Graded Materials (FGM). Functionally graded materials are materials with variation in the composition or structure in order to vary the material properties (e.g., stiffness, density, thermal conductivity, etc.). Standard methods of specifying and verifying functionally graded materials currently do not exist. Furthermore, existing test methods may be leveraged or need to be modified to address considerations when validating their performance.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Characterizing the functional grades in a way that can be specified and measured and integrating solutions into other design and software tools.

Recommendation: Update existing test guidelines for metals and polymers with considerations for materials that have graded properties. If the grade itself needs to be verified versus only its performance, new test methods may be needed. This is a broad topic however and depends on what is being evaluated.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM F04 and F42, SAE AMS-AM, ASME, ISO/TC 261 JG 67

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Unknown

V3 Status of Progress: ☐Green; ☒Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASME Y14.46 discusses the specification of functionally graded materials. New efforts are focusing on verification of lattice FGM specifications. ISO/ASTM TR 52912:2020, Additive manufacturing — Design — Functionally graded additive manufacturing was published as a technical report that addresses design opportunities and challenges of functionally graded materials.

2.1.3 Design Tools

A wide range of tools are commonly used in the design process to exploit AM design opportunities not afforded by traditional manufacturing processes. Some of the new challenges and requirements imposed by AM on design tools that did not exist in traditional manufacturing are described below.

2.1.3.1 A Machine Input and Capability Report

Since different AM processes have different design requirements, manufacturing requirements, and manufacturing capabilities (e.g., overhang angles, minimum member thickness, minimum hole diameter, etc.), it is often challenging to determine if a design is feasible for a given AM process. Ideally, machine inputs (e.g., tool paths, processing parameters, rate, etc.) and capabilities necessary for design tools to assess feasibility would be standardized.

ISO/ASTM 52915:2020 standard specification for AMF file format includes support for 15 specific meta data types, plus a general meta data field that can include additional printing parameters and machine capabilities. This capability can currently support the recommended requirements by defining each new meta data naming convention and range of values/categories, etc. and adding this to the list of current meta data types to an update to this standard (v1.3), which is currently in the planning stage in ISO TC261.assess feasibility would be standardized. Current meta data defined includes: unit of measure, tolerance, material(s), color(s), design file ID, version number, description, designer, company, reference URL, etc. Specific meta data can be applied to individual components within the object, the entire object or an assembly of objects, each with separately defined location and orientation.

The URL meta data element provides a simple and reliable way to link additional detailed information to the file, such as a technical data package, IP notifications, and specific system requirements, while providing the potential for secure access to all this information to authorized users only. This is also applicable to addressing a significant portion of gap DE20 on a Neutral Build File Format. By defining all necessary and appropriate printing requirements and parameters as meta data elements that can be expressed in XML v1.0 in list format, the designer can provide as much design information and machine specific requirements as they want, all integrated within the 3D mesh file, and/or accessed via the embedded URL to provide, for a complete data package.

Published Standards

- ASTM F3490-21, Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree (F42.08)
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2 (2020-03)
- Printer Working Group, PWG 3D Print Job Ticket and Associated Capabilities v1.0 (PJT3D) (2017-08-18)
- Printer Working Group, PWG 5100.21-2019: IPP 3D Printing Extensions v1.1 (2019-03-29)

In-Development Standards

- Printer Working Group, IPP 3D Production Printing Extensions v1.0 (3DPPX) (wd-ipp3dppx-yyymmdd) defines a new specification that updates IPP 3D Printing Extensions v1.1 (PWG 5100.21-2019) for 3D production-level features

Gap DE8: Machine Input and Capability Report. A standard for reporting machine input requirements and the associated AM machine capabilities is required to support new design tools which will be able to determine manufacturing feasibility, optimize manufacturing solutions, and identify AM equipment which would be able to manufacture the part.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: To be determined.

Recommendation: Develop a standard for reporting machine inputs such as printing parameters, laser track, etc. and machine capabilities such as dimensional accuracy, surface finish, material properties, geometry constraints (over hang angle requirements), size, porosity, etc. These reports would be used by software to accomplish the following:

1. Topology Optimization
2. Optimize manufacturing solutions
3. Identification of suitable AM equipment
4. Build Simulation
5. Lattice structure generation
6. Spatial comparisons (e.g., common standard grid)

See also gap DE20 on neutral build file format.

Priority: ☐High; ☒Medium; ☐Low

Organization: 3MF, Consortium of industry, ISO/ASTM, IEEE-ISTO PWG, IPP

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒ Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Proprietary tools and process documentation as well as ISO/ASTM 52915:2020.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: See standards activities above.

2.1.3.2 A Requirement for an AM Simulation Benchmark Model/Part

AM process simulation tools are becoming an important aspect of the AM design process by enabling the designer to predict consequences of material and process parameter choices on objective fabrication or part qualities. These simulations are used (but not limited to) predict microstructural evolution and properties, identify optimal process parameters to enable high density parts, or predict and mitigate residual stress and process dependent deformation. Residual stress and distortion prediction tools are currently at the highest technology readiness level (TRL). There is a growing list of commercially-available simulation tools, internally-developed or proprietary tools in industry, some open-source tools, and many academic examples under development. Standard for an AM benchmark model(s)/part(s) to validate these simulation tools would benefit end users.

ASME VVUQ 50 Verification, Validation, and Uncertainty Quantification of Computational Modeling for Advanced Manufacturing is creating standards to provide procedures for verification, validation, and uncertainty quantification in modeling and computational simulation for advanced manufacturing. While VVUQ 50 has not yet published standards specific to manufacturing processes, other VVUQ standards such as ASME VVUQ 10 or VVUQ 20 have applicable guidelines.

In 2020 NASA, NIST, and FAA held the Technical Interchange Meeting on Computational Materials Approaches for Qualification by Analysis for Aerospace Applications. A workshop report from this meeting identifies critical R&D necessary to further develop AM computational simulation technologies and gaps for their use in qualification and certification framework. Members of NASA, NIST, and FAA created the Computational Materials for Qualification and Certification (CM4QC) steering group to coordinate efforts towards goals identified in the workshop.

Published Standards

- NIST Additive Manufacturing Benchmark Test Series (AM-Bench) and associated datasets.
- ASME VVUQ 1-2022 Verification, Validation, and Uncertainty Quantification Terminology in Computational Modeling and Simulation
- ASME V V 10-2019 Standard for Verification and Validation in Computational Solid Mechanics
- ASME V V 20-2009 (R2021) Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer
- ISO/ASTM 52902-19 Additive manufacturing -- Test artifacts -- Geometric capability assessment of additive manufacturing systems

Gap DE9: AM Simulation Benchmark Model/Part Requirement. Standards for process and simulation type-specific AM benchmark models, tests, and/or parts are needed to enable verification and validation (V&V) of applicable process simulation tools.

R&D Needed: ☒Yes; ☐No; ☐Maybe.

R&D Expectations: R&D is needed to identify proper testing and measurement procedures to evaluate the predictive accuracy of simulations, and determine to what extent a simulation 'validated' through controlled physical tests/measurements may be extensible to alternate part designs. Quantitative (i.e., statistical) metrics need to be defined to appropriately assess model to measurement accuracy and uncertainty. R&D is also needed for development of many computational simulations themselves, with the scale/amount of R&D depending on the simulation type and complexity, and the need for standards rising with the availability of more complex simulation tools.

Recommendation: Develop a set of standardized physical tests (e.g., test artifacts and required controls) and associated measurements that 1) can be quantitatively related to simulation outputs and 2) target or align with the technical objectives of the simulations (e.g., distortion prediction). Develop guidelines and/or metrics for quantifying the accuracy of the models considering measurement uncertainty and model uncertainty, and extensibility to alternate part designs from the validation tests.

Priority: ☒High; ☐Medium; ☐ Low

Organization: NIST, America Makes, ASME V&V 50, ISO/ASTM, AFRL

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: Stakeholders are generating data to validate models (i.e., NIST, AFRL).

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: The 2nd AM Bench test series led by NIST occurred in 2022, and measurement results database is being populated and organized. ASME VVUQ 50 is developing VVUQ methods for advanced manufacturing, including additive. NASA, NIST, and FAA held the Technical Interchange Meeting on Computational Materials Approaches for Qualification by Analysis for Aerospace Applications in 2020.

2.1.3.3 Standardized Design for Additive Manufacturing (DFAM) Process Chain

Additive manufacturing seamlessly connects product design in a virtual environment with rapid manufacturing in the physical domain. It is a unique advantage and natural extension of design for additive manufacturing to fully leverage the power of digitalization to automatically and systematically enable AM potential in product development. To do so, a standardized DFAM process chain needs to be established that delineates and integrates key AM considerations and design tools in the complete product design process.

The industrial product development process can be segmented into the following generic stages: Requirements Study/Specifications, Conceptual Design, Preliminary Design, and Detail Design. Each stage has unique requirements and needs for AM, and therefore demands for particular AM considerations and dedicated design tools. Examples include topology optimization in Preliminary Design exploration, AM checkers/cost estimation in Preliminary and Detail Design, etc. A standardized design for AM process chain would need to define entry points at each design stage to insert the corresponding AM considerations/design tools. It would need to provide a logical, intuitive, and systematic framework for maximizing the use of AM in product development. Such a process chain may be represented as activity diagrams at a high level. With the additional handling of data/tool interfacing, the process chain can be fully digitalized.

The gap that follows identifies a need to expand standardization of the complete DFAM process chain. DFAM would need to fit in with higher level topics (beyond the scope of this document) such as Advanced Manufacturing, Digital Twin, and Digital Thread.

Work is being done across many aspects of the DFAM process chain across industry, academia, the Government, and professional organizations. There are leaders (automotive, aerospace, medical) and CAE/CAD/CAM software that should be involved with developing DFAM process chain standards.

Published Standards

- ISO/ASTM 52910-18, Additive Manufacturing – Design – Requirements, guidelines and recommendations provides guidance on areas for a designer to consider when designing a part for AM. Paragraph 6.2.6 states that a suitable process chain may be needed and focuses on finish and accuracy of the AM part.
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- NIST AM materials database, though not dealing with process chain per se, will aid in developing AM process chain.
- ASTM F3530-22, Standard Guide for Additive Manufacturing — Design — Post-Processing for Metal PBF-LB (F42.04)

In-Development Standards

ISO/TC 261 and ASTM F42 JG 73 is a Joint Group developing guidelines related to digital data configuration control, data integrity checks, and enterprise work flow for files used in the metal PBF process. The guideline covers digital product data workflows, file formats used for printing, automated and manual methods for receiving digital data and build cycle information in the PBF process that can be used for product quality assurance.[4] The guidelines cover saving and storing the build cycle data in order to meet quality system requirements. See also:

- ISO/ASTM DIS 52910 Additive manufacturing — Design — Requirements, guidelines and recommendations
- ISO/ASTM PWI 52951, Additive manufacturing — Data packages for AM parts will address file formats and the integration and preservation of information across the process chain.

Gap DE27: Standardized Design for Additive Manufacturing (DFAM) Process Chain. A standardized design methodology is needed for AM process chain integrating key AM considerations/design tools in each design stage. A standard to address all the stages of a process chain from where the design input would begin (including original or re-design designed part) is needed.

[4] See Shaw C. Feng, Paul Witherell, Gaurav Ameta, Duck Bong Kim, (2017) "Activity model for homogenization of data sets in laser-based powder bed fusion", Rapid Prototyping Journal, Vol. 23 Issue: 1, pp.137-148, https://doi.org/10.1108/RPJ-11-2015-0160

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: TBD

Recommendation: Develop a standardized design for AM process chain that specifies and integrates the key AM considerations and suggested design tools in each generic design stage. The process chain can be expanded from ISO/ASTM 52910-18, Additive manufacturing — Design — Requirements, guidelines and recommendations stages and complimented with design tools to address specific AM needs for each task within the stages. The standardized design for AM process chain can be used by various industries to roll out site-specific DFAM process and digitalization implementation.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM F42/ISO TC 261 JG 73, NIST

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☒Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Design processes could be sector/agency specific. See standards activities above.

2.1.4 Design for Specific Applications

AM has continued to expand throughout industry creating new opportunities in many sectors such as medical and electronics. Consequently, in addition to general standards assisting with design for AM, specific AM applications will also require standards.

2.1.4.1 Design for As-built Assembly

For purposes of this roadmap, "design for as-built assembly" is the ability to create, in a single build, a functioning assembly composed of multiple parts that have relative linear or rotational motion between the parts. This eliminates the process of having to assemble multiple parts into one functioning assembly so that no assembly is required afterwards. AM assemblies built in this fashion range from simple tools such as the NASA wrench[5] to complex assemblies with gears and other moving parts. The ability to create a functioning assembly in one build can lead to new and innovative assemblies not possible with traditional manufacturing methods.

AM design for as-built assembly shares all of the requirements that traditionally built assemblies have for individual part tolerances, assembly tolerance stack-up analysis, and surface finish to ensure the operational objectives and design intent of the assembled parts is obtained. In addition, AM design for as-built assembly needs to consider the removal of excess build material between parts in the assembly and non-contact measurement and inspection methods to verify tolerances and surface finish to ensure proper operation of an assembly. These issues are also common to individual AM parts. For example, the excess build material for an AM part with internal cooling channels needs to be removed from the channels, and non-contact inspection is necessary to verify inaccessible features.

Similar to conventional manufacturing, functional requirements for AM design for as-built assembly also depend on how the assembly is used. The NASA wrench, built with material extrusion, might not require tight tolerances to function properly. It may only be used a few times. Conversely, an AM assembly of gears built with metal PBF might have to carry high loads and endure many usage cycles.

Published Standards

- ASME Y14.46-2022, Product Definition for Additive Manufacturing
- ISO 8887-1:2017, Technical product documentation - Design for manufacturing, disassembling and end-of-life processing - Part 1: General concepts and requirements
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2, supports assembly multi-mesh definition, location and orientation. It also supports meta data fields at component level and assembly level to specify some essential meta data, and it supports inclusion of additional meta data, but lacks defined schema for all meta data described in the gap

AM standards related to individual AM parts will also apply to parts in an assembly.

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[5] http://nasa3d.arc.nasa.gov/detail/wrench-mis

Gap DE10: Design for As-built Assembly. Guidelines do not exist for AM design for as-built assembly which is the ability of an AM process to create an assembly with multiple parts with relative motion capabilities in a single build. Design for Manufacture and Assembly (DFMA) practices do not account for considerations of single build AM assemblies and assemblies constructed from individual AM parts. Design approaches and additional design parameters (meta data) may need to account for complexity of support structures, removal times, post-processing complexity, inter-part tolerances, and manufacturing time/quality using different parameter sets. In regard to parameters sets, factors of interest could include feed rate and diameters for Directed Energy Deposition (DED), layer thickness and laser scan speed for PBF. Furthermore, how these all factors interact must also be considered.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Additional research is needed related to individual AM part definition, including tolerances, and non-contact measurement and inspection methods for AM assemblies. If AM design for as-built assembly is to become a viable alternative for creating functioning assemblies, there needs to be rigorous academic research, practical pilot projects, and real industry use cases. These are critical elements in identifying the gaps that will result in the tailoring of existing standards and the development of new standards for AM design for as-built assembly.

Recommendation: ISO 8887-1:2017, ISO/ASTM 52915:2020 and other DFMA standards can be reviewed and further developed to address AM related issues.

Priority: ☐High; ☐Medium; ☒Low

Organization: R&D: Academia, government, industry, national laboratories. Standards: DoD, ISO, ASME, ASTM, AAMI, NEMA/MITA

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Unknown, as-built assembly is not common because guidance does not currently exist.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASME Y14.46 was revised in 2022 and ISO/ASTM 52915 was published in 2020 however the gap is still considered open.

2.1.4.2 Design for Printed Electronics

The main effort in developing design standards for printed electronics is being led by the D-61a Flexible Printed Electronics Design Standard Task Group out of IPC, which is the industry leading standards organization in electronics manufacture. The main document is IPC-2292, Design Standard for Printed Electronics on Flexible Substrates (Rev A 2022-11-28), which establishes the specific requirements for the design of printed electronic applications and their forms of component mounting and interconnecting structures on flexible substrates. Flexible substrates, as pertaining to IPC-2292 are materials, devices or functionalized circuitry which have some amount of flexibility or bendability (not rigid) but are not considered to be stretchable. This standard may be used in conjunction with IPC 2221B-2012, Generic Standard on Printed Board Design (2012-11-20) and IPC 2223E-2020, Sectional Design Standard for Flexible Printed Boards (2020-01-24) when printing on flexible printed circuit boards (copper flex). The D-61a Task Group works in tandem with other IPC printed electronics task groups under the D-62, Base Material/Substrates; D-63, Functional Materials; D-64, Final Assembly; and D-65, Test Method Development and Validation Subcommittees for Printed Electronics. The task group also works with the D-73a E-Textiles Printed Electronics Design Standard Task Group which developed IPC-8952-2022, Design Standard for Printed Electronics on Coated or Treated Textiles and E-Textiles. IPC-8952 establishes specific requirements for the design of printed electronic applications and their forms of component mounting and interconnecting structures on coated or treated textile substrates. Textile substrate, as pertains to this standard, could be a bare textile or an integrated e-textile (e.g., woven or knitted e-textile). Coated or treated textile substrates, as pertain to this standard, are textile substrates which have or will have a coating or treatment localized or across the full substrate.

Gap DE11: Design for 3D Printed Electronics. There is a need to develop standards on design for 3D printed electronics, including flexible and rigid substrates.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Complete work on IPC-2292, develop standard for 3D based on IPC-2292 requirements

Priority: ☐High; ☒Medium; ☐Low

Organization: IPC

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☒Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: IPC 2292 was published in March 2018 and revised in November 2022 but does not address this gap. With respect to the development of a design standard like IPC-2292, the group is of the view that it is far too early in the maturation of this technology to develop design requirements, but they will revisit this topic at future meetings. See also gap DE4.

2.1.4.3 Design for Medical

AM has caused a revolution in healthcare delivery. New medical devices embody the true meaning of personalized medicine. Medical device designers and practitioners can practically and efficiently create devices that were very difficult or impossible to create before. In addition to using AM to create standard medical devices with features like intricate lattice structures, clinicians and engineers work in conjunction to produce what are known as patient-specific or patient-matched devices. These are medical devices designed to fit a specific patient's anatomy, typically using medical imaging from that patient. Anatomically matched devices have very complex geometrical contours and shapes. Several challenges exist in the design process between the input data and the final device design. While the gaps described below are tailored to medical specific concerns, the general community may have similar concerns.

Many groups, including the FDA, have used AM techniques to create reference parts that mimic natural anatomic shape and imaging properties (e.g., radiopacity, conductivity). These biomimetic designs have advantages over geometric grids and patterns because they are more representative of a patient and the real-world imaging capacity rather than the idealized geometric grids. A range of geometric complexities and material properties afforded by newer technologies and AM techniques enables greater representation of patient anatomy and real-world applications.

For pharmaceutical drug printing, shape flaws may be unimportant, but distribution (of active ingredient across both halves) and particle size (for how fast it dissolves to deliver drug) are crucial. The U.S. Pharmacopeia chapter 1119 for Near-Infrared (NIR) Spectroscopy[6] would be useful for AM. The FDA developed a discussion paper[7] which presents areas associated with Distributed Manufacturing (DM) and Point-of-Care (POC) manufacturing that FDA has identified for consideration as FDA evaluates our existing risk-based regulatory framework as it applies to these technologies.

Input Data (CT, MRI, Ultrasound scan and X-Ray)

Published Standards

- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data
- ISO/IEC 23510:2021, Information technology — 3D printing and scanning — Framework for an Additive Manufacturing Service Platform (AMSP)
- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

ISO/IEC JTC1/WG12 for "3D Printing and Scanning" has been established and is working on the following:

- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)
- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)

Gap DE12: Imaging Consistency. There are currently no standard best practices for creation of protocols and validation procedures to ensure that medical imaging data can be consistently and accurately transformed into a 3D printed object. Individual companies have developed internal best practices, training programs and site qualification procedures. The details of a device's individual imaging and validation plan is developed specifically for each process or product. However, a set of consensus best

[6] http://www.pharmacopeia.cn/v29240/usp29nf24s0_c1119.html

[7] U.S. Food and Drug Administration. Center for Drug Evaluation and Research (CDER). 2022. *FDA Distributed Manufacturing and Point-of-Care Manufacturing of Drugs, Discussion Paper,* Silver Spring, MD.: Food and Drug Administration.

practices for developing these plans and key validation metrics could reduce the overhead in developing them and reduce the burden on imaging sites. This framework should rely on input from clinical experts to ensure that it accounts for and defers to clinical best practices where appropriate.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A; The information is housed within individual institutions and could be combined through participation in clinical associations, consortiums or standards development organizations.

Recommendation: Develop a set of best practices for the development and qualification of imaging protocols and imaging sites that provide inputs to patient-matched devices. The focus should be on validation metrics and standard reference parts (phantoms) that can either be simple geometric patterns, or more appropriately designed to mimic the shape and density of natural anatomy so that the fidelity of an imaging sequence can be measured and calibrated. See also gaps QC7, QC9, QC14.

Priority: ☒High; ☐Medium; ☐Low

Organization: RSNA (Radiological Society of North America), ASTM F42/ISO TC 261 JG 70, ISO/IEC JTC 1/WG 12

Lifecycle Area: ☒Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: An RSNA 3D Special Interest Group (SIG) is working on best practices, not a standard. ISO/ASTM TR 52916:2022 Additive manufacturing for medical — Data — Optimized medical image data from ISO/TC 261 JG 70 deals with imaging quality. This is a secondary priority for the DICOM WG. ISO/IEC 3532-1 (approved) and ISO/IEC DIS 3532-2 (in development) are addressing critical issues about image quality and consistency.

Data Processing

Gap DE13: Image Processing and 2D to 3D Conversion. Data acquired as a stack of 2D images is converted to a 3D model that could be a device by itself or be a template to build the device on. Tissues such as bone, soft tissue and vascular structures are isolated by the process of segmentation. Variability of the output depends on factors such as spatial and grey scale resolution of the images which in turn are driven by other factors such as the x-ray dosage, MRI protocol, operator capability, and reconstruction algorithms. Computational modeling groups, software developers, research laboratories, and the FDA have investigated methods of validating segmentation processes. However, the wide variety of patient geometries, frequent inability to identify a ground truth due to imaging constraints, and variability in the manual aspects of imaging have caused validation procedures to be developed by individual entities.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Data to develop protocols exists but there is still a need for standardized, physiologically relevant imaging phantoms that can be used to challenge many segmentation techniques. Round robin testing for biomimetic imaging phantoms to validate segmentation techniques for a test method is highly recommended. See also gap QC14 on Segmentation.

Recommendation: 1) Develop a standard test method to use biomimetic imaging phantoms to validate a segmentation technique. Round robin testing of this type of test method is highly recommended. Best practices may include capturing enough information to set accurate threshold values and understand geometric norms for a data set of interest. 2) Develop training standards that operators must meet to ensure that they are able to adequately reproduce a validated image processing pipeline.

Priority: ☐High; ☒Medium; ☐Low

Organization: Methods: NEMA/MITA, ASME V&V 40, ASTM F4, ASTM F42/ISO TC 261. Phantoms: NIH, NIST, FDA, RSNA, ISO/IEC JTC 1/WG 12

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: On the R&D side, FDA research groups are developing phantoms but haven't yet interfaced with SDOs. On the standards side, ISO/ASTM TR 52916:2022 Additive manufacturing for medical — Data — Optimized medical image data from ISO/TC 261 JG 70 covers this gap. ISO/IEC 3532-1 deals with 3D reconstruction and visualization and 2D to 3D conversion calibration and validation. An RSNA SIG is also looking at this.

3D Modeling

The initial 3D model is post-processed creating a model that becomes the input data, a template for the design of the final device, or the device itself. During this process of data deletion, shape detection, smoothening, and texturing functions are used to arrive at the final part to be manufactured.

The IEEE EMB Standards Committee has the P3333.2 Working Group for Standards Projects in Medical 3D Printed & Virtual Reality Models which is working on several projects including:

- IEEE P3333.2.2, Standard for Three-Dimensional (3D) Medical Visualization
- IEEE P3333.2.3, Standard for Three-Dimensional (3D) Medical Data Management
- IEEE P3333.2.4, Standard for Three-Dimensional (3D) Medical Simulation
- IEEE P3333.2.5, Standard for Bio-CAD File Format for Medical Three-Dimensional (3D) Printing
- IEEE P3333.2.5.1, Standard for Soft Tissue Modeling for Medical 3D Printing
- IEEE P3333.2.5.2, Standard for Hard Tissue Modeling for 3D Printing
- IEEE P3333.2.5.3, Standard for Surgical Guide Design Modeling for Medical 3D Printing
- IEEE P3333.2.5.4, Standard for Artificial Joint Implant Design Modeling for Medical 3D Printing
- IEEE P3333.2.5.5, Standard for In Vivo Evaluation of 3D Printed Polymeric scaffolds in bone defects

Published Standards

- IEEE P3333.2.1
- -2015, Recommended Practice for Three-Dimensional (3D) Medical Modeling

In AMSC Roadmap version 2.0, gaps DE14, DE15, and DE16 focused on medical were incorporated here. For this version, the gaps were moved to the Design Guides section of the chapter because the needs identified by these gaps are currently considered applicable to additional sectors beyond the medical sector.

2.1.5 Design Documentation

In most cases, upon completion of an engineering design, there will be a requirement to completely document it. This requirement exists for many reasons. These include quality assurance requirements following manufacture, in service engineering needs following fielding equipment, legal requirements, as well as many other reasons. Traditionally, most engineering designs have been done with 2D drawings constructed in accordance with ASME Y14.100-2017, Engineering Drawing Practices and documented in a technical data package. However, AM offers the capability to create new designs that were never conceived of before. These include new geometries such as gradient structures, intentionally designed porosity, a means to modify material properties through track laser paths, as well as many other new capabilities. Consequently, new standards are required to assist in the documentation of these designs. ASME Y14.46 and ASTM/ ISO JG 73 will aim to address aspects of the product data package for AM.

Some new challenges and requirements imposed by AM that did not exist in traditional manufacturing are described below.

2.1.5.1 Data Package Content

Data Packages, sometimes referred to as technical data packages (TDPs in defense industry) or technical files (in medical sector), are used to procure parts by specifying the material requirements, tolerances, geometry and manufacturing processes for a part. This works well for parts made via traditional manufacturing processes as these processes have been standardized over time and are performed to specifications and standards that bound their use and may be referenced as part of the data package. Additive manufacturing processes have not yet been standardized, and as a result the use of typical data package content is not sufficient to procure parts made via these processes.

Published Standards

- ASME Y14.46 – 2022, Product Definition for Additive Manufacturing
- ASME Y14.47 – 2019, Model Organization Practices
- AWS D20.1/D20.1M:2019, Standard for Fabrication of Metal Components using Additive Manufacturing
- ISO/ASTM52911-1-19, Additive manufacturing — Design — Part 1: Laser-based powder bed fusion of metals
- ISO/ASTM52911-2-19, Additive manufacturing — Design — Part 2: Laser-based powder bed fusion of polymers
- ISO/ASTM 52915:2020, Specification for Additive Manufacturing File Format (AMF) Version 1.2
- MIL-STD-31000B, Technical Data Packages (not AM-specific).
- SAE EIA649C, Configuration Management Standard (G-33)

In-Development Standards

- ASTM WK71395, New Guide for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process (F42.01)
- ISO/ASTM PWI 52951, Additive manufacturing — Data packages for AM parts
- MIL-STD-31000C, Technical Data Packages (will address AM)

Gap DE17: Contents of a Data Package. The contents of a data package that is sufficiently complete such that it could be provided to a vendor and result in components that are identical in physical and performance characteristics has not been defined.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: On how to best identify level of granularity and information identification to meet different application and process needs

Recommendation: Develop a standard(s) to describe all required portions of a data package and adopt them into a formal standard(s), regardless of manufacturing process (AM, subtractive, casting). The standard(s) should address issues such as the following (not a comprehensive list):

- Performance/functional requirements (form, fit assembly)
- Qualification requirements
- Definition of "as-designed" part, versus "as-printed" part, versus "finished" part
- Post-processing requirements (including finishing, removal of parts from AM machine such as separation from build plate)
- Applicable AM process as defined in ISO/ASTM 52900
- Tailorable and non-tailorable build parameters
- Cybersecurity requirements (if necessary)
- Long term archival and retrieval process (including acquisition)

Priority: ☒High; ☐Medium; ☐Low

Organization: ASME Y14.46, ASME Y14.47, ASTM F42/ISO TC 261, AWS, DoD, NIST, SAE G-33

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASME Y14.46 has been published and it deals with data packages. MIL-ST31000C is in development and will address AM. The ISO/ASTM PWI 52951 is being developed.

Data Packages, sometimes referred to as technical data packages (TDPs in defense industry) or technical files (in medical sector), are used to procure parts by specifying the material requirements, tolerances, geometry and manufacturing processes for a part. These parts made via traditional manufacturing processes are often limited to geometry and functional requirements conveyed with 2D drawings. These drawings are also often in a portable document format (pdf). However, to procure parts fabricated with AM processes, additional process information (in addition to the geometric information, is often required. Further, the organic shapes of AM parts are often difficult to document any way other than 3D (thus are to be documented in 3D format per ASME Y14.46). Consequently, a 3D PDF utilizing an embedded Product Representation Compact (PRC) file is often used to document the designs of AM items. This has led to some significant challenges due to gaps in the current available 3D PDF. First, the 3D PDF files often need to have a Standard for the Exchange of Product model data file (STEP) file attached to them to support manufacture and inspection. The STEP file as well as the PRC both become authoritative definitions of the part. This leads to large file sizes, but more importantly, it become problematic have multiple definitions of the part. Second, current STEP files have no features and are not parametric. This makes sharing and editing the models difficult.

Published Standards

- ASME Y14.46 – 2022, Product Definition for Additive Manufacturing
- STEP-AP242 / ISO 10303-242:2022 Industrial automation systems and integration — Product data representation and exchange — Part 242: Application protocol: Managed model-based 3D engineering (2022-12) but is not AM specific.
- ISO 32000-1:2008 Document management — Portable document format — Part 1: PDF 1.7 which was reaffirmed in 2019 but is not AM-specific.
- ISO 24517-1:2008, Document management — Engineering document format using PDF — Part 1: Use of PDF 1.6 (PDF/E-1) which was reaffirmed in 2022 but is not AM-specific.
- MIL-STD-31000 B, Technical Data Packages (TDP) (2018-10-31) but is not AM-specific).

In-Development Standards

- MIL-STD-31000 C, Technical Data Packages (will address AM)
- ISO/ASTM PWI 52951. Additive manufacturing -- Data packages for AM parts.
- ISO/TS 24064 Document management — Portable document format — RichMedia annotations conforming to the ISO 10303-242 (STEP AP 242) specification (2023-03)

New Gap DE30: STEP Based 3D PDF. PDF is a common means for viewing 3D parts and annotations, but current capabilities are limited by the PRC file. AM geometry and specifications can be complex and are not well handled by PRC. There is a need for a specification for a pdf file based on a STEP file, which handles these additional complexities, as opposed to the PRC file in ISO spec.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Complete work on ISO/DTS 24064.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASME

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Uses current 3D pdf format with a STEP file attached.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap DE31: Feature-based Support for STEP. There is a need for STEP – 242 to be updated to include feature-based information, which is parametric, to better preserve geometry when developed with AM-specific characteristics (generative design, lattice body).

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Consider how different software handle the development of AM-specific design strategies and what requirements are necessary for their neutral representation.

Recommendation: ISO revise STEP 242 to address requirements identified in this gap.

Priority: ☒High; ☐Medium; ☐Low

Organization: ISO / NIST

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: Use existing STEP - 242

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.1.5.2 New Dimensioning and Tolerancing Requirements

AM offers the opportunity to create geometries never before envisioned. These include new complex features, unit cell structures, and gradient structures. There also exist new requirements for identifying datum directional properties, coordinate systems, part orientation, support material, and build location.

Published Standards

- ASME Y14.5 - 2018, Dimensioning and Tolerancing, published by the American Society of Mechanical Engineers, is currently under revision to enable better application toward model-based definitions. ASME Y14.5 provides geometric dimensioning and tolerancing (GD&T) language for communicating design intent, ensuring that parts from technical drawings have the desired form, fit, function and interchangeability. Its intent is to establish uniform practices for stating and interpreting GD&T and related requirements for use on engineering drawings and in related documents. The fundamentals of this document can be applied to AM design.

- ASME Y14.41 - 2019, Digital Product Definition Data Practices, is an AM related but not AM-specific standard published by ASME to establish requirements for model-based definitions upon Computer-Aided Design (CAD) software and those who use CAD software to create product definitions within the 3D model.
- ASME Y14.46 - 2022, Product Definition for Additive Manufacturing [Draft Standard for Trial Use] which establishes uniform TDP practices for AM. It incorporates, expands, and refines current practices and symbology to enable AM TDPs to be created, interpreted, and consumed. It ensures that these component parts and component assemblies are subject to a single interpretation of engineering specifications and requirements for the purpose of conformance and verification.
- ISO/ASTM 52915:2020, Specification for Additive Manufacturing File Format (AMF) Version 1.2 is an interchange format to address the current and future needs of AM technology and provides a method of including tolerance meta data in the design file.

In-Development Standards

- ASME Y14.46 is being revised with further work to be done on verification and validation methods.
- ASME Y14.48 on Universal Direction and Load Indicator is underway and will provide the ability to unambiguously specify directional requirements for aspects such as: geometric tolerances, elemental tolerance zones, surface texture, application of decals and decorative elements on products, orientation of parts in assemblies, orientation of fibers in composite materials, directions in additive manufacturing, rotational requirements of parts in assemblies, and movement requirements for components in assemblies. Load indicator requirements are planned to include tools for defining such things as: direction, load, fixity, the shape of contact area, load sequence, and other variables needed when applying loads to non-rigid parts.

Gap DE18: New Dimensioning and Tolerancing Requirements. ASME Y14.46 has been published and specifically deals with dimensioning and tolerancing requirements but additional work is needed on verification and validation.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Data to develop new methods and validation practices

Recommendation: Complete work on ASME Y14.46. See also gap DE26 on Design for Measurement of AM Features/Verifying the Designs of Features such as Lattices, etc.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASME Y14.46, ASME Y14.48, NIST

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.1.5.3 An Organization Schema Requirement and Design Configuration Control

It is critical that designers be able to communicate everything that controls the AM part functionality and maintain configuration management (model version control) to ensure the model definition has not changed for production, quality assurance, and design verification and validation (V&V). AM parts and process definitions can be completely digital and AM parts are tied to how they are made. For example, changes in AM production (such as processing parameters, build orientation, location of part in the build volume, using a different revision of the machine processing software, etc.) could result in materials properties that were not intended for the AM part design.

Published Standards

- ASME Y14.47 – 2019, Model Organization Practices

- ASTM F3490-21, Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree
- AWS D20.1/D20.1M:2019, Standard for Fabrication of Metal Components using Additive Manufacturing
- MIL-STD-31000B, Technical Data Packages (not AM-specific).
- SAE G-33's SAE EIA649C, Configuration Management Standard

In-Development Standards

- ASTM WK71395, New Guide for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process
- ISO/ASTM PWI 52951 -- Additive Manufacturing — Data — Data packages for AM parts

Gap DE19: Organization Schema Requirement and Design Configuration Control (CLOSED). AM parts are intrinsically tied to their digital definition. In the event of a design modification, proper methods of configuration and parameter curation are needed for verification. This could include verification of the digital material parameters, process parameters, or software version, if applicable. A comprehensive schema for organizing related information in an AM digital product definition data set will provide traceable, consistent data content and structure to consumers of the data.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: ASME Y14.47-2019, *Model Organization Practices*, formerly known as Y14.41.1 may partially address this gap but AM related aspects need to be further developed. ASME Y14.47 is based on Appendix B of MIL-STD-31000A. ASME could also consider multiple schemas (e.g., scan data) that are not currently under consideration within Y14.47. ASME Y14.47 and ISO/TC 10 could incorporate the digital configuration control into their developing standards if they have not already. SAE's G-33 Configuration Management Committee is developing SAE EIA649C, Configuration Management Standard, which is targeted for publication by the third quarter of 2018.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASME Y14.47, ISO/TC 10, ASTM F42/ISO TC 261 JG 73, AWS, NIST, SAE G-33

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☒Closed; ☐New

V3 Update: The gap D19/DE19 in roadmap version 2 has been satisfied with the publication of Y14.47 and the common data dictionary (ASTM F3490) has been published.

2.1.5.4 A Neutral Build File Format

The current industry standard for file formats is the stereolithography (STL) file. As AM technology has matured, several shortcomings with the STL format have become apparent, such as lack of color, material, density, and orientation. The ISO/ASTM 52915:20 additive manufacturing file format (AMF) was developed with the assistance of ASTM to address the shortcomings of STL and to be extensible to support future needs of the industry. It has not been fully adopted throughout the industry. It does address STL shortcomings and is extensible; however, it is still not considered a complete solution for some AM process categories and applications such as laser-based AM systems.

In a separate development, a consortium led by Microsoft and other partners developed the 3D Manufacturing Format (3MF) standard; however, this standard also does not fully address the requirement. A requirement exists to have a neutral build file as an input to AM machines which would be similar to having a STEP file in subtractive manufacturing; however, it would include supporting structure and laser path as well as other important parameters required by a machine to manufacture a part. When using laser-based AM systems, it is extremely difficult to document many of the existing parameters and the laser scan paths in a data package. Further, it is impossible to semantically identify this information in anything other than a vendor proprietary format and impossible to associate any of this data with any human readable information. Without a neutral build format, full and open competition can never be fully realized. This lack of competition creates a barrier to government procurements and stifles innovation and development. However, in the current landscape, it will be difficult to realize the goal of a standard since so much of this information is currently in proprietary formats.

Published Standards

- ASTM F3490-21, Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree (F42.08)
- ISO 14649-17:2020, Industrial automation systems and integration — Physical device control — Data model for computerized numerical controllers — Part 17: Process data for additive

manufacturing. Developed independently by ISO TC 184, not yet aligned with ASTM F42 / TC 261.

- ISO/ASTM 52915:2020, Specification for Additive Manufacturing File Format (AMF) Version 1.2. includes the capability of incorporating the additional technical information described here as meta data attributes. Updates to ISO/ASTM 52915:20 could expand the current support for inclusion of meta data and other essential information within the file to address gap DE20.
- ISO 10303-242:2022, Industrial automation systems and integration -- Product data representation and exchange -- Part 242: Application protocol: Managed model-based 3D engineering. Commonly referred to as STEP AP242, this ISO standard "specifies the application protocol for Managed model-based 3d engineering." STEP AP242 can represent exact model geometry, tessellated model geometry, and associated geometric and dimensional tolerances all in one file. Some AM-specific information such as build orientation and location, build surface dimensions, and support geometry are planned for the second edition of AP242.
- STEP AP238 or STEP-NC is a machine tool control language that extends the ISO 10303 STEP standards with the machining model in ISO 14649-1:2003, adding geometric dimension and tolerance data for inspection, and the STEP product data management model for integration into the wider enterprise. The combined result has been standardized as ISO 10303-238:2022 (also known as AP238).
- 3D Manufacturing Format (3MF) is a 3D printing format developed and published by the 3MF Consortium. The 3MF format allows CAD applications to send 3D models to additive manufacturing printers. This technical specification is a resource being considered in relation to the below gap.

In-Development Standards

- ASTM WK48549, New Specification for AMF Support for Solid Modeling: Voxel Information, Constructive Solid Geometry Representations and Solid Texturing. ASTM F42.04 (JG64) is developing this document which "describes existing features for Solid Modeling support within the present Standard Specification of the AMF format and formulates propositions to further AMF interoperability with Voxel Information, Constructive Solid Geometry (CSG) Representation and Solid Texturing."
- ISO/ASTM CD TR 52918, Additive manufacturing — Data formats — File format support, ecosystem and evolutions

As noted above, some standardization has been done in this area through the AMF format developed by ISO/TC 261 and ASTM F42 in close cooperation under their partner standards developing organization (PSDO) cooperation agreement. However, significantly more needs to be done. Industry has not adopted a single standard for AM file format. Having to assess, interpret, or manage differing file formats makes translation of CAD files or their transportability more problematic, making qualification of a design difficult between machines. ISO/TC 184/SC4 has published the ISO 10303 standards and done similar work with CAD files as well as product lifecycle management schemas.

Gap DE20: Neutral Build File Format. A standard is needed to provide explicit definitions of process specifications that can be directly interpreted and used by different machines for complete part fabrication. Many other parameters remain unsupported. Ideally, the same file could be used as the input into an AM machine regardless of the vendor of the machine and provide for a uniform output. Industry should work to coalesce around one industry standard for (technology specific) am process specification, which will help to better enable qualification of a design across various platforms. However, the unique technologies of the different vendors could make such an effort challenging.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Developing information models that expand current AP238 and 242 capabilities and extend them to AM. Testing these information models at NIST to drive a build.

Recommendation: Update standards content (such as within ISO/ASTM 52915:20; 3MF; or ISO 10303-238:2022) for the computer-interpretable representation and exchange of additive manufacturing product and process information that can represent all of the applicable slice files, build path, print orientation, layer height, precision, tolerances, and feedstock materials, as well as the other applicable parameters into a single neutral file. This file would be used to exchange data between AM vendors and have the capability to be used instead of proprietary file formats and material parameter sets. See also gap DE8 on machine input and capability report.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/TC 184/SC4, ISO/TC 261/ASTM F42, consortium of industry, IEEE-ISTO PWG

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☒Directed Energy Deposition; ☒Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Proprietary formats used by individual vendors. Neutral representations are limited to the original geometry files and the orientation and meta data supported in ISO/ASTM 52915:20 AMF format files, including but not limited to: unit of measure, name, author, company, revision, tolerance, producer, constellation(assembly), color(by file, object, component, facet), material,(by object, component, or gradient), elastic modulus, poisson ratio, unique ID, reference .url, orientation of multi-part assemblies; and general meta data fields for adding additional meta data in XML format.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: See standards list above. ISO/ASTM 52915:20 v1.2 was published in May 2020. It specifies the ISO/ASTM additive manufacturing file format that includes specifications for the majority of meta data listed in this gap and methods for incorporating additional information through optional meta data fields, support for inclusion of other files in XML format, as well as support for inclusion of additional files in other formats, and a reference .url for linking to additional files and information, such as a data package.

Since publishing v1.2, the ISO TC261 J64 technical working group on additive manufacturing formats has been working to draft a technical implementation guideline to aid users in utilizing the current specification to address new needs, including the ones listed in this gap, and to develop an expanded set of meta data schema in the next version of AMF to address this and other gaps in a manner that will be acceptable and useful to industry on a global basis.

2.1.5.5 New Terminology in Design Documentation

In AM, numerous new terms (e.g., build volume, staircase effect) are used which are often referred to in design documentation. These terms need to be clearly and legally defined if they are to be used in a data package.

Published Standards

- ASME Y14.46-2022, Product Definition for Additive Manufacturing establishes uniform TDP practices for AM. It incorporates, expands, and refines current practices and symbology to enable AM TDPs to be created, interpreted, and consumed. It ensures that these component parts and component assemblies are subject to a single interpretation of engineering specifications and requirements for the purpose of conformance and verification.
- ASTM F3490-21, Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree (F42.08)
- ISO 17295:2023, Additive manufacturing — General principles — Part positioning, coordinates and orientation
- ISO/ASTM 52900-21, Additive manufacturing - General principles – Fundamentals and Vocabulary.
- ISO/ASTM 52921-13 (2019), Standard terminology for additive manufacturing - Coordinate systems and test methodologies.
- ISO/ASTM 52950-21, Additive manufacturing — General principles — Overview of data processing

Gap DE21: New Terminology in Design Documentation (CLOSED). While some AM terminology standards already exist, they do not include certain terms referred to in design documentation. Terminology in a data package needs to be clear.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: ASME Y14.46 has identified terms for design documentation that are not defined in existing AM terminology standards. Once this work is completed, it should be referred to ISO/TC 261 and ASTM F42 for inclusion in existing standards such as ISO/ASTM 52900.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASME, ISO/ASTM

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify) Terminology

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☒Closed; ☐New

V3 Update: The gap, as originally framed, has been closed. Terminology standards will continue to be regularly revised. ASME Y14.46-2022 has been published. ASME Y14.46 references ISO/ASTM AM terminology standards (ISO/ASTM 52900 and ISO/ASTM 52921) as much as possible but also had to create new AM terminology specific to AM Product Definition. The ASME Y14.46 AM-related terms were sent to ASTM.

2.1.5.6 In-Process Monitoring

Additive manufacturing offers the capability to have significant in-process monitoring. The availability of in-process monitoring has grown significantly, and development is still expected in the next several years. This will dictate what data should be captured and when and how this data may be used to provide assurances that a part was made to a required specification. The ability to qualify a material, process, or part(s) using in-process monitoring is anticipated to eventually support design allowables and quality assurance, either directly or through validation of computational models. Currently, metal additive manufacturing involves multiple physical phenomena and parameters that potentially affect the quality of the final part. To capture the dynamics and complexity of heat and phase transformations that exist in the AM process, computational models and simulations ranging from low- to high-fidelity have been developed. Since it is difficult to monitor all physical phenomena encountered in an AM process, computational models rely on assumptions that may neglect or simplify some physical phenomena. Modeling uncertainty plays a significant role in the predictive accuracy of such AM models, and 'ground truth' validation data, potentially from in-process monitoring, is necessary to evaluate this uncertainty. There is a lack of standards for validated physics- and properties-based predictive models for AM that incorporate geometric accuracy, material properties, defects, surface characteristics, residual stress, microstructure properties, and other characteristics (NIST, 2013).

Though not specifically targeting model validation, ASTM CoE's "Strategic Guide: Additive Manufacturing In-Situ Technology Readiness" illustrates existing technological and standardization gaps for in-process monitoring.

A related gap (PC16) is mentioned in section 2.2.2.12 Process Monitoring. The in-process monitoring data covered by PC16 includes real-time data obtained on the feedstock (supply ratios and other metrics), process conditions (atmosphere, humidity), process parameters (beam diagnostics such as location, laser power, scan width, scan rate), and the part during build (dimensions, surface finish, microstructure, density, hot spots, defect state). The R&D Expectations and Recommendations for Gap PC16 are largely the same for applications of In-process Monitoring for design and/or model validation (see also to gap DE9: AM Simulation Benchmark). Gap PC16 replaces the need for the Roadmap version 2.0 design gap D22 on in process monitoring which was withdrawn**.**

2.1.5.7 Documentation of New Functional Features and Surface Features

Additive manufacturing offers the opportunity for design of new functional features and surface finishes as described in section 2.1.4. Design for Specific Applications. Features and surfaces may be optimized to meet different functional requirements including, increased friction, thermal cooling, light weighting, or increased biologic activity. For instance, the outer portion of a part may contain regular grid lattice structures that can be used to reduce the weight of a solid part or improve bone attachment in orthopedic implants. Typically, these features are described by highlighting the area and identifying that they will be porous, grid, or lattice with leader lines. Basic information on the pattern is then provided in a table, but it is often insufficient to duplicate the part consistently. They can sometimes be documented by specifying the central axis length of each strut and its thickness. However, this quickly becomes ambiguous if the lattice is random, algorithmic, or does not cleanly match the part profile.

Additionally, similar complex patterns could be incorporated into the part's surface finish. Additively manufactured parts can also have unique surface finishes that are characteristic of the manufacturing processes, rather than the design. Either intended or unintended, the resulting surfaces are difficult or even impossible to characterize and document by currently available methods and metrics. New standards are needed to characterize and specify AM surface finishes.

There are currently no established standardized means to document the geometric/tolerancing requirements of these complex features and surface finishes.

Published Standards

- ASME Y14.46-2022, Product Definition for Additive Manufacturing [Draft Standard for Trial Use], which establishes uniform TDP practices for AM.
- ASME B46.1 – 2019, Surface Texture (Surface Roughness, Waviness, and Lay)

In-Development Standards

- ASME B46 Project Team 53 is working on this effort and will either revised B46.1 or develop a separate document.
- ASTM WK65929, New Specification for Additive Manufacturing-Finished Part Properties and Post Processing - Additively Manufactured Spaceflight Hardware by Laser Beam Powder Bed Fusion in Metals (F42.05)
- ASTM WK65937, New Specification for Additive Manufacturing -- Space Application -- Flight Hardware made by Laser Beam Powder Bed Fusion Process (F42.05)
- ASTM WK66682, Guide for Evaluating Post-processing and Characterization Techniques for AM Part Surfaces (F42.01)
- ASTM WK83110, Practice for Additive Manufacturing – Powder bed fusion – Measurement for load-bearing area for mechanical testing with as-printed surfaces (F42.01)

Gap DE23: Documentation of New Functional and Complex Surface Features. There is a need for a specification on design documentation for intentionally introducing new bulk or surface geometries which can be created through AM.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: ASME Y14.46 should consider an annex describing a method to document functional and complex geometric features.

Priority: ☐High; ☐Medium; ☒Low

Organization: ASME

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: For documentation for design, unknown. For inspection, micro-CT (measure vs model evaluation) or optical profilometry may be used.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the recommendation. ASME Y14.46-2022 been published but does not address the recommendations at this time.

Gap DE28: Specification of Surface Finish. There is a need for a specification on desired surface finishes of AM parts that can later be measured and validated against. Current surface finish metrics, such as Ra, do not adequately specify surface finish requirements. A surface metric which can be correlated with fatigue is needed.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Continued characterization of AM surfaces in order to confidently relate to the performance of the part.

Recommendation: ASME revise ASME B46.1 to address specification requirements of AM surface finishes. ASTM to complete its work on ASTM WK66682.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASME, ASTM

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: All machining of critical surfaces, and design point solutions as opposed to process-oriented solutions.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASME B46.1-2019 was published which added a section to Appendix B of the standard regarding surface texture of AM parts. This is currently a generalized section with several references to ISO, ASTM, and ANSI standards or guides. In the future, the section will be expanded upon, possibly moving to a section within the standard, as opposed to being an appendix. ASTM AM CoE Strategic Roadmap for Research & Development notes that AM CoE Projects 1802 (WK66682) and 1804/1907 (WK65937, WK65929) address AMSC Gap DE28.

2.1.5.8 An Acquisition Specification

A specification will be required to procure AM parts from third parties. In version 2.0, gap D24 for An Acquisition Specification recommended completion of ASTM WK51282. The work was published in 2017 as ISO/ASTM 52901, Additive manufacturing - General Principles - Requirements for Purchased AM Parts.

Published Standards

- ISO/ASTM 52901:2017, Additive manufacturing – General Principles – Requirements for Purchased AM Parts (2017-08, reconfirmed in 2023)
- SAE AMS7004, Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate, Ti-6Al-4V, Stress Relieved (2019-01-31)
- SAE AMS7008, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 47.5Ni – 22Cr – 1.5Co – 9.0Mo – 0.60W – 18.5Fe (2019-03-26)

- SAE AMS7012, Precipitation Hardenable Steel Alloy, Corrosion and Heat-Resistant Powder for Additive Manufacturing 16.0Cr – 4.0Ni – 4.0Cu – 0.30Nb (2019-11-14)
- SAE AMS7013, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 60Ni – 22Cr – 2.0Mo – 14W – 0.35Al - 0.03La (2019-01-03)
- SAE ARP7043, Recommendations for an Additive Manufacturer Designing/Repairing Aircraft Components (2022-08-05)

In-Development Standards

- SAE AS7041, Distributor for AM build distributors Requirements (AMS AM)

There were no new standards gaps identified with regards to this issue.

2.1.6 Design Verification and Validation

The verification and subsequent validation (V&V) of a design are important steps to ensure it fulfills its goals and application. V&V requirements are also common in most quality management standards such as ISO/IEC 17025 and ISO 9000. For the purpose of this document, verification is defined as the confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. Validation is defined as confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.[8] Guidelines to inform design decisions that will facilitate their measurement and subsequent verification and validation would be advantageous.

A design is the basis of verification, which can be accomplished using a variety of methods depending on the application needs. To explore how AM specifically impacts V&V, it is assumed that some design elements will frequently arise during verification. These elements—listed below—formed the basis of the current gap analysis. Verifying an AM design likely requires specific guidelines for:

- developing of specifications or methods of comparing to specifications
- structural, thermal, physical, and chemical performance
- requirements for post-processing
    - Standard practices and specifications for newer post-processing techniques for surface finishing will be required to standardize these practices. This includes the measurement of surface finishes during validation, if surface texture is a critical feature.
- dimensional analysis

[8] Definitions of verification and validation are taken from ISO 9000:2015.

  - Geometric dimensioning and tolerancing specifications and practices must be fully applicable to AM. Evaluating these components will likely occur in most design review processes.
- methods of model version/configuration control in the digital definition of AM designs
  - Geometrical dimensioning and tolerancing will likely be included in these models, and the feature definitions must be fully compatible with AM.

Validation standards are application specific. Space, health/medical, industrial, food, petroleum, construction, mechanical (welding, pressure vessels, etc.). AM validation will likely require testing for defects. See Chapter 2.4 Nondestructive Evaluation (NDE) for related standards activities.

Published statistical guides for guiding sample sizes for experiments are under the jurisdiction of ASTM Committee E11, though specific sampling recommendations for AM materials testing likely fall under jurisdiction of ASTM F42. Currently open questions include:

1) What is the minimal number of builds to validate a design for AM with respect to costs?
2) How much of the build volume needs to be captured?

Test Methods

Both verification and validation depend on the final application. Therefore, AM designs should be verifiable using existing guidelines and methods for each application. One case, design for manufacturing and assembly, may require additional guidelines for AM. Listing each approach that can be used for validation of a design is a significant undertaking and outside the scope of this section, and addressing individual tests used for validation is left to the remaining sections of this roadmap.

An approach that could form the basis of some validation approaches is Gage Repeatability and Reproducibility (R&R) studies. Currently, the repeatability of AM is not well characterized, and the R&R process may play a role in maturing the manufacturing technologies. Standards BS ISO 21748:2017, Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation (British Standard) and ISO 5725, Accuracy of Measurement Methods and Results Package (managed by ISO/TC 69/SC 6) provide guidelines for this approach; further information can be found in ISO/TR 12888:2011, Selected illustrations of gauge repeatability and reproducibility studies (ISO/TC 69/SC 7).

Published Standards

- ASME PTC 19.1-2018, Test Uncertainty
- BS ISO 21748:2017, Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation (British Standard)

- FDA-2016-D-1210[9], Technical Considerations for Additive Manufactured Medical Devices (2017-12).
- ISO 5725, Accuracy of Measurement Methods and Results Package
  - ISO 5725-1:1994, Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions (reconfirmed in 2018)
  - ISO 5725-2:2019, Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method
  - ISO 5725-3:1994, Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method (reconfirmed in 2013)
  - ISO 5725-4:2020, Accuracy (trueness and precision) of measurement methods and results — Part 4: Basic methods for the determination of the trueness of a standard measurement method
  - ISO 5725-5:1998, Accuracy (trueness and precision) of measurement methods and results — Part 5: Alternative methods for the determination of the precision of a standard measurement method (reconfirmed in 2018)
  - ISO 5725-6:1994, Accuracy (trueness and precision) of measurement methods and results — Part 6: Use in practice of accuracy values
- ISO/ASTM 52910-18, Additive manufacturing — Design — Requirements, guidelines and recommendations
- ISO/TR 12888:2011, Selected illustrations of gauge repeatability and reproducibility studies

In-Development Standards

In-development standards for the topics above are limited, especially for AM-specific applications. Below are works-in-progress for material properties and design guides.

- ASME Y14.46 – 2022, Product Definition for Additive Manufacturing, ASME is also in the process of producing AM design guides, which may provide guidelines for design verification.
- ASTM WK71395 New Guide for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process (F42.01)
- ASTM WK72659, New Guide for Guideline for Material Process Validation for Additive Manufacturing of Medical Devices (F42.07)
- ISO/ASTM CD 52918, Additive manufacturing — Design — Requirements, guidelines and recommendations (see also WK83512)

[9] See also FDA background information on *Process of 3D Printing Medical Devices*. Last accessed on April 5, 2023. https://www.fda.gov/medical-devices/3d-printing-medical-devices/process-3d-printing-medical-devices

Gap DE26: Design for Measurement of AM Features/Verifying the Designs of Features such as Lattices, etc. As noted in gap DE18, working groups are currently developing methods to standardize the geometric dimensioning and tolerancing (GD&T) of AM parts. As these mature, existing V&V methods of checking part conformance to GD&T specifications must be investigated for their compatibility with AM. As part of the design process for AM, the availability of methods to measure and verify AM-unique features must be considered, especially to meet critical performance requirements. This may result in adapting existing NDE methods or creating new methods. This will likely be relevant when measuring AM features such as helixes or other complex shapes, or internal features that are not compatible with common methods such as Go/No-Go gauges or coordinate measuring machines (CMM). Especially in the case of internal features, assessing the ability of ultrasonic or radiographic methods to validate high tolerances will be required.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Investigation of high resolution radiographic and ultrasonic methods and the maximum achievable resolution and accuracy for GD&T of complex AM designs.

Recommendation: As GD&T standards continue to develop, perform parallel investigations of validation methods to ensure V&V is possible. See also gap NDE4, Dimensional Metrology of Internal Features.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/TC 261/ASTM F42, ASTM E07.01, ASTM E07.02, ASME B89, ASME Y14.46, ISO/TC 10

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Policy and regulations would address this. The medical sector is using FDA guidance and ASTM F1854 for design of lattices although not optimized for CT or AM related. Military leverages contractual agreements.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: A standard on methods to verify that complex AM parts meet design requirements is needed. ASME Y14.46 will address how to document AM-unique design features, but not how to inspect/verify the design. Y14.46 included a non-mandatory appendix with guidance on quality assurance (QA) parameters and references that may be used to develop design validation methods. ASME B89 (dimensional metrology) is working jointly with Y14.46. ISO/ASTM 52910-18 provides guidance for AM designers to "work with their quality groups to ascertain if appropriate inspection and qualification processes are available or need to be developed for the types of parts that they are designing."

2.1.7 Design for Anti-counterfeiting

Anti-counterfeiting is a concern in manufacturing and relevant in AM applications, including printed electronics, medical, aviation, and automotive, along with performance athletics, toys, and other branded goods. Products that appear genuine may contain flaws. Designing anti-counterfeiting measures into products (vs. forensic analysis after a failure) offers better chances of preventing sabotage and injury. Best practices include:

Design for anti-counterfeiting features. Make it possible to include an identifying feature such as a chemical taggant mix including graded materials options; porosity; a void pattern; or an electronic tag.

Covert features are preferred. Surface features can be scanned and reproduced by a counterfeiter, and may not survive post-processing. In existing markets with high levels of counterfeiting (e.g., luxury goods, pharmaceuticals), overt features reassure consumers but have been quickly replicated by counterfeiters.

Overt features. Where item identification information is to be used to enable automatic data capture the design must accommodate the inclusion of them required marking on the part such as 2 dimensional barcodes for unique identification or capture of general part information. Human readable information may also be required. In both cases the design should also consider the application of covert features for authentication as described above.

Simple validation techniques protect better. When testing is simple (e.g., fast, easy, field-friendly, non-destructive, inexpensive, off-the-shelf, etc.), it is more widely deployed.

Coordinate with cybersecurity. Materials-based and pattern-based features can be part of the build, e.g., as a covert sub-surface mark. Instructions for such features can be encrypted and subject to appropriate security controls, including blockchain, in the build file.

Align with Data Package. Incorporating anti-counterfeiting at the design stage enables fast data package compliance screening in the final product. Products that lack anti-counterfeiting measures may warrant additional scrutiny. See Process Control section 2.2.2.13 Anti-counterfeiting and NDE section 2.4.7 NDE of Counterfeit AM Parts.

Source Authentication. Source authentication takes anti-counterfeit measures to another level. In this case the material that makes up the object must come from an authentic material that is not a prohibited source. This may be required due to a contractual, political or economic reason. Methodology for displaying intellectual property notifications is addressed in gap DA22 Technical and IP Authentication and Protection.

Published Standards

- A4A SPEC2000, Automated Identification and Data Capture (Ch. 9)
- AIAG B-4 Parts Identification and Tracking Application Standard (October 2018)
- AIAG B-17 2D Direct Parts Marking Guideline (July 2009)
- ISO/ASTMTR52906-EB, Additive Manufacturing—Nondestructive Testing—Intentionally Seeding Flaws in Metallic Parts (see also ISO/ASTM TR 52906:2022)
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- ISO/IEC 15434:2019, Information technology – Automatic identification and data capture techniques – Syntax for high-capacity ADC media
- ISO/IEC 15459-4:2014, Information technology – Unique identifiers – Part 4: Individual items (reconfirmed in 2020)
- ISO 22380:2018, Security and resilience — Authenticity, integrity and trust for products and documents — General principles for product fraud risk and countermeasures
- ISO 28219:2017, Packaging -- Labelling and direct product marking with linear bar code and two-dimensional symbols (formerly MHI MH10.8.7)
- MHI MH10.8.2 Data Identifier (2021-02-11)
- MIL-STD-129P, Military Marking for Shipment and Storage
- MIL-STD-130N, Standard Practice for Identification Marking of U.S. Military Property
- SAE AS5553D-2022, Counterfeit Electrical, Electronic, and Electromechanical (EEE) Parts; Avoidance, Detection, Mitigation, and Disposition (2022-04-14)
- SAE AS6174A-2014 (SAE AS6174A-2014), Counterfeit Materiel; Assuring Acquisition of Authentic and Conforming Materiel (2014-07-29)

There were no in-development standards identified.

New Gap DE29: Best Practices for Design for Anti-counterfeiting. Anti-counterfeiting design methods, such as discontinuities, watermarks and even voids, may be intentionally introduced in order to address the concern of counterfeiting, e.g., by inserting other materials or varying internal texture as a hidden signature. Alignment of anti-counterfeiting feature detection with broader quality testing captures the fact that a counterfeit AM part is a quality failure. Standards exist for detection, mitigation, etc., however design standards are needed for intentionally introducing discontinuities for AM parts.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: TBD

Recommendation: Develop best practices which address how to design in covert features, such as internal patterns, physical or chemical, and electronic tags, avoid those vulnerabilities which provide techniques for IP management. Develop standards which provide guidance on how to:

(1) Design anti-counterfeiting features so that their monitoring can be folded into existing test protocols. Counterfeits and quality failures both encompass potential deviations in materials, tolerances, and print parameters.

(2) Design with an eye toward coordinated testing, to reduce the economic burden of separate anti-counterfeiting measures and to enhance the likelihood of adoption of IP protection.

See also sections 2.2.2.13 Anti-counterfeiting (process control), 2.4 NDE gaps NDE2 and NDE7) and 2.6.7.3 Technical and IP Authentication and Protection (gap DA22)

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ISO/ASTM

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Proprietary efforts.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.2 Process and Materials

It is rare that a finished product can be entirely manufactured within a single process. Normally, a series of operations and sub-processes are required to achieve the intended combination of geometrical shape and desired properties. However, in the context of AM there is a distinction between which operations are indispensable parts of the additive process and which are more product- and application-dependent pre-processing and post-processing operations. This section discusses AM materials and processes in accordance with the four subgroupings around which the AMSC has organized itself, starting with Precursor Materials, moving on to Process Control, then Post-processing, and, finally, Finished Material Properties.

2.2.1 Precursor Materials

2.2.1.1 Introduction[10]

Additive manufacturing is not a singular manufacturing technique. It covers a variety of technologies to build parts directly from three-dimensional design data and using different precursor materials. These include metals, polymers, ceramics, and composites, which could vary greatly in their type, form, properties, and characteristics.

The technologies used to build a part will determine the various physical forms of the precursor materials, including but not limited to: powders, wires, pellets, filaments, conductive inks, and liquids. As new technologies enter the market, this list may grow. For the industry to be able to confidently select the precursor material and produce consistent parts with predictable quality for a critical application, it is necessary to determine the properties of the precursor materials. The industry will therefore benefit from a standardized measurement of the absolute properties of the precursor materials and the impact of their change through the AM process. This will also open up opportunities to develop new and novel materials for the AM processes and platforms that currently rely, for the most part, on off-the shelf material systems designed for specific manufacturing techniques.

While a large body of work pertaining to standard test methods is being carried out globally, more work is needed to address the variation in precursor materials. What is applicable for metals may have no relevance to polymers and liquids. The reciprocal is also true. The impact of the energy input to material conversion will further complicate standardization. For example, the energy directed at the materials to build a part may come from a variety of sources (e.g., electric arc, plasma transfer arc, laser, electron beam gun, etc.).

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[10] The Precursor Materials working group defined the scope of this section as encompassing everything related to the precursor material up until it is used to make a component.

Today, precursor material requirements differ, even within one materials family, from one AM equipment manufacturer or application to another. For example, a metal part being built using a laser as the energy source may specify differing powder particle sizes and particle size distributions. The differences arise from earlier development work done by the equipment manufacturers or the facilities manufacturing the AM parts. An added layer of complexity comes from the desire to achieve differing levels of surface resolution on the as-built part. The finer the resolution, the less surface preparation or machining is needed. The list of permutations is extensive.

The numerous alternatives are exacerbated by the individual AM equipment manufacturers, high liability versus low-liability market requirements, and the fitness-for-use of every unique part.

The need is clear. Industry-wide standards and specifications for precursor materials must be established and published.

Metals

Metal feedstock is generally in the form of powders, wires, and sheets. Below are some examples of how the metal feedstock is used. This is not an exhaustive list.

For example, powder bed fusion (PBF) processes using laser (L) and electron beam (EB) rely on metal powder with a chemistry, particle size, and morphology tailored for the specific AM metal process. Spherical powder is sieved to an acceptable particle size distribution (PSD) to suit PBF-L or PBF-EB processes. The number of common engineering alloy powders optimized for PBF processes and specific applications is currently limited but will increase with greater adoption of the technology. Commercial metal powders used by the directed energy deposition (DED) laser process offer a wider range of alloy selection. These alloys include hard facing alloys and materials in wider use, such as those used for laser cladding. Issues associated with AM metal powders include consistency of chemistry, PSD, shape morphology, micro-porosity, or contaminants picked up during powder production.

DED processes using electron beam and electric arcs currently rely on solid wire feedstock optimized for use in conventional weld processing. Production of weld wire is covered under existing industrial standards. Standards exist for commercial material shapes such as build plates that become integral to the final AM part. In addition, part complexity in manufacturing 3-dimensional parts, repairing, refurbishing, or re-engineering used parts by powder-based DED processes may necessitate varieties of precursor materials.

Polymers

The precursor materials for additively manufactured polymer components are based on amorphous or semicrystalline thermoplastics, elastomers, epoxies, photopolymers, and sometimes polymer composites and filled polymers. The most frequently used AM processes are: (i) Powder Bed Fusion (PBF), sometimes referred to as Laser Sintering, Selective Laser Sintering (SLS) or Melting (SLM); (ii) Material Extrusion, e.g., Fused Deposition Modeling (FDM); (iii) Vat Photopolymerization, e.g., Stereolithography (SLA) or Digital Light Processing (DLP); and (iv) Material Jetting, e.g., Plastics Jet

Printing (PJP). As described in the preceding sentence, the precursor material is in the form of powder for process (i), monofilaments or pellets for (ii), and liquid for (iii) and (iv) above.

Hybridization of AM with other processes, such as Laser Direct Writing (LDW), is also used for structural electronics where conductive and insulating materials are deposited.

The current repertoire of polymer materials available for PBF includes: acrylonitrile butadiene styrene (ABS), polycarbonate (PC) polymer blends based on ABS and PC, polyamide (PA), polylactic acid (PLA), polyvinyl alcohol (PVA), polyether ketone (PEKK), polyether ether ketone (PEEK), thermoplastic flame retardant (FR) compounds, epoxies, etc. AM also allows combinations of plastics with carbon fiber and polymer matrix composites (PMC).

The PBF process relies on the flow properties of polymeric powders for sensitive differentiation: cohesion of powder affecting packing (static) and flow efficiency (dynamic), flowability of powder during powder layer application, and packing efficiency of powders inside the feeders and build chambers. Requirements on powder qualities and interaction of process parameters with intrinsic (melting point, melt flow) and non-intrinsic (shape, size, flowability) properties of powders need to be understood.

The FDM process is a polymer extrusion process. The strength of the fused layer formed by the deposited molten polymer beads depends on many factors such as temperature gradient (process parameter) and polymer structure (molecular weight, branching, heat of fusion, glass transition temperature), molten bead surface roughness, and spacing.

Ceramics

Currently, ceramic feedstocks include: powder, for powder bed process, such as ink jet printing and indirect SLS; filament, blended ceramic and polymer for FDM process; paste/slurry, UV curable paste/slurry, for stereolithography process; and paste, for extrusion-based 3D printing and direct ink writing process. Ceramic and polymer blended sheets are still used in certain laminating ceramic AM. However, the application is limited and with no significant growth in the past decades.

The requirements of rheological properties, particle morphology, and particle size/size distribution should be same for ceramic as for metal materials. The purpose is to form a smooth and high packing density powder bed, and further achieve dense and defect-free sintered parts. The property controls should be focused on flowability and packing density. Higher flowability[11] and packing density usually generate high ceramic green density and less defects. Flowability is normally determined by ceramic particle morphology, particle size, and particle size distribution, while the green density is determined

[11] It should be noted that powder flowability is not an inherent property of the powder. It not only depends on particle sizes, shapes, and moisture content in the powder but also on the equipment and methods used. For example, the powder that cannot flow through a Hall funnel can still flow in other rheometers.

by packing density that is related to particle size and particle size distribution. Usually, bi-model or tri-model particle size distribution is required to achieve high powder bed packing density. Powder rheometry should be incorporated in characterization of ceramic powders. The binder system is important for forming a strong green. Two aspects should be characterized for a binder system. The first is the binding strength and the second is the burnout behavior during post-processing.

Many types of thermal plastic can be blended with ceramic powders to form filaments that are suitable for FDM. The thermal properties and rheological properties are important. High solids loading ceramic/polymer filament with ideal rheological properties at the processing temperature is critical for a ceramic FDM process. The other aspect for polymers used for ceramic filament is the burnout behavior during the post-processing.

Ceramic stereolithography additive manufacturing uses UV curable resins blended with ceramic powders to form a UV curable slurry that can be cured to the depth at least 30 µm. If the curing depth is less than 30 µm, it will be difficult for current ceramic stereolithography printers. The critical properties of UV curable ceramic slurries also include ceramic solids loading; less than 40 vol.% will generate difficulties in achieving high sintering density. High polymer (binder) loading in the ceramic greens makes the binder burnout more challenging for thick wall components (>10 mm thick). Defects can form during the binder burnout if the binder decomposition is too fast and builds up high pressure in local areas. The high pressure will break the components and form defects. The parts may explode completely if the binder burnout cycle is too aggressive. Characterizing feedstock materials should focus on curing ability, ceramic solids loading, and post-processing behaviors.

Most of extrusion-based ceramic AM uses aqueous paste/slurry to form 3D ceramic green. It involves only a limited binder. The most important characteristics of the feedstock material are the rheology properties and ceramic solids loading. Direct ink writing involves organic-based slurry. Rheology is most important since most of direct ink-write do not involve post-processing.

<u>Composites</u>

Composites in Additive Manufacturing broadly speaking encompasses not just fiber reinforced polymer materials, but should also be seen to include aggregate reinforced materials. The precursor standards for the primary or matrix material are substantially the same as that for that material and process without the addition of functional secondary materials. Specifications for the functional secondary materials must include those generally applicable for the composite material (e.g., fiber sizing), with additional controls for the AM process to be implemented.

2.2.1.2 **Storage, Handling, and Transportation** (metals, polymers)

Metals[12]

In any manufacturing process, proper storage and handling of raw materials is paramount to safety and the quality of the resultant product.

In storage, it is necessary to take steps to protect the product and limit the size of a fire or explosion. All containers should be kept sealed and stored unopened in an area separate from handling areas. When a container of powder is opened for loading or inspection, it should be closed and resealed as quickly as possible. To prevent contamination and moisture pick up, powder containers should be opened in areas with controlled atmosphere (temperature, humidity) and clean environment. This not only ensures greater safety against fire from external sources, but also prevents possible entrance of minor contaminants or moisture from the air. All containers in work areas should be closed and sealed. Only those in actual use should be open at any time.

Published Standards

- ISO/ASTM 52907:2019, Additive manufacturing – Feedstock materials – Methods to characterize metallic powders
- ISO/ASTM 52931:2023, Additive manufacturing of metals — Environment, health and safety — General principles for use of metallic materials

Dust generated when handling powders is inherently dangerous therefore care must be taken to store and use powders in accordance with the guidelines provided by OSHA and the suppliers' Material Safety Data Sheets (MSDS or just SDS.) Applicable standards for the preparation of those MSDS may be found in ANSI Z400.1/Z129.1-2010, *Hazardous Workplace Chemicals - Hazard Evaluation and Safety Data Sheet and Precautionary Labeling Preparation*.

Below are some of the standardized tests that can be conducted to characterize **combustibility of flammable solids/powders**. This is by no means a complete list.

- ASTM D1929-20, Standard Test Method for Determining Ignition Temperature of Plastics
- ASTM E1226-19, Standard Test Method for Explosibility of Dust Clouds
- ASTM E2019-03(2019), Standard Test Method for Minimum Ignition Energy of a Dust Cloud in Air
- DOT/UN Division 4.1 - Burning Rate Test
- DOT/UN Division 4.2 – Self-Heating Substances Test

[12] This section does not discuss metal wire.

The National Fire Protection Association (NFPA) also maintains a number of relevant standards and other documents supporting the **safe storage and handling** of metal powders as follows:

- NFPA 68-2018, NFPA 68 Standard on Explosion Protection by Deflagration Venting, 2018 Edition
- NFPA 69-2019, Standard on Explosion Prevention Systems, 2019 Edition
- NFPA 70-2020, National Electric Code (NEC) Softbound, 2020 Edition
- NFPA 77-2019, Recommended Practice on Static Electricity, 2019 Edition
- NFPA 91-2020, Standard for Exhaust Systems for Air Conveying of Vapors, Gases, Mists, and Particulate Solids, 2020 Edition
- NFPA 484-2022, Standard for Combustible Metals
- NFPA 499-2021, Recommended Practice for the Classification of Combustible Dusts and of Hazardous (Classified) Locations for Electrical Installations in Chemical Process Areas
- NFPA 652-2019, Standard on the Fundamentals of Combustible Dust, 2019 Edition
- NFPA 654-2020, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, 2020 Edition
- NFPA Fire Protection Handbook, 20th Edition

The Department of Homeland Security (DHS) requirements of The Chemical Facility Anti-Terrorism Standards (CFATS) requires all facilities to submit a Top Screen if they possess/store more than 100 pounds of aluminum or magnesium metal powder.

Labeling is governed by OSHA 29 CFR 1910.1200 for hazard communication. **Shipping** is governed by the Code of Federal Regulations (CFR) Title 49 Transportation Part 173.124 Class 4, Divisions 4.1 Flammable Solid, 4.2 Spontaneously Combustible Material, and 4.3 Dangerous when wet material (49 CFR §173.124) for combustible metal powders. Note that other **chemical hazardous material classifications** may be relevant to some powders as well, such as chromium. See also CFR 49 Transportation in and out of the USA.

In-Development Standards

- ASTM WK80171, New Guide for Additive Manufacturing of Metals – Feedstock Materials – Measurement and Classification of Feedstock Contamination

New Gap PM11: Segregation of Powder. A standard practice is not yet established to homogenize powder that may segregate on size or other attributes throughout the lifecycle of handling or usage during an additive manufacturing workflow. This includes activities such as transportation, handling, storage, and consumption within batch and closed-loop AM equipment.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Evaluation of the effectiveness of different blend methods

Recommendation: Recommended practices should be drafted to address potential scenarios where segregation may occur (e.g., during transport). Techniques and tools may differ based upon those scenarios. The recommended practices will work toward ensuring that the sampling and testing is representative of the bulk powder.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM F42, ASTM B09, MPIF, SAE

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap PM12: Requirements for Large Storage and Transport Vessels of Powder Feedstock. Powder produced for additive manufacturing is commonly sold in small metal or plastic containers in weights able to be handled by operators. However, without complicated support equipment and workflows using gloveboxes, the usage of such containers requires the feedstock to be exposed to atmosphere upon introduction into an AM machine. Some users are beginning to request powder be loaded into larger, reusable, metal containers by a supplier, refillable upon exhaustion. These portable storage vessels act as transport, storage, and loading mechanisms into AM machines. Frequently these containers are purged and backfilled with inert atmosphere, sometimes with onboard environmental monitoring and control. No standardization for such vessels, their interfaces, or performance requirements currently exists. Language for this document must be cognizant of DOT requirements (e.g., positive pressure).

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Write a requirements document for large storage and transport vessels of powder feedstock.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM, SAE

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ___

Current Alternative: None

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Polymers

Proper handling of raw material (powder, pellet, or filament) is equally important for polymers. It is important to address all of the following:

- mitigation of exposure to powder and dust;
- emission of volatile organic chemicals (VOC) during raw material storage, delivery, pre-treatment, or in-process;
- prevention of static electricity;
- mitigation of environmental factors such as moisture and heat;
- proper handling of powder or filament waste; and
- exposure to nanomaterial component of specialty compound material.

Among the standards previously listed for metals, the ones most relevant to polymers are ANSI Z400.1/Z129.1-2010, and NFPA 654-2020. In addition, NFPA 652-2019, Standard on the Fundamentals of Combustible Dust could also provide additional guidelines for proper handling of polymer dust.

See also new gap PM12 on transport of large vessels.

2.2.1.2.1 Environmental Conditions: Effects on Materials

AM materials can be sensitive to changes in environmental conditions including temperature, humidity, and ultraviolet radiation.

Published Standards. None identified.

In-Development Standards

- ISO/ASTM DIS 52928, Additive manufacturing of metals— Feedstock materials — Powder life cycle management

Gap PM13 (was Gap PC9 in v2): Environmental Conditions: Effects on Materials. General guidance is needed to ensure the environmental conditions in which material is stored and used remain within acceptable ranges for all material types. Specific material packaging requirements are addressed in Section 2.2.1.2.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: See recommendation

Recommendation: Develop guidance on the storage of AM materials and their need for protective atmospheres so that AM materials are stored and used in environments with acceptable conditions. Research should be conducted to identify these ranges.

Priority: ☐High; ☐Medium; ☒Low

Organization: ASTM F42/ISO TC 261, NIST, SAE, UL, Powder Manufacturers/Suppliers

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.2.1.3 Characterization of Powders

Powder characteristics which are measured for other applications may not be sufficient for additive manufacturing applications. Ensuring that precursor materials are fit for purpose presents a need for a comprehensive understanding of their chemical composition, physical morphology and structure, and mechanical, thermal, and other properties relevant to the AM process and the manufactured product. Characterization is often referred to as a broad and general process by which the composition, structure and properties are probed and measured. This often incudes several analytical techniques (spectroscopic, microscopic, macroscopic) appropriate to the type of materials and the intended purpose of the study. Provided below are some of the material characteristics influencing their handling, AM process steps, and the finished product quality and integrity. A list of applicable test methods to obtain the material information is listed, and possible gaps in the test method development are identified.

2.2.1.3.1 Chemical Composition (metals, polymers, ceramics)

AM powder chemical characterization (including elemental composition, surface chemistry, chemically reactive components, intermediate phases developed during the process, and trace elemental impurities) is important to define the feedstock and therefore to determine the characteristics of built parts. This is applicable equally for virgin and recycled feedstock for the AM process. Chemical characterization may require a combination of conventional analytical methods on samples from various stages in the AM process.

Metals

Equipment and standards for determining the composition of metal powders are the same as used in the traditional metals industry for products such as cast/wrought mill products and powder metallurgy.

Nickel base and ferrous alloy powders have been produced for decades. A typical technique for determining metallic element levels is X-ray spectroscopy. Residual elements often measured in part per million (PPM) use mass spectrometers. Elements such as oxygen, hydrogen, and carbon use specialized analyzers. All of these chemical testing processes are used worldwide.

Applicable standards and specifications include:

- ASTM E353-19e1, Standard Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys
- ASTM E572-21, Standard Test Method for Analysis of Stainless and Alloy Steels by Wavelength Dispersive X-Ray Fluorescence Spectrometry
- ASTM E1019-18, Standard Test Methods for Determination of Carbon, Sulfur, Nitrogen, and Oxygen in Steel, Iron, Nickel, and Cobalt Alloys by Various Combustion and Inert Gas Fusion Techniques
- ASTM E1085-16, Standard Test Method for Analysis of Low-Alloy Steels by Wavelength Dispersive X-Ray Fluorescence Spectrometry
- ASTM E1479-16, Standard Practice for Describing and Specifying Inductively Coupled Plasma Atomic Emission Spectrometers
- ASTM E2465-19, Standard Test Method for Analysis of Ni-Base Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry
- ASTM E2594-20, Standard Test Method for Analysis of Nickel Alloys by Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based)
- ASTM E2823-17, Standard Test Method for Analysis of Nickel Alloys by Inductively Coupled Plasma Mass Spectrometry (Performance-Based)
- MPIF Standard Test Method 06, Method for Determination of Acid Insoluble Matter in Iron and Copper Powders
- MPIF Standard Test Method 66, Method for Sample Preparation for the Determination of the Total Carbon Content of Powder Metallurgy (PM) Materials (excluding cemented carbides)
- MPIF Standard Test Method 67, Guide to Sample Preparation for the Chemical Analysis of the Metallic Elements in PM Materials (used for inductively coupled plasma, atomic absorption, optical emission, glow discharge, and X-ray fluorescence spectrometers)

Applications using **titanium alloy powder** are emerging and the volume consumed is growing rapidly. Chemical analysis techniques for titanium, as in the case of nickel base and ferrous alloys, are well established. It is possible that over time revisions to procedures may be required due to the large relative surface area of powder and reactivity of titanium with oxygen. However, existing specifications and standards are working well.

Applicable standards and specifications include:

- ASTM E539-19, Standard Test Method for Analysis of Titanium Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry
- ASTM E1409-13(2021), Standard Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion

- ASTM E1447-22, Standard Test Method For Determination Of Hydrogen In Reactive Metals And Reactive Metal Alloys By Inert Gas Fusion With Detection By Thermal Conductivity Or Infrared Spectrometry
- ASTM E1941-10(2016), Standard Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis
- ASTM E2371-21, Standard Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)

Test methods used to analyse the chemical composition of **aluminum** include the following:

- ASTM E34-11e1, Standard Test Methods for Chemical Analysis of Aluminum and Aluminum-Base Alloys
- ASTM E1251-17a, Standard Test Method for Analysis of Aluminum and Aluminum Alloys by Spark Atomic Emission Spectrometry
- DIN EN 14242, Aluminium and aluminium alloys - Chemical Analysis - Inductively coupled plasma optical emission spectral analysis

New Gap PM14: Test Method to Assess Hydrogen Content in Aluminum Powder Feedstocks. Aluminum powder is commonly prone to the accumulation of both moisture and surface salts that affect produced parts via supersaturation of hydrogen upon consolidation via additive manufacturing. Supersaturation of hydrogen within consolidated material may result in material defects such as hydrogen pores at the time of fabrication or hydrogen pore formation with subsequent welding (or other high temperature processing). Measurement of hydrogen content is one method to assess the potential for such deleterious material behavior before usage of powder feedstock. Assessing the hydrogen concentration within and on the surface of aluminum powders requires both a test method and an available calibration standard specimen.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Feasibility of developing a commercially available test specimen for calibrating the test method. Also, determine if low concentrations are repeatably detectable. Establishing hydrogen thresholding also would be desirable.

Recommendation: Develop a test method to spur industry to generate calibration samples and/or specialized test equipment.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ___

Current Alternative: None

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒ New

The chemical compositions of material specifications currently lack information for non-critical elements and their level of impurities.

Published Standards

- The Aluminum Association maintains a registry of designations and chemical composition limits for aluminum powder and aluminum alloy powders (aka Purple Sheets) in accordance with ANSI H35.1 / H35.1(M)-2017, Alloy and Temper Designation Systems for Aluminum. Those elements that only have a maximum composition limit and no minimum limit are considered impurities, as their composition is not controlled in the manner identical to other alloying elements.
- ISO 17034:2016, General requirements for the competence of reference material producers
- SAE AMS2280D, Trace Element Control Nickel Alloy Castings (2019-11-05)

No in-development standards have been identified.

New Gap PM15: Identification and Quantification of Impurities in Chemical Compositions. There is a need to identify the level of impurities in material chemical compositions.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop a standard to identify, quantify and report the level of impurities in chemical composition of material specifications for critical and non-critical elements. For aluminum powder and aluminum powder alloys, note the Aluminum Association Purple Sheets registry that captures alloy composition as noted in the text, and ANSI H35.1 / H35.1(M)-2017.

Priority: ☐High; ☐Medium; ☒Low

Organization(s): ISO, ASTM, Aluminum Association

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Polymers

Specifications and standards are well established to determine molecular weight of polymers, structure, chemistry of fractions, end groups, tacticity, unreacted monomer and oligomers, co-polymer content and blend composition, catalyst residues, contamination analysis, chemical trace analysis and polymers volatile organic compounds. It is necessary to consider the utilization of recycled materials in AM applications which use thermoplastic polymer precursors to ensure their conformance to all requirements.

In-Development Standards

- ASTM WK75265. Guide for Additive Manufacturing of Polymers -- Powder Bed Fusion -- Guidelines for Feedstock Recycling and Sampling Strategies

Gap PM8: **Use of Recycled Polymer Precursor Materials.** Feedstock/precursor material can be sourced from either virgin polymer resin, recycled polymer resin, or a combination of the two. Recycled resin can be obtained from a number of different sources including in-house processed product of the same material which may not have met all the requirements when initially produced but is still functional, commercial recyclate from commercial sources, and post-consumer recyclate. Recycled feedstock, depending on its source and usage level, can introduce problems in the printing or end-use application due to the recyclate's thermal/mechanical history, consistency and composition.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: To determine the acceptable limits and other constraints of incorporating reprocessed materials. This may be machine, material, and/or application specific.

Recommendation: Develop a general guidance document to address best practices in regard to sources, handling, and characterization of recycled materials. In some cases, such as medical and aerospace applications, more stringent guidelines may need to be developed such as identification of recycled material use. Complete standards development in ASTM WK75265.

Priority: ☐High; ☐Medium; ☒Low

Organization: ASTM F42/D20, SAE AMS-AM

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: The aerospace and medical sectors need to demonstrate compliance to requirements. Organizations use their own internal practices.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; New

V3 Update: As noted in the text.

Ceramics

Ceramic chemical composition is not a significant issue for ceramic additive manufacturing because most ceramic compositions are stable and will not change during the additive manufacturing process. Ceramic composition is important in post-processing, such as sintering. The sintering process is the same as for a conventional ceramic process. There are no specific chemical composition issues for ceramics that need to be addressed. Industries have well established their own chemical composition control frameworks. Standard test methods have been used for ceramic composition determinations.

Most ceramics are stable during additive manufacturing, while some non-oxide ceramics can be oxidized during storage, the additive manufacturing process, and post-processing. However, this only affects the post-processing sintering process. The oxidation behavior is like a conventional ceramic process. There is no specific need to be addressed for additive manufacturing.

Some unmatured ceramic additive manufacturing technologies, such as laser and E-beam direct melting, will be affected by ceramic compositions. The composition changes the melting temperature and that affects the process significantly.

Since ceramic additive manufacturing involves polymer binders, the binder composition is significant for the ceramic additive manufacturing process. For binder composition, refer to the polymer composition section.

2.2.1.3.2 Flowability

The materials used in AM are often required to flow. The performance of these materials, in regards to their flowability, must be characterized.

Published Standards

- ISO/ASTM 52907:2019, Additive manufacturing – Feedstock materials – Methods to characterize metallic powders

Identified published standards **not specific to AM** include:

- ASTM B213-20, Standard Test Methods for Flow Rate of Metal Powders Using the Hall Flowmeter Funnel
- ASTM B855-17, Standard Test Method for Volumetric Flow Rate of Metal Powders Using the Arnold Meter and Hall Flowmeter Funnel
- ASTM B964-16, Standard Test Methods for Flow Rate of Metal Powders Using the Carney Funnel
- ASTM D1895-17, Standard Test Methods for Apparent Density, Bulk Factor, and Pourability of Plastic Materials
- ASTM D7891-15, Standard Test Method for Shear Testing of Powders Using the Freeman Technology FT4 Powder Rheometer Shear Cell

- ISO 4490:2018, Metallic powders – Determination of flow rate by means of a calibrated funnel (Hall flowmeter)
- MPIF Standard Test Method 03, Method for Determination of Flow Rate of Free-Flowing Metal Powders Using the Hall Apparatus

In-Development Standards

- ASTM WK55610, New Test Methods for the Characterization of Powder Flow Properties for Additive Manufacturing Applications (formerly WK49272), being jointly developed as JG 63 by ISO/TC261 and ASTM F42
- ASTM WK66030, New Guide for Quality Assessment of Metal Powder Feedstock Characterization Data for Additive Manufacturing (F42.01)
- ASTM WK71393, New Practice for Additive manufacturing -- assessment of powder spreadability for powder bed fusion (PBF) processes (F42.01)
- ISO/ASTM DTR 52913-1, Additive manufacturing — Feedstock materials — Part 1: Parameters for characterization of powder flow properties
- ISO/ASTM DTR 52952, Additive Manufacturing of metals — Feedstock materials — Correlating of rotating drum measurement with powder spreadability in PBF-LB machines

Gap PM1: Flowability. Existing standards for flowability do not account for the range of conditions that a powder may encounter during AM processes.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to collect data as a useful metric regarding flowability, especially with powder bed processing. Current test methods do not represent the flow behavior inside of an AM process, at best correlative but not representative. ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Project 1803 (WK66030) addresses AMSC gap PM1.

Recommendation: Standards are needed to address test methods which encompass the variety of flow regimes encountered in AM processes. Recommend completion of ASTM WK55610, *New Test Methods for the Characterization of Powder Flow Properties for Additive Manufacturing Applications*, (not specific to metal powders) which addresses dynamic flow, aeration, permeability, consolidation and compressibility test procedures using, for example, a powder rheometer. See also gap PC12 on precursor material flow monitoring.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM F42/ISO TC 261, NIST, ASTM B09, ASTM E29

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: There are no known alternatives.

V3 Status of Progress: ☐Green; ☒Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text, ASTM WK55610 is in development. Completion of those work items may partially but not fully address the gap.

2.2.1.3.3 Spreadability

Multiple AM processes involve the spreading of powder; however, there are no AM standards specifying how to quantitatively assess powder spreadability.

Published Standards

- ISO/ASTM 52907:2019, Additive manufacturing – Feedstock materials – Methods to characterize metallic powders

In-Development Standards

- ASTM WK55610, New Test Methods for the Characterization of Powder Flow Properties for Additive Manufacturing Applications. This draft document addresses shear and dynamic flow properties but does not directly address spreadability. In terms of shear properties, the draft document points to existing ASTM standards for shear cell tests and wall friction tests (ASTM D6128-22, D6773-22, and D7891-15).
- ASTM WK66030, New Guide for Quality Assessment of Metal Powder Feedstock Characterization Data for Additive Manufacturing (F42.01)
- ASTM WK71393, New Practice for Additive manufacturing -- assessment of powder spreadability for powder bed fusion (PBF) processes
- ISO/ASTM DTR 52913-1, Additive manufacturing — Feedstock materials — Part 1: Parameters for characterization of powder flow properties
- ISO/ASTM DTR 52952, Additive Manufacturing of metals — Feedstock materials — Correlating of rotating drum measurement with powder spreadability in PBF-LB machines

Gap PM2: Spreadability. There is no known description of spreadability or standard for how to quantitatively assess powder spreadability.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to (1) measure and quantify spreadability (direct measurement / scoring value) and (2) to correlate powder characteristics with spreadability (performance metric via a combination of measurements of intrinsic properties).

Recommendation: A standard should be created that guides the measurement of a powder's spreadability. This standard may be comprised of a series of tests that together describe a powder's spreading performance.

Priority: ☐High; ☒Medium (direct measurement); ☒Low (characterization aspects)

Organization: ASTM F42/ISO TC 261, NIST, universities, ASTM B09, ASTM E29

Lifecycle Area: ☐Design; ☒Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒ All/Material Agnostic; ☐ Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None known for powder spreadability specifically. A combination of flowability methods, moisture content, PSD, particle morphology could be loosely applied but is not a direct alternative.

V3 Status of Progress: ☒Green (metals); ☐Yellow; ☐Red; ☒Not Started (other materials); ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASTM WK71393 is focused on the assessment of powder spreadability for metals. Polymer and ceramic standards and the 2nd part of the recommendation on the performance metrics have not begun.

2.2.1.3.4 Density (Apparent vs. Tapped)

The powder deposition has a large effect on the quality of a final AM part. Therefore, the loose (apparent) density as well as the consolidated (tapped) density must be known.

Published Standards

- ASTM B212-21, Standard Test Method for Apparent Density of Free-Flowing Metal Powders Using the Hall Flowmeter Funnel
- ASTM B527-20, Standard Test Method for Tap Density of Metal Powders and Compounds
- ISO 3923-1:2018, Metallic powders - Determination of apparent density - Part 1: Funnel method
- ISO 3953:2011, Metallic powders - Determination of tap density
- MPIF Standard Test Method 46, Method for Determination of Tap Density of Metal Powders
- MPIF Standard Test Method 04, Method for Determination of Apparent Density of Free-Flowing Metal Powders Using the Hall Apparatus

Existing standards are likely sufficient for guiding the measurement of the tapped and apparent density of AM powders. No standards in development and no gaps have been identified at this time.

2.2.1.3.5 Particle Size and Particle Size Distribution

Particle size and particle size distribution are critical to the outcome of the AM build. The size of particles and distribution requirements are specific to the powder deposition process and to the fusion mechanism.

The particle size will be limited to achieve the appropriate temperature at the particle core. Particle size must also be chosen appropriate to the layer thickness of the build process. While some systems allow for variation in the layer thickness to accommodate various sized powders (directed energy systems tend to be more flexible in terms of the layer thickness than powder bed systems), thinner layers lead to better resolution. Typically, finer powders do not flow as well as those with larger particle size.

Published Standards

There are a number of **measurement techniques** for determining particle size, including dry sieving, laser diffraction, and image analysis via optical or scanning electron microscope.

- ASTM F3049-14(2021), Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes, addresses measurement techniques for particle size, making use of references to existing powder size measurement methods that exist for powder metallurgy.

AM-specific **powder metallurgy standards** include the following:

- ASTM F3560-22 Standard Specification for Additive Manufacturing – Data – Common Exchange Format for Particle Size Analysis by Light Scattering
- ISO/ASTM 52907:2019, Additive manufacturing – Feedstock materials – Methods to characterize metallic powders
- SAE AMS7025, Metal Powder Feedstock Size Classifications

A number of **powder metallurgy standards** exist that are not AM-specific but that can be applied to AM powders. Such standards include but are not limited to:

- ASTM B214-16, Standard Test Method for Sieve Analysis of Metal Powders
- ASTM B215-20, Standard Practices for Sampling Metal Powders
- ASTM B822-20, Standard Test Method for Particle Size Distribution of Metal Powders and Related Compounds by Light Scattering
- ISO 9276 Parts 1-6, Representation of results of particle size analysis
- ISO 13320:2020, Particle size analysis — Laser diffraction methods
- ISO 13322-1:2014, Particle size analysis — Image analysis methods — Part 1: Static image analysis methods
- ISO 13322-2:2021, Particle size analysis — Image analysis methods — Part 2: Dynamic image analysis methods
- MPIF Standard Test Method 32, Methods for Estimating Average Particle Size of Metal Powders Using Air Permeability

In-Development Standards (AM-Specific)

- ASTM WK66030, New Guide for Quality Assessment of Metal Powder Feedstock Characterization Data for Additive Manufacturing (F42.01)
- ASTM WK78812, New Test Method for Measurement of Particle Size and Shape of Additive Manufacturing Base Materials by Dynamic Imaging Analyzers (B09.02)

New Gap PM16: Universal Reference Standard on Size Distribution. No current product is recognized as a universal reference standard to establish comparisons on precision and accuracy of measurement methods and equipment when assessing particle size distribution. If no one single reference standard is available, a document to relate the results of using different standards for specific, respective tools should be drafted.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Validation of various measurement techniques for reliability, repeatability, and correlation is required when using a proposed reference standard. If none is determined suitable, then a working relationship between different standards and their corresponding measurement method should be generated.

Recommendation: See R&D Expectations

Priority: ☐High; ☐Medium; ☒Low

Organization(s): ASTM F42, ASTM B09, MPIF

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap PM17: Error Quantification of PSD Measurement Methods. Round robin and/or analytical examination and uncertainty quantification related to the sources of error for different measurement methods/techniques should be critically examined and documented in a guidance document or standard.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Establish effective repeatability and systematic error associated with measurement methods commonly used in industry. Understand reproducibility, i.e., the sources of error that are introduced by differences in operators, equipment, and techniques.

Recommendation: See R&D Expectations

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM F42, ASTM B09, MPIF

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.2.1.3.6 Particle Morphology

Particle shape and surface quality affect flow characteristics as well as packing density. Smooth spherical particles provide less resistance to flow than non-spherical particles or those with a rough surface.

Light scattering techniques and image analysis can be used to observe particle morphology. These techniques provide a basis for qualitative comparison of powder lots. However, they do not allow for detection of hollow particles, which are important to detect as their presence may lead to porosity in the built parts.

Published Standards

There are no AM-specific standards describing how to quantitatively assess particle morphology. There is a specification for general powder metallurgy, ASTM B243-22, Standard Terminology of Powder Metallurgy, that defines typical powder shapes. ASTM B09 is planning to add AM-specific terms to B243. In addition, ISO 9276-6:2008, Representation of results of particle size analysis – Part 6: Descriptive and quantitative representation of particle shape and morphology, provides rules and nomenclature for describing and quantitatively representing particle morphology. Other relevant published standards include:

- ASTM F3571-22, Guide for Additive Manufacturing Feedstock Particle Shape Image Analysis by Optical Photography to Identify and Quantify the Agglomerates/Satellites in Metal Powder Feedstock (previously WK74905)
- ISO/ASTM 52907:2019, Additive manufacturing – Feedstock materials – Methods to characterize metallic powders
- ISO 13322-1:2014, Particle size analysis — Image analysis methods — Part 1: Static image analysis methods
- ISO 13322-2:2021, Particle size analysis — Image analysis methods — Part 2: Dynamic image analysis methods

In-Development Standards

- ASTM WK66030, New Guide for Quality Assessment of Metal Powder Feedstock Characterization Data for Additive Manufacturing (F42.01)
- ASTM WK78812, New Test Method for Measurement of Particle Size and Shape of Additive Manufacturing Base Materials by Dynamic Imaging Analyzers (B09.02)

Gap PM4: Particle Morphology. There is a need for AM-specific standards describing how to quantitatively assess particle morphology.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to measure and quantify particle morphology as well as determine impacts to process performance. ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Project 1803 (WK66030) addresses AMSC gap PM4.

Recommendation: Based on the results of R&D, a terms, definitions and taxonomy (which can assist with categorizations and define appropriate/inappropriate uses) standard may be needed for powder morphology and criteria for determining acceptable powder morphology characteristics. Because powder morphology may affect powder flow, powder spreadability, and density of the AM built object, it could possibly be addressed indirectly by standards governing flow and spreadability requirements for a powder, taking into account the density of the powder. Upon completion of this, additional standardization work can be determined.

Priority: ☐High; ☒Medium; ☐Low

Organization: NIST, ASTM F42/ISO TC 261 JG 66, ASTM B09, ASTM E29

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted, ISO/ASTM 52907 has been published.

2.2.1.3.7 Feedstock Sampling

Control of powder is key to obtaining consistent and predictable properties of AM objects. Metrics for assessing powder characteristics depend upon testing of a representative sample. Considerations for powder sampling include:

- Methods of retrieval of a sample from a powder batch to ensure a random and representative sample is taken.
- Quantity of powder to be sampled, possibly as a function of total batch size.
- Frequency at which to sample the powder, including how long the powder can be stored prior to use before necessitating repeat sampling.
- Requirements for sampling of reused powder and of blends/mixtures of different powder batches, in the case where the original powders were sampled. See also section 2.2.1.4 on precursor material handling: use, reuse, mixing, and recycling feedstock.

Published Standards

- ASTM B215-20, Standard Practices for Sampling Metal Powders
- ASTM F3049-14(2021), Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes, which references existing powder metallurgy sampling practices covered in ASTM B215
- ISO/ASTM 52907:2019, Additive manufacturing – Feedstock materials – Methods to characterize metallic powders
- ISO/ASTM 52925:2022, Additive manufacturing of polymers — Feedstock materials — Qualification of materials for laser-based powder bed fusion of parts

- ISO 3954:2007, Powders for powder metallurgical purposes—Sampling
- MPIF Standard Test Method 01, Method for Sampling Metal Powders (2022), which is the equivalent standard to ASTM B215
- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05), contains requirements for feedstock powder handling and storage plan.

In-Development Standards

- ASTM WK66030, New Guide for Quality Assessment of Metal Powder Feedstock Characterization Data for Additive Manufacturing
- ISO/ASTM DIS 52928, Additive manufacturing of metals— Feedstock materials — Powder life cycle management

Gap PM5: Metal Powder Feedstock Sampling. Existing powder metallurgy standards may be leveraged for AM use; however, they require tailoring for AM-specific situations, such as the following:

1) sampling practices for a reused powder that has been through an AM build cycle are needed to establish how to collect representative powder samples. These practices should take into account the variation caused by build exposure on powder in multiple locations.

2) sampling practices for preparation of small samples (e.g., 15 mg to 20 mg for scanning by electron microscopy) need to be established, including prescribing an acceptable percentage of powder lost during processing. For example, the powder particles can in some cases stick to the vials depending on the equipment used.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: With respect to the reuse of powder during the build. See also gap PM18.

Recommendation: Standards are needed for sampling of powders used for AM, with considerations for unique aspects of AM not considered in powder sampling standards for general powder metallurgy, including reuse of powder.

Priority: ☐High; ☒Medium; ☐Low

Organization: NIST, SAE AMS-AM, ASTM B09, MPIF, ASTM D20 (for polymers), ASTM F42, ASTM E29

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Internally developed best practices

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Recently published and/or updated standards and standards in development are noted above.

2.2.1.3.8 Hollow Particles and Hollow Particles with Entrapped Gas

The fitness-for-use requirements of metal powders for additive manufacturing differ from traditional metal powder applications. One area is the potential impact of the presence of hollow particles and hollow particles with entrapped gas that occurred during the atomization process. Hollow particles and hollow particles with entrapped gas may exist in metal powder lots regardless of the powder making and atomization processes and therefore may be an uncontrolled variable.

Published Standards

- ASTM B311-17, Test Method for Density of Powder Metallurgy (PM) Materials Containing Less Than Two Percent Porosity
- ASTM B796-20, Standard Test Method for Nonmetallic Inclusion Content of Ferrous Powders Intended for Powder Forging (PF) Applications
- ASTM B922-22, Standard Test Method for Metal Powder Specific Surface Area by Physical Adsorption
- ASTM B923-22, Standard Test Method for Metal Powder Skeletal Density by Helium or Nitrogen Pycnometry
- ISO 13947:2011, Metallic Powders - Test Method For The Determination Of Non-Metallic Inclusions In Metal Powders Using A Powder-Forged Specimen

The above standards do not address the measurement of powder inclusions or closed porosity measurements for AM specific applications.

Other published standards include:

- ISO/ASTM 52907:2019, Additive manufacturing – Feedstock materials – Methods to characterize metallic powders

The following methods are currently used in R&D to determine internal powder porosity:

- Gas and liquid pycnometry – Measurement of True Density of powders. Method suitable for powders where a large fraction of the population has porosity. Also, suitable for single element composition exact mixtures. Variation in alloy composition decreases measurement accuracy. Do not obtain pore size distribution.
- Metallography with image analysis – Suitable for powder where a large fraction of the population has porosity. Limited by large number of measurements needed for accurate statistics.
- CT with image analysis – Bulk analysis for powder porosity.
- Ultrasonic Non-Destructive Testing (NDT) – Suitable for bulk materials. Development of experimental database for powder is needed.

Research on powder porosity measurement techniques has been conducted at NIST, industrial labs, and universities.

There are no ASTM, ISO, or MPIF standards for measuring internal powder porosity/inclusions for AM specific applications.

Gap PM6: **Hollow Particles and Hollow Particles with Entrapped Gas.** No standards exist for measuring how to determine the presence and percentage of hollow particles and hollow particles with entrapped gas or their impact upon part properties and in-service performance.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to establish the impact of hollow powder particles, if any.

Recommendation: Dependent upon R&D, a standard may be needed that specifies how to determine the percentage of hollow particles and hollow particles with entrapped gas in lots of metal powders. Testing may be needed to determine the level of hollow particles and hollow particles with entrapped gas that are acceptable without negatively affecting the properties and performance of finished parts.

Priority: ☐High; ☐Medium; ☒Low

Organization: For R&D: NIST, ASTM, America Makes, Oak Ridge National Laboratory, universities. For standards: ASTM F42/ISO TC 261, SAE, ASTM B09, ASTM E29

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided

2.2.1.3.9 Metal Powder Specifications for Procurement Activities in Support of AM

Currently, most manufacturers of AM equipment also offer metal powder for purchase. In fact, they provide data containing representative final material properties for parts created using both their equipment and powder.

Published Standards

- ASTM F2924-14(2021), Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
- ASTM F3001-14(2021), Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
- ASTM F3055-14a(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion
- ASTM F3056-14(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
- ASTM F3184-16, Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion
- ASTM F3213-17, Standard for Additive Manufacturing – Finished Part Properties – Standard Specification for Cobalt-28 Chromium-6 Molybdenum via Powder Bed Fusion
- MPIFStd35, Materials Standards for PM Structural Parts
- SAE AMS7001, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 62Ni - 21.5Cr - 9.0Mo - 3.65 Nb (2018-06-08)
- SAE AMS7002A, Process Requirements for Production of Metal Powder Feedstock for Use in Additive Manufacturing of Aerospace Parts (2022-05-16)
- SAE AMS7006, Nickel Alloy, Corrosion- and Heat-Resistant, Powder for Additive Manufacturing 52.5Ni - 19Cr - 3.0Mo - 5.1Cb (Nb) - 0.90Ti - 0.50Al - 18Fe (2022-03-21)

- SAE AMS7008, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 47.5Ni - 22Cr - 1.5Co - 9.0Mo - 0.60W - 18.5Fe (2019-03-26)
- SAE AMS7012, Precipitation Hardenable Steel Alloy, Corrosion and Heat-Resistant Powder for Additive Manufacturing 16.0Cr - 4.0Ni - 4.0Cu - 0.30Nb (2019-11-14)
- SAE AMS7013, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 60Ni - 22Cr - 2.0Mo - 14W - 0.35Al - 0.03La (2019-01-03)
- SAE AMS7014, Titanium Alloy, High Temperature Applications, Powder for Additive Manufacturing, Ti - 6.0Al - 2.0Sn - 4.0Zr - 2.0Mo (2019-03-11)
- SAE AMS7015, Titanium 6-Aluminum 4-Vanadium Powder for Additive Manufacturing (2022-04-22)
- SAE AMS7017 Titanium 6 - Aluminum 4 - Vanadium Powder for Additive Manufacturing, Extra Low Interstitial (ELI) (2022-04-07)
- SAE AMS7018, Aluminum Alloy Powder 10.0Si – 0.35Mg (2020-05-11)
- SAE AMS7020, Aluminum Alloy Powder 7.0Si - 0.55Mg - 0.12Ti (2021-11-09)
- SAE AMS7021, Precipitation Hardenable Steel Alloy, Corrosion and Heat Resistant, Powder for Additive Manufacturing, 15.0Cr - 4.5Ni - 3.5Cu - 0.30Nb (2020-11-19)
- SAE AMS7023, Gamma Titanium Aluminide Powder for Additive Manufacturing, Ti - 48Al - 2Nb - 2Cr (2021-06-01)
- SAE AMS7025, Metal Powder Feedstock Size Classifications (2021-04-22)
- SAE AMS7026, Titanium Ti-5553 (Ti - 5Al - 5Mo - 5V - 3Cr) Powder for Additive Manufacturing (2021-07-28)
- SAE AMS7033, Aluminum Alloy Powder, 4.6Cu - 3.4Ti - 1.4B - 0.75Ag - 0.27Mg (2021-06-22)
- SAE AMS7035, Precipitation Hardenable Steel Alloy, Corrosion and Heat-Resistant, Powder for Binder Jet Additive Manufacturing, 16.0Cr – 4.0Ni – 4.0Cu -0.30Nb (2021-06-22)
- SAE AMS7037, Steel, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 17Cr - 13Ni - 2.5Mo (316L) (2021-11-23)

In-Development Standards

- SAE AMS7012A, Precipitation Hardenable Steel Alloy, Corrosion and Heat-Resistant Powder for Additive Manufacturing 16.0Cr - 4.0Ni - 4.0Cu - 0.30Nb (2020-03-24)
- SAE AMS7045, Aluminum Alloy Powder, 5.3Zn – 3.3Mg - 1.7Zr – 1.6Cu (Composition Similar to 7A77.50) (2022-01-14)
- SAE AMS7047, Low Alloy, Medium Carbon Steel Powder for Binder Jet Additive Manufacturing, 1.0Cr – 0.20Mo – 0.30C (Composition Similar to UNS G41300) (2022-01-14)
- SAE AMS7054, Aluminum alloy powder A6061-RAM2 (2022-12-22)
- SAE AMS7055, Precipitation Hardenable Steel Alloy Powder for Additive Manufacturing (2023-01-18)

Gap PM7: **Metal Powder Specifications for Procurement Activities in Support of AM.** There is a need for more specifications to inform procurement decisions and establish requirements and acceptance criteria of metal powder for purposes of quality assurance.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to determine the effect of powder parameters/characteristics on final part properties and on the suitability of a given powder for use in a given AM machine. Some of these powder parameters may include:

1) Particle Size Distribution
2) Particle Morphology
3) Flow Rate
4) Tap Density
5) Angle of Repose
6) Shear Stress
7) Chemistry
8) Specific Surface Area

ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Project 1803 (WK66030) addresses AMSC gap PM7.

Recommendation: Develop specifications to facilitate procurement of metal powders for use in AM machines.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/ASTM, SAE AMS-AM, AWS, industry OEMs, Defense Contract Management Agency, government procurement activities

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Recently published standards and projects started are noted in the text.

2.2.1.4 Precursor Material Handling: Use, Reuse, Mixing, and Recycling Feedstock

Handling of feedstock materials during the manufacturing process must be controlled to minimize, if not eliminate, the risk of contamination and product defects. Storage and shipment of feedstock material should also meet the precursor material requirements and protect these properties throughout its shelf life. Mixing and reuse of materials must meet the precursor material requirements. Similarly, handling of unused material is a critical enabler for product quality and reuse or recycle in subsequent additive part production. One cannot assume that material at the end of an additive process meets precursor material requirements or is otherwise qualified for production. See also gap PM5 in section 2.2.1.3.7 and Gap PM8 in section 2.2.1.3.1.

Published Standards

- ASTM F3456-22, Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials
- SAE AMS7031, Batch Processing Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-03-29)
- SAE ARP7044 - Powder History Scoring Metric and Labeling Schema (2022-11-22)

In-Development Standards

- ASTM WK75184, New Guide for Additive Manufacturing of Metals -- Powder Bed Fusion -- Guidelines for Feedstock Recycling and Sampling Strategies
- ASTM WK75265, New Guide for Additive Manufacturing of Polymers -- Powder Bed Fusion -- Guidelines for Feedstock Recycling and Sampling Strategies
- ISO/ASTM DIS 52928, Additive manufacturing of Metals — Feedstock materials — Powder life cycle management
- SAE AMS7052, Continuous, Closed-Loop Process Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-06-20)

Gap PM18 (was Gap PC7 in v2): Recycle & Reuse of Materials. There are many practices in the materials industry of how to recycle, reuse, and revert materials in production. They are also highly material dependent. Processes to prepare used powder for reuse can currently only be verified against precursor material specifications defined in their virgin state.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Research should be conducted on testing conditions, properties of concern, and feedstock usage history, to understand the effects of using reused material.

Recommendation: Develop guidance built upon published evidence from white papers as to whether and how reused material may be used when assessed for metrics such as number of build cycles, build cycle exposure time, or some other metric. Parts made from this reused material should factor in such aspects as part criticality, redundancy, environmental conditions, costs, etc. Considerations should be made as to whether the feedstock has been exposed to a build cycle of the AM process or exited the container it was delivered in at the virgin state.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F42/ISO TC 261, ASTM D20, AWS, MPIF, NIST, SAE, trusted end user-group

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Published standards and standards in development are noted in the text.

New Gap PM20: Recycling the Polymeric Structures to Fabricate Filaments. 3D-printed polymers (e.g., thermoplastics) can be reused and recycled by an extruder to fabricate filaments. However, the material properties may be reduced. Standards are needed to determine which materials are recyclable, combinable, and the resultant properties thereof.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Determine which polymers are functionally combinable or independently recyclable, such that a feedstock is produced and subsequent parts or coupons can be assessed to determine the quality of the material.

Recommendation: Develop a standard to quantify or measure the degradation of material properties of recycled polymers

Priority: ☐High; ☐Medium; ☒Low

Organization(s): SDOs

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☒Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.2.1.4.1 Terminology Related to Reuse of Feedstock Materials

Industry tends to use terms interchangeably and inconsistently when it comes to powder reuse. Conformance to requirements is key regardless of whether or not powder has been used.

Published Standards

General terminology standards include:

- ASTM F3456-22, Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials
- ISO/ASTM 52900:2021, Additive manufacturing – General principles – Terminology, contains the following terms and definitions: Material supplier; Feedstock; Part cake; Batch; Powder blend; Lot; Used powder.
- SAE AMS7031, Batch Processing Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-03-29)

In-Development Standards

- ASTM WK75184, New Guide for Additive Manufacturing of Metals -- Powder Bed Fusion -- Guidelines for Feedstock Recycling and Sampling Strategies
- ASTM WK75265, New Guide for Additive Manufacturing of Polymers -- Powder Bed Fusion -- Guidelines for Feedstock Recycling and Sampling Strategies
- ISO/ASTM DIS 52928, Additive manufacturing of Metals — Feedstock materials — Powder life cycle management
- SAE AMS7052, Continuous, Closed-Loop Process Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-06-20)

New Gap PM19: Terminology Related to Reuse of Feedstock Materials. Define terms that today are in practice that may establish a common vocabulary for metallic, polymer, ceramic feedstock materials. A dictionary may include different definitions for the same terms based on the material class. Colloquially, terms such as “recycling” and “reuse” are used interchangeably but have different meanings.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Do a side-by-side comparison between existing published standards on how to interpret terms and definitions as they relate to their corresponding documents and why they are different.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ISO/ASTM, SAE, MPIF

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Individual documents where defined. For example, ISO/ASTM 52900, SAE AMS7031, SAE AMS7044

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.2.1.5 Characterization of Material Extrusion Feedstock (Filaments & Pellets)

Filaments are produced by extruding plastic pellets or powders (generally derived from ground pellets) into the appropriate filament geometry required for the AM process in which the filaments are reheated, melted, and deposited onto the build. Pellet feedstock for AM processing is a variant which eliminates the need to produce filaments and relies on the direct feeding, heating, and melting of the plastic as part of the AM process. In most cases, these are fully formulated materials containing appropriate stabilizers and other components as required. The chemical requirements for filament feedstock and pellet feedstock could be identical but the physical requirements are different.

2.2.1.5.1 Chemical Composition

Chemical characterization (including composition, molecular weight of polymers, chemical structure, co-polymer content and blend composition, impurity content, formulation, and polymers volatile organic compounds) is important to define the feedstock and therefore to determine the characteristics of built parts. This is applicable equally for virgin and recycled feedstock for the AM process, see gap PM8.

Published Standards

- ASTM D4000-20, Standard Classification System for Specifying Plastic Materials
- Specific ASTM Material classification documents (per D4000), for example:
  - ASTM D6779-21, Standard Classification System for and Basis of Specification for Polyamide Molding and Extrusion Materials (PA)
  - ASTM D4101-17e1, Standard Classification System and Basis for Specification for Polypropylene Injection and Extrusion Materials
  - SAE AMS7101A, Material for Fused Filament Fabrication (2022-07-08)

2.2.1.5.2 Geometry

The geometry of the filament or pellets can affect how well the material will process and can affect the final AM part density and fill, as well as the potential for defects. The geometry needed is very dependent and will be defined by the individual OEM machine.

2.2.1.5.3 Melt Flow

The materials used in material extrusion are required to melt and flow through a nozzle to be deposited on the build. The performance of these materials, in regards to their flow, must be characterized. They are typically characterized by their rheological (melt) and thermal properties.

Published Standards

- ASTM D1238-23, Standard Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer
- ASTM D3418-21, Standard Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry
- ASTM D4440-15, Standard Test Method for Plastics: Dynamic Mechanical Properties Melt Rheology
- ASTM D7028-07(2015), Standard Test Method for Glass Transition Temperature (DMA Tg) of Polymer Matrix Composites by Dynamic Mechanical Analysis (DMA)
- ISO/ASTM 52903-1:2020, Additive manufacturing – Material extrusion-based additive manufacturing of plastic materials – Part 1: Feedstock materials
- SAE AMS7101A, Material for Fused Filament Fabrication (2022-07-08)

Gap PM9: Characterization of Material Extrusion Feedstock (Filaments & Pellets). There are many classification systems and test procedures that are available and applicable to characterizing the feedstocks used for filaments or pellets. However, these are based on “conventional” processes and requirements and, in many cases, will need to be adapted to AM requirements and, in some cases, new, more specific systems and procedures may be required.

Conventional rheometry is usually torsional while the behavior in AM systems is more accurately represented by capillary rheometry. While a few standards exist for this, their scope is often limited. ASTM D1238 for example only uses a 2.095 mm die while extrusion systems have a wide variety of orifice diameters. Research will need to be done to determine the effect of this difference, as well as other differences in the stress state like potential for back flow, and new standards should be developed accordingly.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: To define the specific requirements and evaluate if these can be addressed by existing systems and procedures and, if not, to develop new ones.

Recommendation: Since this will be very dependent on specific materials and process requirements, existing documents need to be evaluated on a case-by-case basis and, if necessary, new documents need to be developed. This is another aspect that needs to be considered by a possible ASTM F42 and D20 collaboration.

Priority: ☐High; ☐Medium; ☒Low

Organizations: ASTM F42/D20, SAE AMS-AM

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☐Ceramic; ☒Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☒Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: N/A

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Standards published or new projects started since v2 are noted in the text.

2.2.1.5.4 Moisture Content

The moisture content of the material extrusion feedstock must be characterized. Moisture within the feedstock has a large effect on potential defects within the AM part.

Published Standards

- ASTM D6980-17, Standard Test Method for Determination of Moisture in Plastics by Loss in weight
- ASTM D7191-18, Standard Test Method for Determination of Moisture in Plastics by Relative Humidity Sensor

- ISO/ASTM 52903-1:2020, Additive manufacturing – Material extrusion-based additive manufacturing of plastic materials – Part 1: Feedstock materials
- SAE AMS7101A, Material for Fused Filament Fabrication (2022-07-08)

2.2.1.5.5 Thermal Stability

Since these processes involve exposure to elevated temperatures in their production and in the melting or softening of the material in the AM process, the thermal stability is critical as excessive temperatures or exposure times can result in degradation and changes in the composition and material properties.

Published Standards

- ASTM D3012-19, Standard Test Method for Thermal-Oxidative Stability of Polypropylene Using a Specimen Rotator Within an Oven
- ASTM D3895-19, Standard Test Method for Oxidative-Induction Time of Polyolefins by Differential Scanning Calorimetry
- ISO/ASTM 52903-1:2020, Additive manufacturing – Material extrusion-based additive manufacturing of plastic materials – Part 1: Feedstock materials

2.2.1.6 Characterization of Liquid Feedstock

Liquid feedstock is often produced by mixing a variety of monomers, oligomers, initiators, pigments, stabilizers, etc. These materials are chemically reactive and need to be carefully characterized to ensure the liquid feedstock has not begun to react and is still viable for use within the additive manufacturing process.

2.2.1.6.1 Chemical Composition

Chemical characterization (including composition, molecular weight of oligomers, chemical structure, and impurity content) is important to define the feedstock and therefore to determine the characteristics of built parts. Specifications and standards are well established to determine molecular weight, structure, end groups, and degree of conversion.

2.2.1.6.2 Viscosity

The viscosity of the liquid feedstock is extremely important to how well the material can be processed through the specific AM technique (SLA or Material Jetting). It is often monitored throughout the process to indicate the liquid precursor health. Large changes in the viscosity can indicate a change in chemical composition (material be slowly polymerized, filler content increasing of stratifying) and can affect how well the material is processed, the final AM part density and mechanical strength. Characterization may require samples from various stages in the AM process.

Identified published standards not specific to AM include:

- [ASTM D1084-16(2021), Standard Test Methods for Viscosity of Adhesives]()
- [ASTM D4212-16, Standard Test Method for Viscosity by Dip-Type Viscosity Cups]()

2.2.1.6.3 Feedstock Sampling

Control of liquid feedstock is key to obtaining consistent and predictable properties of AM objects. Metrics for assessing liquid material characteristics especially in an open system depend upon testing of a representative sample. Considerations for liquid sampling include:

- Methods of retrieval of a sample to ensure a random and representative sample is taken.
- Quantity of liquid to be sampled, possibly as a function of total batch size.
- Frequency at which to sample the liquid, including how long the liquid can be stored or in use before necessitating repeat sampling.

Gap PM10: **Sampling of Open Liquid Feedstock System.** There is a need to develop a standard for monitoring and sampling open liquid feedstock systems to ensure the consistent chemical composition and mechanical properties in the final AM part.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: R&D is needed to determine how much the viscosity can change before having a significant effect on the mechanical and chemical properties of the final AM part, how fast the change can happen and the frequency and method for sampling the open liquid feedstock system.

Recommendation: Develop a process-specific standard to indicate how often the liquid feedstock viscosity must be monitored throughout the feedstock's lifetime (both in storage and in an open system).

Priority: ☐High; ☐Medium; ☒Low

Organization: ISO/ASTM, Industry OEMs

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; Metal; ☒Polymer; ☐Ceramic; ☒Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

2.2.2 Process Control

2.2.2.1 Introduction

For purposes of this document, process control refers to the control of variables that affect the quality of parts fabricated via AM. These variables are encountered in every step of the AM process, including creation and control of the 3D part model, selection and characterization of feedstock material, operator training, selection of machine parameters used for the part build, calibration and maintenance of equipment, and part post-processing. Control of such a wide range of variables is particularly important in the AM industry because inspection techniques that are commonly used to verify part quality can be challenging to apply to AM parts and must be taken into consideration when factoring in the qualification of a given component. This section discusses various aspects of AM process control and describes the standards that already exist or that are needed to ensure that acceptable AM parts can be consistently fabricated. Operator training and qualification is addressed in the Qualification and Certification section.

Published Standards and Specifications

- API Standard 20S, Additively Manufactured Metallic Components for Use in the Petroleum and Natural Gas Industries, First Edition (2021-10-01)
- API Standard 20T Additively Manufactured Polymer-Based Components for Use in the Petroleum and Natural Gas Industries, First Edition (2022-08-01)
- ASTM F3091/F3091M-14, Standard Specification for Powder Bed Fusion of Plastic Materials
- ASTM F3187-16, Standard Guide for Directed Energy Deposition of Metals
- AWS D17.1/D17.1M:2010-AMD1, Specification for Fusion Welding for Aerospace Applications - AMD
- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing
- DIN 65124, Aerospace series - Technical specifications for additive manufacturing of metallic materials with the powder bed process
- DNV-ST-B203 Additive manufacturing of metallic parts Edition 2022-10
- ISO/ASTM 52903-2:2020, Additive manufacturing — Material extrusion-based additive manufacturing of plastic materials — Part 2: Process equipment (reviewed/confirmed in 2022)

- ISO/ASTM 52904:2019, Additive manufacturing — Process characteristics and performance — Practice for metal powder bed fusion process to meet critical applications
- NCAMP NPS 89085 Rev D ULTEM 9085 April 18, 2021 (NCAMP Process Specification)
- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05)
- SAE AMS7005, Wire Fed Plasma Arc Directed Energy Deposition Additive Manufacturing Process (2019-01-31)
- SAE AMS7007, Electron Beam Powder Bed Fusion Process (2020-07-01)
- SAE AMS7010A, Laser Directed Energy Deposition Additive Manufacturing Process (L-DED) (2021-10-28)
- SAE AMS7022, Binder Jet Additive Manufacturing (BJAM) Process (2020-11-19)
- SAE AMS7027, Electron Beam Directed Energy Deposition-Wire Additive Manufacturing Process (EB-DED-Wire) (2020-11-18)
- SAE AMS7100, Fused Filament Fabrication, Process Specification for (2019-10-09)
- VDI 3405-2 Blatt 2:2013, Additive manufacturing processes, Rapid Manufacturing, Beam Melting of Metallic Parts, Qualification, Quality Assurance and Post Processing

Another published document is ASME PTB-13-2021: Criteria for Pressure Retaining Metallic Components Using Additive Manufacturing (May 31, 2021). It was prepared by the ASME Board on Pressure Technology Codes and Standards (BPTCS)/Board on Nuclear Codes and Standard (BNCS) Special Committee on Use of Additive Manufacturing. The criteria provided in this Pressure Technology Book (PTB) address the construction of pressure retaining COMPONENTS by means of the AM Powder Bed Fusion process (PBF) using both Laser and Electron Beam energy sources. This is not a standard; rather it is a criteria document meant to be used in conjunction with the construction codes that may wish to address components constructed with additive manufacturing. The Special Committee is currently discussing direct energy deposition, but it is too early to estimate if there will be a second document, or a revision of this PTB.

Also, not a standard but relevant is the auditing checklist AC7110/14, Nadcap Audit Criteria for Laser and Electron Beam Metallic Powder Bed Additive Manufacturing.

2.2.2.2 Digital Format and Digital System Control

Process control of digital format throughout CAD, CAM, and additive programming systems is critical to maintain production quality. In the event of software revisions and upgrades, the complexity of the systems requires the user to confirm that parts produced maintain the same level of quality: form, fit, and function/material properties. Inexperienced operators may not be aware of automated or OEM installed system upgrades and may assume status quo when restarting operations.

Published Standards and Specifications

- 3D Manufacturing Format (3MF)

- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing. Paragraph 7.2 requires that a contractor have a digital control plan in place and defines the items that must be included in such a plan.
- ISO/ASTM 52904:2019, Additive manufacturing – Process characteristics and performance – Practice for metal powder bed fusion process to meet critical applications
- ISO/ASTM 52915:2020, Specification for Additive Manufacturing File Format (AMF) Version 1.2.
- ISO 14649-17:2020 Industrial automation systems and integration — Physical device control — Data model for computerized numerical controllers — Part 17: Process data for additive manufacturing
- NCAMP NPS 89085 Rev D ULTEM 9085 April 18, 2021 (NCAMP Process Specification)
- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05)
- SAE AMS7005, Wire Fed Plasma Arc Directed Energy Deposition Additive Manufacturing Process (2019-01-31)
- SAE AMS7007, Electron Beam Powder Bed Fusion Process (2020-07-01)
- SAE AMS7010A, Laser Directed Energy Deposition Additive Manufacturing Process (L-DED) (2021-10-28)
- SAE AMS7022, Binder Jet Additive Manufacturing (BJAM) Process (2020-11-19)
- SAE AMS7027, Electron Beam Directed Energy Deposition-Wire Additive Manufacturing Process (EB-DED-Wire) (2020-11-18)
- SAE AMS7100, Fused Filament Fabrication, Process Specification for (2019-10-09)

In-Development Standards

- ISO/ASTM DIS 52904, Additive manufacturing of metals — Process characteristics and performance — Metal powder bed fusion process to meet critical applications
- ISO/AWI 10303-238 E4 Industrial automation systems and integration — Product data representation and exchange — Part 238: Application protocol: Model based integrated manufacturing

Gap PC1: Digital Format and Digital System Control. Existing process control standards do not adequately address digital format and digital system control.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: NIST is putting R&D into the ISO 10303 AP 238 E4 that aims to support (to an extent) process control for PBF AM processes.

Recommendation: Leverage ongoing NIST research and work with SDOs to ensure that AM process control standards include digital format and digital system control.

Priority: ☐High; ☒Medium; ☐Low

Organization: NIST, ISO/ASTM JG 56, ISO TC 184 SC4, SAE, IEEE-ISTO PWG, AWS

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.2.2.3 Machine Calibration and Preventative Maintenance

Machine calibration and preventative maintenance can impact output quality and require periodic measurement in addition to any OEM maintenance. Users must confirm that an AM machine continues to generate products which meet all quality requirements after maintenance is performed. For example, the requalification process can range between a full first article to a subset thereof and may include metallographic analysis.

Additionally, routine maintenance and performance checks of machine components vary between OEMs and are often not open to the end user. Standard tests of machine components, however, can allow end users to regularly assess machine performance. This will create confidence that a machine is functioning as expected and allow the end user to alert the OEM of required maintenance prior to build failures. Research is required to determine how, and at what magnitude, errors in machine components affect output quality so that machine calibration and preventative maintenance checks with appropriate tolerances can be developed.

For example, in the case of laser-based powder bed fusion, the motion control components are trusted to provide accurate positioning. Scanner calibration, which measures galvanometer-driven mirror performance, is currently performed at installation of the machine by the OEM, but not all OEMs perform this test and calibration at the time of maintenance. Errors in the scanner system can lead to reductions in build quality and, at a minimum scanner calibration should be performed annually. The OEMs currently will not allow users to calibrate the scanner, but a standardized test could quantify any changes and flag when a calibration would be needed. In addition to the scanner calibration, "fine tuning" may address this requirement. Fine tuning is a quick build that is run to check many different inputs from process parameters. After measuring the "fine tuning" build, adjustments could be made or the OEM could be alerted of required adjustments to improve the quality of the builds that follow.

As another example, in ink-based powder bed fusion, part accuracy and powder health depend on lamp irradiance and ink-deposition accuracy. Irradiance is calibrated at installation. Ink-deposition is also calibrated at installation. Actual ink deposition is monitored during part manufacturing to determine if the print will continue as expected. In addition to process calibration and monitoring, part quality can be monitored using current quality and process control (QPC) methods. Standardized methods could be developed to enable a better QPC method specific to additive manufacturing, which can often include high-mix, low-volume applications. In addition, for low-mix, high-volume applications, the QPC standard may be extended to take advantage of the flexibility of additive manufacturing.

This issue is closely linked to digital format and digital system control, and machine qualification. See also section 2.5.2 on maintenance and sustainment of machines.

Published Standards

- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing
- ISO/ASTM 52904:2019, Additive manufacturing – Process characteristics and performance – Practice for metal powder bed fusion process to meet critical applications
- ISO/ASTM 52910:2018, Additive manufacturing — Design — Requirements, guidelines and recommendations
- ISO/ASTM 52941:2020, Additive manufacturing — System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application
- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05)
  SAE AMS7032, Machine Qualification for Fusion-Based Metal Additive Manufacturing (2022-08-17)
- SAE AMS7100, Fused Filament Fabrication, Process Specification for (2019-10-10)
- SAE AMS7100/1, Fused Filament Fabrication Process - Stratasys Fortus 900mc Plus with Type 1, Class 1, Form 1, Grade 0 Natural Color Material for (2022-07-06)

In-Development Standards

- ASTM WK65929, New Specification for Additive Manufacturing-Finished Part Properties and Post Processing - Additively Manufactured Spaceflight Hardware by Laser Beam Powder Bed Fusion in Metals
- ASTM WK65937, New Specification for Additive Manufacturing -- Space Application -- Flight Hardware made by Laser Beam Powder Bed Fusion Process

- ASTM WK71395, New Guide for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process
- ASTM WK78092, New Practice for Additive Manufacturing -- Powder Bed Fusion -- Condition-defined Maintenance for Optical Systems
- ISO/TC 261/JG 52, Joint ISO/TC 261-ASTM F 42 Group: Standard test artifacts
- ISO/ASTM DIS 52904, Additive manufacturing of metals — Process characteristics and performance — Metal powder bed fusion process to meet critical applications
- ISO/ASTM DIS 52945, Additive manufacturing for automotive — Qualification principles — Generic machine evaluation and specification of key performance indicators for PBF-LB/M processes
- SAE AMS7100/2 - Fused Filament Fabrication – Markforged X7 with Onyx FR-A Type, Class, Grade, Black (2021-10-21)
- SAE AMS7104, Continuous Fiber Reinforced Fused Filament Fabrication (2021-10-21)
- SAE AMS7104/1, Continuous Fiber Reinforced Fused Filament Fabrication Markforged (2021-10-21)
- SAE ARP7064, Machine Requalification Considerations for Fusion-Based Metal Additive Manufacturing (2022-07-22)

Gap PC2: **Machine Calibration and Preventative Maintenance.** Standards are needed to explain how to address machine calibration and preventative maintenance for additive manufacturing in a way that does not inhibit innovation. A challenge is that there may be different process variables by machine and so machine OEM recommended practices are relied upon. Current users may not have established best practices or their own internal standards and often assume that the machine OEM maintenance procedures are sufficient to start/restart production. Additionally, AM machines have many mechanical components that are similar to conventional subtractive machinery. The motion control components are trusted to provide accurate positioning and it is currently unknown how errors in these systems affect the output quality. This is important during machine qualification and could be addressed in a standard. Lastly, there is a need to address Reliability-Centered Maintenance (RCM), Conditioned-Based Maintenance (CBM+), and possibly the Modular Open Systems Approach (MOSA) for DoD applications. Knowing the end user is just as critical from both a successful maintenance task accomplishment and repeatability of quality products perspective.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Research is required to determine how errors in machine components affect output quality so that tolerances can be developed for machine calibration and preventative maintenance checks

Recommendation: Complete work on standards in development (e.g., ISO/ASTM 52945) addressing machine calibration and preventative maintenance. Machine OEM and end user best practices should ensure adequate and recommended calibration and maintenance intervals that have been documented with data from different materials and process control documents (PCDs). Machine OEMs and SDOs should develop technical reports that incorporate case studies related to machine restart after maintenance. In addition, define benefits/burdens and address standards needs for MOSA, RCM, and CBM+ approaches applied to AM which are specifically relevant to DoD applications.

Priority: ☒High; ☐Medium; ☐Low / There is an urgent need to develop guidelines on day-to-day machine calibration checks.

Organization: AWS D20, ASTM F42/ISO TC 261, SAE AMS-AM, NIST, OEMs, end users, experts in machine metrology

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

Gap PC3: Machine Health Monitoring. Standards are needed to address AM machine health monitoring. Machine health monitoring is a process of observing the machinery to identify changes that may indicate a fault. The use of a machine health monitoring system allows maintenance to be scheduled in a timely manner so as to prevent system failure.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Project 1901 (WK71395) under F42.01 addresses AMSC gap PC3.

Recommendation: Adapt existing health monitoring (diagnostics and prognosis) standards for use in the additive manufacturing industry. Examples of such standards are the semiconductor industry "Interface A" collection of standards and ISO 13379-1:2012, Condition monitoring and diagnostics of machines - Data interpretation and diagnostics techniques - Part 1: General guidelines and ISO 13381-1:2015, Condition monitoring and diagnostics of machines - Prognostics - Part 1: General guidelines. Additional information can be found in NISTIR 8012, Standards Related to Prognostics and Health Management (PHM) for Manufacturing. Further research/guidelines/specifications may be needed. For example, NIST may be able to identify critical indicators that need to be documented or controlled to assist end users with quality assurance. See also gap M6 on Tracking Maintenance.

Priority: ☐High; ☐Medium; ☒Low

Organization: NIST, ISO, ASTM, AWS, IEEE-ISTO PWG, ASME

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASME has a non-AM-specific project concerning Advanced Monitoring, Diagnostics, and Prognostics for Manufacturing Operations which is being conducted by the ASME Prognostics and Health Management (PHM) Subcommittee. Current efforts are focused on the development of a guideline that manufacturers can use to identify opportunities and implement advanced monitoring, diagnostic, and prognostic technologies within their facilities. The guideline is being written in an agnostic manner such that it could be applied to operations involving subtractive machine tools, robotics, or additive processes. The draft guideline will cover: baseline metrics and identification of pain points, PHM readiness characterization, where to deploy and improve existing PHM deployments, and the determination of a PHM business case for manufacturing systems. The PHM guideline is targeted to be published in 2023.

2.2.2.4 Machine Qualification and Re-Qualification

To ensure repeatability in AM builds, it is necessary to ensure that the machine is qualified. Machine qualification encompasses installation (IQ), operation (OQ), and performance (PQ). From a pure machine qualification standpoint, it is OQ. PQ comes into play in ensuring that the machine is building the part you want.

The Air Force has identified a gap in terms of re-qualification. During 2023, AFRL/America Makes issued a call for proposals on re-qualification (delta qualification). Under this roughly 21-month program a joint group of Federal Stakeholders from the Department of Defense and from a "Red Team" of subject matter experts in the area of AM Qualification will perform reviews of the program's progress approximately every 4 months and elicit formal lessons learned and evaluate Key Performance Parameters (KPPs). Proposers should recognize that material and process specifications, control documentation, and other relevant controls will be communicated and reviewed by the "Red Team" to ensure a valid delta qualification is successfully demonstrated. It is anticipated that discussions of approach, data management, and workflow control will occur between teams executing novel delta qualifications and other teams executing baseline qualification efforts. An award is anticipated to be announced toward the end of June 2023 timeframe. More information is available at [insert URL].

Published Standards and Specifications

Some of these documents may only cover aspects of IQ, OQ, PQ):

- API Standard 20S, Additively Manufactured Metallic Components for Use in the Petroleum and Natural Gas Industries, First Edition (2021-10-01)
- API Standard 20T Additively Manufactured Polymer-Based Components for Use in the Petroleum and Natural Gas Industries, First Edition (2022-08-01)
- ASTM F3301-18, Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion
- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing
- DNV-ST-B203 Additive manufacturing of metallic parts Edition 2022-10
- SAE AMS7003, Laser Powder Bed Fusion Process
- SAE AMS7032, Machine Qualification for Fusion-Based Metal Additive Manufacturing
- SAE AMS7100, Fused Filament Fabrication, Process Specification for
- ISO/ASTM 52903-2:2020, Additive manufacturing — Material extrusion-based additive manufacturing of plastic materials — Part 2: Process equipment (reviewed/confirmed in 2022)
- ISO/ASTM 52904:2019, Additive manufacturing – Process characteristics and performance – Practice for metal powder bed fusion process to meet critical applications
- ISO/ASTM TS 52930:2021, Additive manufacturing — Qualification principles — Installation, operation and performance (IQ/OQ/PQ) of PBF-LB equipment

- ISO/ASTM 52941:2020, Additive manufacturing — System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application
- NASA-STD-6030, Additive Manufacturing Requirements for Spaceflight Systems
- NASA-STD-6033, Additive Manufacturing Requirements for Equipment and Facility Control
- NAVSEA S9074-A2-GIB-010/AM-PBF - Requirements For Metal Powder Bed Fusion Additive Manufacturing
- NAVSEA S9074-A4-GIB-010/AM-WIRE DED - Requirements For Metal Directed Energy Deposition Additive Manufacturing

In-Development Standards

- ASTM WK71395, New Practice for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process
- ASTM WK72659, New Guide for Guideline for Material Process Validation for Additive Manufacturing of Medical Devices
- ASTM WK73231, Additive manufacturing -- System performance and reliability -- Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application
- ASTM WK73688, New Specification for Additive manufacturing -- Qualification principles -- Generic machine evaluation and KPI Definition for LPBF-M Processes in Automotive Applications
- AWS is developing D20.2 for wire processes. D20.1 is being revised to only cover metal powder processes (PBF, blown powder DED).
- ISO/ASTM CD 52904, Additive manufacturing of metals — Process characteristics and performance — Metal powder bed fusion process to meet critical applications (revision of 2019 version)
- ISO/ASTM DIS 52945, Additive manufacturing for automotive — Qualification principles — Generic machine evaluation and specification of key performance indicators for PBF-LB/M processes
- SAE ARP7064, Machine Requalification Considerations for Fusion-Based Metal Additive Manufacturing (2022-07-22)

Gap PC4: Machine Qualification and Re-Qualification. There have been advances in developing standards related to machine qualification (e.g., SAE AMS7032 and ISO/ASTM TS 52930), largely focused on powder bed fusion and metals. Additional standards may be needed to address machine qualification and re-qualification for different AM processes, materials, and applications.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: In relation to test artifacts, evaluating process monitoring against NDE. More developed machine performance characterization tests (e.g., through test artifacts that enable machine-to-machine comparison of performance, and day-to-day performance of the same machine).

Recommendation: Develop standards for machine qualification and re-qualification for different AM applications, processes, and materials (primarily polymers and ceramics) where they do not currently exist.

Priority: ☐High; ☒Medium; ☐Low

Organization: NIST, AWS, SAE AMS-AM, ASTM F42, NAVSEA, NASA, America Makes

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.2.2.5 Parameter Control

Parameter control is integrally linked to software, maintenance, and machine qualification protocols. Parameters are typically controlled through software but also require that calibrations be within periodic measurement to ensure part quality.

Variability within and among AM parts has been widely reported in the AM industry. Variability has been noted among parts with different inter-layer (i.e., interpass) times, along the z-direction within a single part, within a part that contains features of varying thickness, among parts built in different locations on the same build platform, among parts built with different surroundings on the build platform, between as-built and machined parts, between parts built with different AM machines of the same model, etc. Most material property variability within and among AM parts is the result of varying thermal histories and their effect on local material microstructures and defect formation. Recognition of these build anomalies also has been widely mitigated in industry best practices.

As has been widely noted in the AM industry, there are a vast number of process parameters that are either programmed by the operator via AM machine software or are controlled by the AM machine without operator input. In some instances, AM machines are manufactured such that the buyer cannot know or control all of the process parameters. This is an intellectual property (IP) issue that is a barrier to the full understanding of the effects of process parameters on AM part performance. Additionally, many AM part producers treat process parameters that they have developed as IP in order to maintain a competitive advantage in the AM industry.

Most material specifications identify the need to have parameter control. Those listed below are limited to those that discuss how to specifically control process parameters.

Published Standards

- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing
- ISO/ASTM 52904:2019, Additive manufacturing – Process characteristics and performance – Practice for metal powder bed fusion process to meet critical applications
- ISO/ASTM 54941:2020, Additive manufacturing — System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application
- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05)

In-Development Standards

- ISO/ASTM CD 52904, Additive manufacturing of metals — Process characteristics and performance — Metal powder bed fusion process to meet critical applications (revision of 2019 version)

Gap PC5: Parameter Control. As a result of the many sources of variability within and among AM parts, and because a complete understanding of the specific effects of so many build process parameters on AM part performance is not currently available in the AM industry, standards are needed to identify requirements for demonstrating that a set of build process parameters produces an acceptable part, and for ensuring that those build process parameters remain consistent from build to build.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Projects 1804/1907 (WK65937, WK65929) address AMSC gap PC5. Develop and establish a set of verifiable, accurate, and unambiguous process parameters for different materials and processes where this is not already available.

Recommendation: Develop a standard(s) that identifies what key build process parameters need to be controlled for AM, taking into account the different processes, materials, industry-specific applications, and machines involved. Parameter control may require detailed standards describing calibration or elements of the equipment such as gas flow, meter, position indicator accuracy, etc. Such a standard(s) would not necessarily describe how to control the parameters due to intellectual property considerations. Some documents already exist, e.g., AWS D20.1, that address process parameters for PBF and DED. It is important to develop standards addressing parameter controls for polymer AM (nylon powder bed fusion, material extrusion, binder jetting, vat photopolymerization). See also gap QC3 on harmonizing Q&C terminology for process parameters.

Priority: ☐High; ☒Medium; ☐Low

Organization: AWS D20, ISO/TC 261-ASTM F42, SAE AMS-AM, IEEE-ISTO PWG

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.2.2.6 Adverse Machine Environmental Conditions: Effect on Component Quality

AM machines may be used in environments where they are subject to vibration, minor seismic activity, roll and pitch (e.g., shipboard), or gradients in temperature, pressure, humidity, dew point, etc. AM machines need to be qualified not only for the manufacture of a set population of parts, but also to operate in the requisite environment. For example, a machine could reside in a plant where other machines are constantly in operation or heavy trucks drive past. The vibrations that could carry through structures and/or the floor/ground need to be sufficiently mitigated during manufacturing. Otherwise, the machine should only be used when those types of adverse factors are not present. The final product must not be adversely impacted due to environmental conditions.

For the defense industry, the forwardly deployed environment (e.g., in theatre or shipboard) has unique impacts on AM processes that are not fully understood at this point. Usage of AM machines in these environments needs to be performed by or under the guidance of qualified AM operators, using qualified machines.

Published Standards

- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05)
- SAE AMS7005, Wire Fed Plasma Arc Directed Energy Deposition Additive Manufacturing Process (2019-01-31)
- SAE AMS7007, Electron Beam Powder Bed Fusion Process (2020-07-01)
- SAE AMS7010A, Laser Directed Energy Deposition Additive Manufacturing Process (L-DED) (2021-10-28)
- SAE AMS7022, Binder Jet Additive Manufacturing (BJAM) Process (2020-11-19)
- SAE AMS7027, Electron Beam Directed Energy Deposition-Wire Additive Manufacturing Process (EB-DED-Wire) (2020-11-18)
- SAE AMS7031, Batch Processing Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-03-29)

In-Development Standards

- SAE AMS7029, Cold Metal Transfer Directed Energy Deposition (CMT-DED) Process (2020-02-03)
- SAE AMS7034 - Hybrid Laser Arc Directed Energy Deposition (HLA-DED) (2020-08-31)

Gap PC6: **Adverse Machine Environmental Conditions: Effect on Component Quality.** There is a need for more research as well as standards or specifications that address AM machines being able to work in adverse environmental conditions.

R&D Needed: ☒Yes; ☐No; ☒Maybe

R&D Expectations: An investigation needs to be conducted to assess the effect and significance of all expected environmental conditions on AM processes. This would likely be limited to one technology but could include several different machines. Such investigation might need to be multivariate- in nature.

Recommendation: Develop standards and specifications to address external environmental factors that could negatively impact component quality.

Priority: ☐High; ☐Medium; ☒Low

Organization: OEMs, DoD for military-specific operational environments, ASTM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None Specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Published standards and standards in development are noted in the text.

2.2.2.7 Stratification

Metal powders used in additive manufacturing are composed of a distribution of attributes (e.g., particle size, morphology, moisture, chemistry, etc.) which can be unique based on supplier and process. Stratification involves generation of non-homogenized powder lots that may occur with the use of powder during batch or closed loop equipment. Users must be aware of the existence of stratification and its potential impact on traceability to precursor materials used to produce parts. Powder specifications and their associated requirements may still apply but how that applies to stratification is application specific.

Published Standards

- ASTM F3456-22, Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials
- SAE AMS7031, Batch Processing Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-03-29)

In-Development Standards

- ISO/ASTM DIS 52928, Additive manufacturing of metals— Feedstock materials — Powder life cycle management
- SAE AMS7052, Continuous, Closed-Loop Process Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-06-20)

Gap PC8: Stratification.[13] There is currently a lack of guidance regarding stratification in virgin and reused metal powder scenarios.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Research should be conducted to understand the effect of stratification on particle size distribution and other metal powder attributes of as-received powder and mixed/blended powder prior to being put into service.

Recommendation: Develop guidelines on how to maintain traceability of metal powder feedstocks or create new lots of powder feedstock across stratification boundaries or gradients throughout the build cycle(s) impacted.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/ASTM, SAE

Lifecycle Area: ☐Design; ☒Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☒Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Published and in-development standards are noted in the text

[13] Gap PC8 was substantially overhauled from what appeared in roadmap v2, retaining only the same number and topic. Issues of powder use and reuse are generally discussed in the precursor materials section of this roadmap.

2.2.2.8 Powder Blending and Powder Mixing Terminology

During discussion of stratification, it was noted that there are differences in terminology on powder blending and powder mixing in relevant industry documents from ISO/ASTM and SAE. Definitions are noted below.

From ISO/ASTM 52900:2021, Additive manufacturing — General principles — Fundamentals and vocabulary, section 3.8, Processing: powder bed fusion:

> **3.8.6**
>
> **powder blend**, noun
>
> quantity of powder made by thoroughly intermingling powders originating from one or several powder *lots* (3.6.2) of the same nominal composition
>
> Note 1 to entry: A common type of powder blend consists of a combination of *virgin* (3.6.4) powder and *used powder* (3.8.9). The specific requirements for a powder blend are typically determined by the application or by agreement between the supplier and end-user.
>
> Note 2 to entry: A distinction is made between blended powders and mixed powders, in which case blended powders are combinations of powders with nominally identical composition, whereas mixed powders are combinations of powders with different compositions.
>
> **3.8.7**
>
> **powder mix**, noun
>
> **powder mixture**
>
> quantity of powder made by thoroughly intermingling powders of different nominal composition
>
> Note 1 to entry: A distinction is made between blended powders and mixed powders, in which case blended powders are combinations of powders with nominally identical composition, whereas mixed powders are combinations of powders with different compositions.

From SAE AMS7031, Batch Processing Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts, section 8.2.1, Definitions:

> POWDER BLENDING: The process of combining powder of the same nominal size, chemistry, and physical attributes in such a way that the characteristics of the powder are uniform throughout. The powder to be blended may be from a single machine or multiple machines, originating from a single or set of nominally similar lots of feedstock and with similar process history. Powder blending is limited to powder lots, in-process and/or virgin, where each constituent is

conforming to the same specification for all compositional and morphological requirements. See 4.5 for implementation.

POWDER MIXING: The process of combining two or more different batches of powder with distinctly different chemical compositions, original particle size ranges, AM process histories, or other physical characteristics in such a way that makes the resultant mixture homogenous and uniform throughout. Powder mixing describes the combining of lots of powder, in-process and/or virgin, where each constituent is described by powder specifications with different (uncommon; not shared/overlapping) compositional and morphological requirements. (Note: Powder mixing is not allowed in this specification as inhomogeneities, potentially detrimental to properties, may not be detectable through bulk testing alone. The controlled process history requirements of powder blending are intended to improve consistency)

New Gap PC18: Powder Blending and Powder Mixing Terminology. Differences exist in definitions of powder blending/mixing in industry standards such as ISO/ASTM 52900:2021 and SAE AMS7031:2022.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop a technical report (TR) to clarify for the industry the terminology differences in industry standards on powder blending and powder mixing.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ISO/ASTM, SAE

Lifecycle Area: ☐Design; ☒Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.2.2.9 Precursor Material Flow Monitoring

Directed Energy Deposition (powder)

For a DED process, it is critical to have some method to monitor powder flow during the build process as it will have an influence on melt pool dynamics as well as geometry of the part.

ASTM F3187-16, Standard Guide for Directed Energy Deposition of Metals relates to this topic. No standards in development have been identified.

Gap PC12: Precursor Material Flow Monitoring. There is no known standard for defining:

- Method of DED process powder flow monitoring
- Location of monitoring
- Accuracy of flow monitoring
- Standardized calibration process of flow

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop a standard for DED process powder flow monitoring so that operators/users will have a way to ensure the powder flow is coming out consistently and with minimal fluctuations so as to not alter the desired build and its properties. See also gap PM1 on flowability.

Priority: ☐High; ☒Medium; ☐Low

Organization: NIST, ISO/ASTM

Lifecycle Area: ☐Design; ☒Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None Specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided

<u>Inkjet (Material Jetting)</u>

Monitoring and control of all flow-related parameters for material jetting are critical to maintain the high quality of the parts as well as the reliability of the printer.

Gap PC13: Flow Parameters for Material Jetting. No published standards or standards in development have been identified for monitoring and control of all flow related parameters for material jetting.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop a standard for monitoring and controlling all flow parameters for material jetting such as flow rate, temperature, viscosity, pressure level, wetting of the orifice plate, etc. This standard should include:

- Monitoring and controlling similar flow in different material feeding channels. This is needed to allow multi-material printing while minimizing cross talk or non-uniformity between channels keeping quality of all printed materials.
- Controlling the thickness of the printed layer. In material jetting, the material flows to the surface and controlling the thickness of each layer is clearly critical to maintain quality. The layer thickness can be controlled by controlling the material flow within the system and within the printing heads as well as by direct measurement after deposition.
- Expanding the performance envelope to enable more degrees of freedom for the flow of material. For example, to enable a wider range of temperatures, humidity control, oxygen level control, ink recirculation in the print heads, etc. All this can allow using more viscous materials, with larger filler particles and exotic materials that might not be compatible with the print head materials in a standard environment.

Priority: ☐High; ☐Medium; ☒Low

Organization: NIST, OEMs, ASTM, IEEE-ISTO PWG

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☒Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided

2.2.2.10 Environmental Health and Safety: Protection of Machine Operators

Environmental health and safety (EHS) is a key aspect of AM process control. It includes protection of the operators from materials (hazardous and non-hazardous), protection of the materials from operator contamination, disposal of materials, and general operator health and safety in machine operation. The potentially significant weight of the materials, and accessory equipment to move materials, is also a consideration.

Typical hazards to be addressed when operating AM systems include: guarding from moving parts that are not protected from contact; guarding from thermal injury; chemical handling (liquids, powders, wires); housekeeping (surface contamination); air emissions (dusts, vapors, fumes); noise (cleaning apparatus); electrical (water wash systems, electro-static systems); flammable/combustible cleaning materials; solid waste; laser use (sintering processes); and UV light (may require eye and skin protection based on design).

There are general OSHA standards for machine guarding,[14] and for hand protection[15] but more specific standards are needed for AM processes. OSHA 1910.95 addresses noise exposure. OSHA, NIOSH, ASTM and other standard air sampling and analysis methods for gases and dusts exist, and new standards for AM are not needed for these analyses. Areas where standards are lacking that are important for AM include particle-number based exposures to ultrafine particles and skin exposure to chemicals.

Research on indoor air quality, health, and human effects is underway between Underwriters Laboratories, Inc. (UL), Georgia Tech, and Emory University. The National Institute for Occupational Safety and Health (NIOSH) has laboratory- and workplace-based research programs that focus on understanding emissions from AM machines, levels of emissions in workplace atmospheres, engineering controls to reduce or eliminate emissions from AM machines, and toxicology studies to understand the impact of exposures. NIOSH has freely available information resources on their website for protection of machine operators engaged in various types of AM processes. Other Government agencies involved in EHS research related to AM processes include the Environmental Protection Agency (EPA). OSHA and EPA guidance with respect to handling of powders applies, and it is necessary to have proper chemical hygiene in facilities where machine operations are taking place.

General industry standards related to industrial hazards include:

- ANSI/ASSP Z9 series of standards that address industrial ventilation by scope and are specifically written to address dusts, vapors, and fumes
- ANSI/ASSP Z10.0-2019, Occupational Health and Safety Management Systems
- ANSI/ASSP Z244.1-2016 (R2020), The Control of Hazardous Energy Lockout, Tagout and Alternative Methods, that addresses the issue of moving parts and accidental release of energy
- ANSI/ASSP Z590.3:2021, Prevention Through Design Guidelines For Addressing Occupational Hazards And Risks In Design And Redesign Processes
- ANSI/ASSP/ISO Standards for risk management and risk assessment (see below)
    - ANSI/ASSP/ISO 31000-2018 Risk Management - Guidelines (digital only)
    - ASSP/ISO TR-31000-2022 Risk Management – A Practical Guide (digital only)

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[14] 1910.212(a)(1) *Types of guarding.* One or more methods of machine guarding shall be provided to protect the operator and other employees in the machine area from hazards such as those created by point of operation, ingoing nip points, rotating parts, flying chips and sparks. Examples of guarding methods are - barrier guards, two-hand tripping devices, electronic safety devices, etc.

[15] 1910.138(a) *General requirements*. Employers shall select and require employees to use appropriate hand protection when employees' hands are exposed to hazards such as those from skin absorption of harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns; thermal burns; and harmful temperature extremes.

    - ANSI/ASSP/ISO/IEC 31010-2019 Risk Management - Risk Assessment Techniques (digital only)
    - ASSP TR-31010-2020 Technical Report: Risk Management - Techniques for Safety Practitioners (digital only)
    - ANSI/ASSP/ISO 31073-2022 Risk Management - Vocabulary (digital only)
- ANSI B11 series of standards for machine tools safety
- ANSI Z136 series of standards for laser safety
- ISO 11553-1:2020, Safety of machinery - Laser processing machines - Part 1: Laser safety requirements
- ISO 45001:2018, Occupational Health And Safety Management Systems - Requirements With Guidance For Use
- See section 2.2.1.2 of this roadmap for additional health and safety considerations related to storage, handling, and transportation.

Published Standards

- UL 3400 Ed.1-2017, Outline of Investigation for Additive Manufacturing Facility Safety Management, for the evaluation and certification of any additive manufacturing facility that uses powder feedstock to print parts.

In-Development Standards

ASTM WK73227, New Guide for Additive Manufacturing (AM) – Investigation for Additive Manufacturing (AM) – Facility Safety Management. ASTM and UL have signed an MOU to transpose UL 3400 to an ASTM format and this work item is nearing completion.

ISO/TC 261 has a Working Group on *Environment, health and safety* (ISO/TC 261/WG 6), and three Joint Groups with ASTM F42 on AM: *EH&S for 3D printers* (JG68), *EH&S for use of metallic materials* (JG69), and harmonization of safety requirements for PBF-LB machines using metallic feedstock (JB78).

- ISO/ASTM FDIS 52931, Additive manufacturing of metals – Environment, health and safety – General principles for use of metallic materials (aka ASTM WK72391). This document is based on a French national standard XP E67-006 Additive manufacturing - Safety, health and environment - Requirements relating to metallic materials.
- ISO/ASTM AWI 52938-1, Additive manufacturing of metals – Environment, health and safety – Part 1: Safety requirements for PBF-LB machines (aka ASTM WK74933)

Gap PC14: Environmental Health and Safety: Protection of Machine Operators. There is a need for standards to address environmental health and safety (EHS) in the AM process.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop standards addressing EHS issues relative to additive manufacturing machines and processes.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F42/ISO TC 261, UL, ASSP, B11, LIA (Z136), ISO/TC 262

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: General industry standards

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text

2.2.2.11 Configuration Management

Configuration management includes software version control for the digital file and additive system (i.e., machines/equipment) controls.

Cybersecurity issues that arise with respect to AM process control include loss of intellectual property, risk of unqualified aftermarket components, unauthorized modification of build files, and attacks on machine software impacting part quality. Documented cases of malware intrusion in the software of OEM machines have been shown to impact product quality and in some cases destruction of manufacturing equipment. Intellectual property theft through counterfeiting is a growing international concern, with the ease of copying AM process files only increasing this risk. Any modification to the aftermarket components or build file can have significant impact to the part integrity and quality.

Published Standards and Guidance

- ABS Volume 1, Guidance Notes on the Application of Cybersecurity Principles to Marine and Offshore Operations
- ABS Volume 2, Guide for Cybersecurity Implementation for the Marine and Offshore Industries
- ABS Volume 3, Guidance Notes on Data Integrity for Marine and Offshore Operations
- ABS Volume 4, Guide for Software Systems Verification
- ABS Volume 5, Guidance Notes on Software Provider Conformity Program
- IEEE-ISTO PWG 5199.10-2019: IPP Authentication Methods v1.0
- IETF Internet Printing Protocol (IPP) over HTTPS Transport Binding and the 'ipps' URI Scheme – RFC 7472
- NIST Special Publication 800-82 Revision 2, Guide to Industrial Control Systems (ICS) Security
- NIST Cybersecurity for Smart Manufacturing Systems project
- ANSI/CAN/UL (UL 2900-1), Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
- UL 2900-2-1, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
- UL 2900-2-2 Ed. 1-2016, Outline of Investigation for Software Cybersecurity for Network-Connectable Products, Part 2-2: Particular Requirements for Industrial Control Systems
- ANSI/CAN/UL (UL 2900-2-3), Standard for Software Cybersecurity for Network-Connectable Products, Part 2-3: Particular Requirements for Security and Life Safety Signaling Systems

In-Development Standards

- ASTM WK78322, New Guide for Additive Manufacturing -- General Principles -- Guidelines for AM Security
- IEEE-ISTO PWG, IPP Encrypted Jobs and Documents v1.0
- ISO/TC 261-ASTM F 42 Joint Group JG73: Digital product definition and data management

Gap PC15: Configuration Management. Best practices for maintaining and controlling the programming environment for additive processes are needed to ensure repeatable product quality.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop best practices to protect digital files and equipment used in the AM process.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/ASTM JG73, America Makes, NIST, UL, IEEE-ISTO PWG, DoD

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: There are a number of published and in-development standards as noted in the text.

2.2.2.12 In-Process Monitoring

In-process monitoring here refers to measurement systems applied during the fabrication process, and includes measurements of the part(s) being built, process signatures such as melt pool emissions, as well as AM machine conditions such as oxygen, chamber temperature, etc. Machine condition monitoring is relatively high technology readiness level (TRL). In-process monitoring directed at the part fabrication (e.g., melt pool monitoring) is generally at a lower TRL compared to more established NDE methods used to inspect parts after build (see gap NDE3 for the application of NDE to Objects Produced by AM Processes). While systems are emerging and much research is being conducted, an analysis of in-process monitoring data will need to take into account the process engineer's level of knowledge, maturity of the monitoring method, the process design complexity of the build, the requisite rigor needed for in-process monitoring of the component being manufactured, and the ability to incorporate the necessary sensor-based technologies into a given process without interfering with the build.

When feedstock supply, process conditions, or process parameters are monitored during a build, the goal is to have machines that are self-monitoring and self-calibrating, and can self-correct and control important equipment performance parameters during the build.

Published Standards

- ASTM E3353-22, Standard Guide for In-Process Monitoring Using Optical and Thermal Methods for Laser Powder Bed Fusion (previously WK73289 and WK62181)) published by ASTM E07.10

ASTM E3353-22 does not cover conversion of monitoring data to a 3D file (e.g., data alignment/ registration, which is anticipated to be covered by ASTM WK74390). It does cover commercial melt pool monitoring and layer-wise imaging systems, as well as some aspects of machine health monitoring and statistical process control. It does not provide specific details or methodology for linking indications to defects, but provides general guidelines based on the current state of art at time of publication.

The guide E3353-22 covers the general methods by which commercial in-process monitoring systems may be applied (e.g., process development vs. product development), overview of some important related concepts (e.g., data alignment or registration, statistical process control, and machine learning). The guideline provides sections on specific technology categories with more details, including melt pool monitoring, layer-wise imaging, and machine condition monitoring technologies. Details for each technology category include general operating principles, instrument design considerations, potential observable flaws, and other pertinent aspects. It is anticipated that additional process monitoring or in-process NDE technologies will be added to future versions of the standard.

- ASTM F3490-21, Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree. Published by F42.08, this standard lists a set of attributes or metadata that are required to accompany in-process monitoring datasets.

In-Development Standards

- ASTM WK73978, New Specification for Additive Manufacturing – General Principles – Registration of Process-Monitoring and Quality-Control Data (being developed in F42.08)
- ASTM WK74390, New Practice for Additive Manufacturing of Metals – Data – File structure for in-process monitoring of powder bed fusion (being developed in F42.08)
- ASTM WK76983 (AKA ISO/ASTM52958) Practice for Additive Manufacturing -- Powder Bed Fusion – Best Practice for In-situ Defect Detection and Analysis. (being developed in F42.05)
- ASTM WK82605, New Specification for Additive Manufacturing – General Principles – Metal Laser Beam Powder Bed Fusion Machines for Spaceflight Applications (being developed in F42.07).

As a result of the ASTM CoE Specialty Workshop on In-situ Technology Readiness for Applications in AM Qualification and Certification, ASTM WK82605 was registered in ASTM and subsequently accepted for ISO/ASTM development. This work item identifies significant in situ monitoring categories in section 5. They include build chamber oxygen, build chamber temperature and humidity, build chamber pressure, build platform temperature, image capture camera, closed loop control of Z axis controller, recoater motor torque (if applicable), laser power, laser window debris detection, spatter detection, and melt pool monitoring. As illustrated, melt pool monitoring is only one aspect of in situ monitoring. By combining all the in-situ sensor data, the quality of the build cycle can be assessed.

Gap PC16: In-Process Monitoring. Few published standards directly address in-process monitoring technologies. More than likely, there will be no "one size fits all" standard for any given additive process, piece of equipment, or material. It would be highly dependent on end user analytics of OEM or internally developed sensing systems.

In-process monitoring instrument design, particularly those that have been commercialized, are relatively high TRL, whereas the processing and analysis of the measurement data results (e.g., identifying flaws) are lower TRL. As such, standards focused on the instrument calibration for repeatability or relating to absolute values such as temperature, or characterization of sensitivity, range, resolution, etc., may likely be developed earlier than those that instruct users on how to process and analyze the measurement data. Additionally, AM in-process monitoring largely utilizes existing instruments (e.g., thermal imagers, machine vision, pyrometry, etc.) which may refer to associated standards developed outside the scope of AM applications (e.g., thermographic standards from ISO/TC 135/SC 8, ASTM E20.02, ASTM E07.10, or BSI Group GEL/65/2, or machine vision standards from ISO/TC 42 on Photography, European Machine Vision Association (EMVA), Association for Advancing Automation (A3)).

Some concepts regarding in-process data preprocessing or organization are known to be critical and can be potentially standardized sooner than guidelines or methods on data analysis. These include alignment or registration of in-process data (e.g., WK74390 and WK73978), and necessary metadata or schema for transferring or archiving in-process data (e.g., F3490-21).

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: For AM machine condition monitoring, issue standards on in-process monitoring. Aspects to explore include but are not limited to the following examples (not a comprehensive list): the feedstock (supply ratios and other metrics), process conditions (atmosphere, humidity), and performance of systems to achieve accurate process parameters (beam diagnostics such as location, laser power, scan width, scan rate).

For part quality monitoring, issue standards on alignment and registration of in-process measured data with other data (design geometry, post-fabrication NDE, or other in-process data), methods for calibration or characterization of in-process monitoring instruments, methods for evaluating performance or sensitivity of in-process monitoring systems, guidelines for identifying or labelling certain flaws or anomalies within specific in-process monitoring technologies. Issue guidelines or methods on how to determine critical flaw size, magnitude, or concentration thresholds, or statistical process variables and control limits. See also gap DE9 on the use of physics-based models and simulation tools (analytics).

Priority: ☐High; ☒Medium; ☐Low, given the relatively TRL state of the art

Organization: ASTM E07.10, F42

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.2.2.13 Anti-Counterfeiting

Quality is compromised when a counterfeit substitutes for a genuine product. Cybersecurity, addressed in Section 2.2.2.11, protects the digital file, but as AM scale-up creates a supply chain, separate measures are necessary for validating physical additively manufactured objects. Industries with concerns about brand protection may wish to consider incorporating identification features into components to deter counterfeiting.

Counterfeiting, either economically motivated or for the purpose of sabotage, is facilitated through the ubiquity of 3D printers and the ease of 3D scanning. Anti-counterfeiting measures that rely on surface security features (color, texture, patterns, codes) are vulnerable to a counterfeiter with a 3D scanner, and therefore are not secure choices to protect AM. Covert features, including internal patterns, physical or chemical, and electronic tags, avoid those vulnerabilities. Authentication must strike a balance: easy and inexpensive enough to be viable, but not so easy as to facilitate copying. Care should be taken to align quality management goals so that intentional tagging for anti-counterfeiting purposes is permitted, rather than viewed as contaminated material, and so that testing goals are coordinated where possible.

Discontinuities and even voids may be intentionally introduced in order to address the concern of counterfeiting, e.g., by inserting other materials or varying internal texture as a hidden signature. Best practices include:

- Provision of objective evidence for authentication
- Good supply chain procedures for added material such as taggants or RFID tags (e.g., multiple suppliers, multiple countries)
- Non-destructive evaluation for authentication, preferably portable to enable authentication of parts before installation into larger systems
- The placement of an anti-counterfeiting feature so that it does not compromise structural integrity, e.g., where a void or label would otherwise be acceptable. The feature also needs to survive post-processing.

See section 2.1.7 Design for Anti-counterfeiting (gap DE29) and section 2.4 on NDE (gaps NDE2 and NDE7).

2.2.3 Post-processing

2.2.3.1 Introduction

Additive manufacturing consists of a complex series of operations that are required to make a fit-for-use production part. Among the many critical steps are operations that occur after a part is built and before it is ready for qualification, inspection, testing, and certification. These operations as a group are called post-processing. Post-processing differs depending upon the material and part being built and the process used. Considerations include but are not limited to: removing support structures and excess material from the newly built part's external and internal surfaces, freeing the part from the build plate, heat treatment operation(s) in the case of metal and some polymeric parts, machining of the part to final dimensional tolerances, processing to attain the desired surface finish, and imparting compressive residual stresses on the surface to improve fatigue resistance.

ISO/ASTM 52900:2021, Additive manufacturing — General principles — Fundamentals and vocabulary, defines post-processing as a: "*process step, or series of process steps, taken after the completion of an additive manufacturing build cycle in order to achieve the desired properties in the final product*." Post-processing procedures include post-build thermal heat treatments, hot isostatic pressing, sealing, chemical treatments, and surface engineering and finishing. Most post-processing methods and standards likely apply to AM materials, though some may not apply to surface finishing due to the thin, complex features that can be fabricated using AM.

Post-processing of metal AM components is frequently performed to reduce residual stresses, achieve a more desirable microstructure compared to the as-built part, improve surface finish, reduce internal porosity, meet geometric tolerance requirements, and/or establish desired metallurgical characteristics and mechanical properties.

A work item in development is ISO/ASTM DIS 52908, Additive manufacturing — Finished part properties — Post processing, inspection and testing of parts produced by powder bed fusion. Designed to complement ISO/ASTM 52900, this standard covers the testing of components manufactured from metallic materials using additive technologies. It sets requirements for the qualification, quality assurance and post processing for metal parts made by powder bed fusion.

Post-processing of polymeric AM components is frequently performed to complete chemical reactions, homogenize microstructure and/or residual stresses compared to the as-built part, improve surface finish, reduce surface porosity, and/or meet geometric tolerance requirements.

Post-processing of ceramic AM components is required for improved properties. There are three key factors when considering post-processing in 3D printed ceramics – density, surface quality, and microstructure, which affect the part properties. For binder jetting printed ceramics, the typical post heat treatment process includes binder curing stage, polymeric binder burnout stage, followed by sintering stage for densification.

Post-processing is essential to transforming an additively manufactured part into a finished part. In summary, post-processing takes a configured shape, refines its features, and imparts mechanical properties and structure in the case of metal parts.

In terms of process control, post-processing must be applied identically from build-to-build to achieve consistent performance for a given AM part. Additionally, post-processing methods used during development and qualification of the AM procedure parameters must be sufficiently representative of the final component post-processing to ensure that the performance data generated during development and qualification are consistent with the final component.

Given its effects on the consistency of material and part performance, post-processing should be a key feature of calibration and qualification artifacts. Due to the various means of building AM parts and the unique effects each may have on the final materials, ensuring a consistent method of post-processing calibration articles will provide a method of correlating these artifacts across machines and AM methodologies. This application encompasses all the topics discussed in this section, and for this reason the need for a common post-processing methodology for test artifacts is considered the first gap in this section.

Published Standards

Metals

- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing. AWS D20.1 requires that the same post-processing operations that will be performed on the production component be performed on the qualification builds (5.2.1.4 - PBF, 5.2.2.4 - DED). Post-build processing parameters are listed as qualification variables in Table 5.2 (PBF) and Table 5.3 (DED).

- SAE AMS7000A, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion- and Heat-Resistant, 62Ni - 21.5Cr - 9.0Mo - 3.65Nb Stress Relieved, Hot Isostatic Pressed and Solution Annealed (2022-05-16)
- SAE AMS7004, Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate, Ti-6Al-4V, Stress Relieved (2019-01-31)

In-Development Standards

Metals

- SAE AMS7016, Laser-Powder Bed Fusion (L-PBF) Produced Parts, 17-4PH H1025 Alloy (Oct 2018)
- SAE AMS7024, Inconel 718 L-PBF Material specification (Jun 2019)
- SAE AMS7028, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Titanium Alloy, Ti-6Al-4V Stress Relieved, and Hot Isostatic Pressed (Jan 2020)
- SAE AMS7030, Laser- Powder Bed Fusion (L-PBF) Produced Parts of AlSi10Mg (Feb 2020)
- SAE AMS7036, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Steel, Corrosion and Heat Resistant 17Cr – 13Ni – 2.5Mo (316L), Hot Isostatic Pressed (Initiated Mar 09, 2021)
- SAE AMS7038, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion and Heat-Resistant -52.5Ni - 19Cr - 3.0Mo - 5.1Cb (Nb) - 0.90Ti - 0.50Al - 18Fe Stress Relieved, Hot Isostatic Pressed, (Initiated Mar 02, 2021)
- SAE AMS7039, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Steel, Corrosion and Heat Resistant 17Cr – 13Ni – 2.5Mo (316L), Stress Relief and Anneal (Initiated Apr 19, 2021)

Polymers

- ISO/TC 261/JG 55, Joint ISO/TC 261-ASTM F 42 Group: Standard Specification for Extrusion Based Additive Manufacturing of Plastic Materials [STANDBY]

Gap P1: Post-processing Qualification, Validation, and Production Builds. Standards are needed that require post-processing to be applied consistently for qualification, validation, and production builds of AM parts. While a number of standards have been published or are in development that address this issue especially for metals, additional standards work may be needed for other materials and AM processes, to address required part performance.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Develop scientific basis for best practices

Recommendation: New standards and revisions to existing standards should require post-processing for the various materials and AM processes to be applied consistently for qualification, validation, and production builds of AM parts. These standards should be process and material specific and should seek to define minimum best practices for qualification, validation and production builds, along with reporting requirements.

Priority: ☐High; ☒Medium; ☐Low

Organization: AWS D20, ASTM F42/ISO TC 261 JG 55, SAE, ASME

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Each company is setting their own controls with varying degrees of consistency.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: For metals, AWS D20.1 and SAE AMS7000A and AMS7004 have been published and SAE has a number of standards in development. ASME code case 3020 uses the same post weld processing for qualification of additive build procedures (heat treatment, peening, etc.) rules as are used for welds. For polymers, ASTM F42/ISO TC 261 JG 55 is in development for material extrusion but appears to be in Standby according to the ISO/TC 261 website.

2.2.3.2 Heat Treatment (metals, polymers)

Metals

Introduction

Post-build heat treatment (HT) subjects the part to specific thermal cycles involving heating and cooling to a specific time/temperature profile at a specified rate. Multiple heat treatments may be sequenced with other post-processing operations such as rough machining and final machining. Heat treatment may be used to reduce residual stresses induced in the part by the AM building process to minimize warping and improve dimensional stability and machinability. It is also used to achieve the desired properties by changing the metallurgical structure (such as improving strength by precipitation hardening), and to create a part with isotropic properties. Heat treatment is frequently done in an inert atmosphere or vacuum, depending on the material involved, to prevent oxidation and deterioration of the properties of the materials.

Standards for Heat Treatment of AM Parts

Numerous heat treatment standards exist for alloys, many of which can be used for additively manufactured parts, either as-is or with modifications. Existing HT standards specifically address all forms of an alloy such as wrought, forged, cast, etc. but most do not include an additively manufactured variant. The layered build process, fine grain, unique microstructure, and directionally-dependent characteristics may require modified HT schedules to achieve the desired microstructure and properties depending on the material, the AM build process, and the desired properties.

Published Standards

Standards on heat treating process equipment, procedures, and HT cycles for various metals currently exist that are specific to wrought or cast metals. There are several standards that give simplified thermal cycles for additively manufactured metal parts of specific materials produced by powder bed fusion (PBF). For example,

- ASTM F2924-14(2021) - Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
- ASTM F3001-14(2021) - Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
- ASTM F3055-14a(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion
- ASTM F3056-14(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion

However, more standards are needed for other materials and other processes. SAE AMS4999A, Titanium Alloy Direct Deposited Products 6Al - 4V Annealed (2016-09-26) includes thermal processing information. Additional published heat treatment standards which may be applicable for heat treating additively manufactured parts include:

- ASTM F3301-18a, Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion
- SAE AMS2750G, Pyrometry
- SAE AMS2759G, Heat Treatment of Steel Parts General Requirements
- SAE AMS2759/3J, Heat Treatment Precipitation-Hardening Corrosion-Resistant, Maraging, and Secondary Hardening Steel Parts
- SAE AMS2770R, Heat Treatment of Wrought Aluminum Alloy Parts
- SAE AMS2771F, Heat Treatment of Aluminum Alloy Castings
- SAE AMS2774G, Heat Treatment, Wrought Nickel Alloy and Cobalt Alloy Parts
- SAE AMS2801C, Heat Treatment of Titanium Alloy Parts

- SAE AMS7000A, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion- and Heat-Resistant, 62Ni - 21.5Cr - 9.0Mo - 3.65Nb Stress Relieved, Hot Isostatic Pressed and Solution Annealed (2022-05-16)
- SAE AMS7004, Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate, Ti-6Al-4V, Stress Relieved (Jan 2019)
- SAE AMS-H-6875C, Heat Treatment of Steel Raw Materials (Stabilized Sep 2020)

Another committee with relevant published standards is ISO/TC 17/SC 4, Heat treatable and alloy steels.

In-Development Standards

- SAE AMS7016, Laser-Powder Bed Fusion (L-PBF) Produced Parts, 17-4PH H1025 Alloy (Oct 2018)
- SAE AMS7024, Inconel 718 L-PBF Material specification (Jun 2019)
- SAE AMS7028, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Titanium Alloy, Ti-6Al-4V Stress Relieved, and Hot Isostatic Pressed (Jan 2020)
- SAE AMS7030, Laser- Powder Bed Fusion (L-PBF) Produced Parts of AlSi10Mg (Feb 2020)
- SAE AMS7036, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Steel, Corrosion and Heat Resistant 17Cr – 13Ni – 2.5Mo (316L), Hot Isostatic Pressed (Initiated Mar 09, 2021)
- SAE AMS7038, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion and Heat-Resistant -52.5Ni - 19Cr - 3.0Mo - 5.1Cb (Nb) - 0.90Ti - 0.50Al - 18Fe Stress Relieved, Hot Isostatic Pressed, (Initiated Mar 02, 2021)
- SAE AMS7039, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Steel, Corrosion and Heat Resistant 17Cr – 13Ni – 2.5Mo (316L), Stress Relief and Anneal (Initiated Apr 19, 2021)
- SAE AMS7049, Binder Jet Additive Manufacturing (BJAM) Produced Parts, Steel, 1.0Cr – 0.20Mo – 0.30C, Austenitized, Quenched and Tempered (Composition Similar to UNS G41300) (2022-01-14)
- SAE AMS7051, Binder Jet (BJAM) Printed Parts, Precipitation Hardenable Steel Alloy, Corrosion and Heat-Resistant, 16.0Cr - 4.0Ni - 4.0Cu - 0.30Nb Solution Annealed and H900 Aged (2022-06-20)

Gap P2: Heat Treatment (HT)-Metals. Many of the existing and in-development standards for HT of metals built using PBF state the requirements for a specific metal within the standard, but not all metals have been addressed, and stress relief heat treatments in these standards may not be optimized for AM. In addition, differences between laser-based and electron beam-based PBF processes are insufficiently addressed in the existing standards. Both processes are considered to be the same regarding HT requirements, when in reality PBF-EB is performed at much higher temperature and produces a more uniform microstructure so it may require less or no residual stress relief.

Heat treatment requirements for metals made with non-powder processes such as directed energy deposition (DED) using wire feedstock, sheet lamination, etc., are currently not addressed in any standards except for titanium-6Al-4V via DED (SAE AMS7004).

HT standards for parts produced using binder jetting are also needed. There are multiple steps to go from the printed part to the sintered part and additional heat treatment cycles. Starting microstructures may be different than for an L-PBF part and may require additional research. The starting microstructure and ending microstructure need to be understood. That will depend on the technology used to print the part.

In cases where AM material requires HIP processing, the process may be modified to meet HT requirements as well, negating the need for additional HT standards.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to determine the optimized heat treatments for AM materials as a function of materials and process.

Recommendation: As the need arises for new metals, new standards will have to be written for each one, containing specific HT information. Also, as differences are found in required HT for laser versus electron beam processes, these differences should be added to the existing standard for that metal. Standards for metals made with non-powder (e.g., wire, sheets) or non-melting (e.g., ultrasonic, cold spray, friction stir) processes need to be developed that contain HT requirements specific to that metal and optimized for the appropriate production process. As heat treatments are found to reduce anisotropy in properties for particular metals, these should be added to the existing standards for those metals.

Priority: ☐High; ☒Medium; ☐Low

Organization: R&D: universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE AMS-AM, MPIF.

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: A number of standards have been published and or are being developed since the publication of AMSC roadmap v2.

Polymers

Introduction

Post-build heat treatment (HT) for polymeric materials involves heating and cooling to a specific time/temperature profile at a specified rate. Heat treatment of polymeric materials generally involves a single thermal cycle. In the case of thermoset materials, heat treatment, also known as post-curing (see section 2.2.3.6), is intended to ensure that the reactive chemical components are either consumed by the polymerization reaction or driven from the completed part. In some systems, this heat treatment may also be accompanied by irradiation. In the case of semi-crystalline thermoplastic polymeric materials, heat treatment (annealing) is intended to reduce residual stresses induced in the part by the AM building process to minimize warping and improve dimensional stability and machinability. This is accomplished by allowing the time/temperature profile necessary for the maturation of the crystalline domains in the printed part.

Standards for Heat Treatment of AM Parts

There are currently no identified published or in-development standards on specific heat treatments (heating and cooling rates, anneal conditions) which could guide the AM practitioners to arrive at an optimum anisotropic structure and properties for the polymer parts. ASTM and ISO mechanical test standards which have been commonly-used by various research groups to test the properties of the AM built parts such as tensile and compressive strengths, bending, mechanical fatigue, crack propagation and impact, may have to include a consideration of the influence of microstructure. The physical and mechanical properties of the finished part can be considerably affected by the degree of crystallization of polymers which can be controlled by the change of cooling rate during and after the AM process. A better understanding of the microstructure of the as-deposited polymer is necessary to arrive at the mechanical properties most suited for a given application.

Gap P7: **Heat Treatment (HT)-Polymers.** Heat treatment is an effective method to modify the properties of AM built polymer parts. Presence of fillers, as in the case of composites, can alter the nucleation rate causing significant increase in tensile strength and hardness of the finished part. It also becomes essential to consider the variation of morphology of the polymer parts and layers because of the difference in the cooling rate from the surface to the center. The outer surface could end up less crystalline due to a rapid solidification rate and result in less resistance to wear. The contraction of volume due to crystallization in the bulk could increase the residual stresses at the interface. Standards are needed on specific heat treatments (heating and cooling rates, anneal conditions) which could guide the AM practitioners to arrive at an optimum anisotropic structure and properties for the polymer parts.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to determine the conditions for optimized heat treatments of AM built parts as a function of materials (semi-crystalline polymers, composites, etc.) and AM post process parameters.

Recommendation: As AM expands to include new and high performance semi-crystalline polymers, polymer nanocomposites and thermosets, advanced machine design and processing, the standards for the measurement of mechanical properties will have to describe specific HT information on the test samples. These HT requirements (slow cooled vs. quenched vs. gradient cooled) will be specific to the polymer and the production process. A guideline on HT treatment procedures followed by sampling for testing would enable achieving optimum polymer microstructure and properties.

Priority: ☐High; ☐Medium; ☒Low

Organization: R&D: NIST, universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE AMS-AM.

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

2.2.3.3 Hot Isostatic Pressing (HIP) (metals and ceramics)

Introduction

Post-build hot isostatic pressing (HIP) involves subjecting the part to a specific thermo-mechanical treatment cycle involving heating it at a specific ramp rate to a specific temperature for a specific period of time, while applying positive isostatic pressure (often in the range of 100-200 MPa) utilizing an inert atmosphere and then cooling it. The HIP cycle is unique to each material and can be optimized depending on the desired properties for the material.

HIP is used to reduce porosity and heal defects in metals, effectively increasing the alloy’s bulk density. HIPing can improve the alloy's mechanical properties and workability. HIP is important for additively manufactured parts. HIP improves the fatigue properties by healing internal discontinuities, i.e., not extended to the surface, such as lack of fusion, voids, porosity, and cracks. HIP can often improve the ductility and fracture toughness of the material as well. HIP temperature and soak time can be optimized for producing parts with lower residual stress, uniform microstructure, recrystallized grain size, and morphology closer to the equiaxed grain structure.

In modern HIP systems there is the possibility to rapidly cool or quench inside the HIP furnace making it possible to combine the HIP step and the heat treatment for a material in the same cycle in the HIP. With this combined process, it is not only possible to eliminate internal defects in the AM part with HIPing but also to modify the microstructure of the material as desired for optimal mechanical properties just like conventional heat treatment.

For ceramics, densification processes, such as warm and hot isostatic pressing are preferred densification methods over uniaxial hot pressing, because of their application to complex-shaped parts, while hot pressing is only suitable for regular-shaped blocks. Another method commonly employed to increase the density of porous ceramics is infiltration. Gas- or liquid-phase infiltration methods include slurry infiltration, sol–gel infiltration, reactive melt infiltration, polymer infiltration and pyrolysis, and chemical vapor infiltration.

Density and microstructure are directly influenced by the processing parameters in the post-debinding and sintering, such as heating/cooling rate, maximum temperature, holding duration, atmosphere, and pressure.

Standards for HIP of AM Parts

There are a number of HIP standards for metals, some of which can be used for additively manufactured parts, either as is or with modifications. These standards are designed for cast, forged metals, billets, and preforms produced by powder metallurgy technology, sintered components, or metal injection molded parts, and should not therefore be automatically considered for additively manufactured parts. In order to maximize AM material integrity without compromising microstructure properties relationships, the HIP parameters need to be optimized, especially for structural, flight safety parts, and other demanding applications.

Published Standards

ASTM Committee F42 standards that contain specific HIP process parameters[16] for specific metals include:

- ASTM F2924-14(2021) - Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
- ASTM F3001-14(2021) - Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
- ASTM F3049-14(2021), Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes
- ASTM F3055-14a(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion
- ASTM F3056-14(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
- ASTM F3301-18a, Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion

Other ASTM standards include:

- ASTM A988/A988M-17, Standard Specification for Hot Isostatically-Pressed Stainless Steel Flanges, Fittings, Valves, and Parts for High Temperature Service
- ASTM B998-17, Standard Guide for Hot Isostatic Pressing (HIP) of Aluminum Alloy Castings

SAE AMS-AM standards that contain specific HIP process parameters for specific metals include:

- SAE AMS4999A, Titanium Alloy Direct Deposited Products 6Al - 4V Annealed (2016-09-26)
- SAE AMS7000A, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion- and Heat-Resistant, 62Ni - 21.5Cr - 9.0Mo - 3.65Nb Stress Relieved, Hot Isostatic Pressed and Solution Annealed (2022-05-16)
- SAE AMS7004, Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate, Ti-6Al-4V, Stress Relieved (Jan 2019)

In-Development Standards

- SAE AMEC AM2750/2, Pyrometry for Hot Isostatic Pressing

[16] HIP parameters for Titanium, Aluminum, and superalloys (which includes Inconel) are classified as export controlled. Transfer of these parameters from companies to SDOs to include in standards is a matter of concern for some U.S. companies.

- SAE AMS7016, Laser-Powder Bed Fusion (L-PBF) Produced Parts, 17-4PH H1025 Alloy (Oct 2018)
- SAE AMS7024, Inconel 718 L-PBF Material specification (Jun 2019)
- SAE AMS7028, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Titanium Alloy, Ti-6Al-4V Stress Relieved, and Hot Isostatic Pressed (Jan 2020)
- SAE AMS7030, Laser- Powder Bed Fusion (L-PBF) Produced Parts of AlSi10Mg (Feb 2020)
- SAE AMS7036, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Steel, Corrosion and Heat Resistant 17Cr – 13Ni – 2.5Mo (316L), Hot Isostatic Pressed (Initiated Mar 09, 2021)
- SAE AMS7038, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion and Heat-Resistant -52.5Ni - 19Cr - 3.0Mo - 5.1Cb (Nb) - 0.90Ti - 0.50Al - 18Fe Stress Relieved, Hot Isostatic Pressed, (Initiated Mar 02, 2021)
- SAE AMS7050, Binder Jet Additive Manufacturing (BJAM) Produced Parts, Steel, 1.0Cr – 0.20Mo – 0.30C, Hot Isostatic Pressed, Austenitized, Quenched and Tempered (Composition Similar to UNS G41300) (2022-01-14)

Gap P3: Hot Isostatic Pressing (HIP). Just as for heat treatment and gap P2, the existing HIP standards do not fully address AM material-related issues such as: slow cooling rate and its effect on formation of prior particle boundaries and carbide precipitation at grain boundaries, as well as the effect of thermal exposure on excessive grain growth, carbide size, incipient melting, and the effect of removing the part from the base plate before HIP (in the case of PBF). The HIP parameters in the existing AM standards are often developed for castings, forgings and sintered parts and may not be optimal for AM material since the thermal history, as-printed microstructure and property requirements often is a lot different from materials processed with the conventional manufacturing methods. Generally, the existing standards provide guidance for interpretation of processing parameters, tolerances, and conformance to industry accepted practices such as pyrometry, cleanliness, traceability, etc.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop material specific standards based on R&D defined HIP parameters for AM with acceptance criteria for internal discontinuities. Some examples are listed below. It is recognized that this will be difficult to achieve as each material will have parameters that are applicable and those could change as a result of application requirements that are related not just to pores but also to microstructure. It should be possible to develop a standard that defines acceptable end results defined by some of the attributes listed here.

- Effect of max thermal exposure on microstructure evolution (X temperature for more than X hours)
- Effect of cooling rate
- Discontinuities extended to the surface
- Incipient melting with and without voids
- Discontinuities larger than X inches depending on location
- Lack of fusion
- Interconnected porosity

- Nonmetallic contamination
- Cross contamination due to processing of different customer parts in commercial HIP vessels
- Grain morphology
- Material dependent microstructure (e.g., in 718 laves phase, delta phase morphology, etc.)
- Number of discontinuities larger than X in per certain view area (e.g., within 1 sq. inch)
- Number of discontinuities in subsurface area (X microns from the surface) larger than X inch
- Linear formation of discontinuities (other than interconnected porosity) and minimum distance of X inches between adjacent discontinuities

Priority: ☐High; ☒Medium; ☐Low

Organization: R&D: various entities. Standards: ASTM F42, SAE AMS-AM, possibly SAE AMEC

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☒Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Some R&D is taking place in the commercial sector and at the university level. In terms of standards development, the referenced ASTM F42 work items may address the gap. SAE AMS7000A was published in 2022 and SAE AMS AMEC is working on a HIP spec, as noted in the text.

2.2.3.4 Surface Texture (Surface Finish) (metals, polymers, and ceramics)

Introduction

Sometimes referred to as surface finish or topography, surface texture[17] is defined in ASME B46.1-2019, Surface Texture (Surface Roughness, Waviness, and Lay), as: *"the composite of certain deviations that are typical of the real surface. It includes roughness and waviness."* Surface texture is a very important consideration for AM post processing as most processes create unique surface textures that may require post-build finishing, depending on the application. These include as-built surface asperities such as partially fused powder, a degree of striation or stair-stepping typical of layered deposition on an inclined surface, and/or visible layer lines along vertical surfaces. Moreover, components may present different types of surfaces based on their orientation with respect to the build plate. For example, top surfaces at 0° with respect to the build plate will have the characteristic features of the applicable fusing method such as a source pass pattern. At the same time, the overhang or downskin regions can show significant material accumulation, dross formation or the remains of fused support structures. In addition, non-optimized surface parameters, such as a mismatch between core and surface (e.g., contour, upskin, downskin) beam scanning patterns could potentially produce very small voids or areas filled with un-melted powder or un-reacted resin, resulting in subsurface porosity and/or lack of fusion. Some processes, such as DED processes using wire feedstock, display a surface typical of weld-clad surfaces often requiring 100% machining to achieve a finished component. Material selection also significantly impacts surface texture, especially in polymer parts. For example, ABS typically prints in a dull finish, while polylactic acid (PLA) is semi-transparent, often resulting in a glossy and smooth finish. Ultimately, final surface texture is a complex function of material and process parameters including: type of AM process, process parameters (such as beam power, build speed, hatch distance), material type, characteristics of feedstock (such as powder particle size distribution and morphology), layer thickness, and build orientation.

Both surface asperities and subsurface porosity significantly reduce fatigue and fracture properties. Metals, such as Ti-6Al-4V, manufactured using PBF have exhibited reduced fatigue life with increased surface roughness. This is a direct consequence of higher stress concentrations at surface features that can act as micro-notches. Surface defects (such as surface asperities, surface breaking porosity, or poorly fused particle boundaries) and complex internal passages can also entrap fluid or gas during service which can significantly contribute to corrosion. Similarly, these features can entrap solvents, abrasive slurry, abrasive pastes, or chemical etchants used for post processing, thereby complicating the surface finishing process. While these concerns are relevant to most AM materials and properties, low surface roughness can be especially important to ceramic parts as it minimizes the potential of surface crack initiation under mechanical load. Unfortunately, because of the high hardness of sintered

[17] Not to be confused with crystallographic texture

ceramics, direct machining or grinding of sintered ceramics is challenging and expensive and optimizing the surface finish of the as-built part may be necessary. One potential solution is to use fine ceramic particles, as particle size significantly affects the surface texture.

Standards for Surface Finish of AM Parts

The unique surfaces of AM parts create many challenges to the standardization of surface finishing techniques. Many conventional surface measurement techniques struggle to measure rapid changes in surface height and cannot be run on some AM parts without significantly reduced speed, resolution, or risk to the machine. More importantly, most techniques are only capable of measuring the highest point of the surface and are therefore incapable of measuring overhangs or some internal features. These are often the most critical aspect of surface texture for AM parts, however, as they contribute the most to part properties. But, even if one manages to measure these overhangs, current equations for calculating surface texture parameters do no not allow for such data. Current standards should be expanded to allow for these calculations but until then producers may need to remove overhangs through sufficient surface finishing for parts where that is critical. Standards for reliable NDT methods, such as CT scan with high resolution for evaluation of internal passages' surface roughness, are also needed.

Complex curved surfaces, re-entrant features, or lattice structures, easily designed and produced by AM processes, can challenge common finishing methods. The amount of material removed around these features will likely not be uniform but there are currently no standards to either ensure it is or to account for this difference in part design. For many applications, a significant amount of material removal is necessary. For instance, in PBF, the total thickness of material removal that includes both surface asperities and subsurface porosity can be estimated to exceed 250 microns or ~0.010 inch; however, it can be higher. Ensuring this does not deteriorate material integrity, such as through intergranular attack (IGA) / Intergranular Oxidation (IGO), can be challenging, especially for internal surface polishing of surface asperities and subsurface porosity which often require chemical polishing methods. Standards capable of striking this balance are necessary. Other important considerations include edge retention, surface roughness variation throughout the length of internal passages, extent of bell mouthing in internal passages, and achieving the required final surface roughness values. Methods to minimize or account for these concerns are needed.

Published Standards

Definitions and interpretations of surface finish specifications are included in the standards listed below.

Standard	Title
ASME B46.1-2019*	Surface Texture (Surface Roughness, Waviness, and Lay)
ASME Y14.36-2018	Surface Texture Symbols
ISO 21920-1:2021	Geometrical Product Specifications (GPS) - Surface Texture: Profile - Part 1: Indication Of Surface Texture

ISO 21920-2:2021	Geometrical Product Specifications (GPS) - Surface Texture: Profile - Part 2: Terms, Definitions And Surface Texture Parameters
ISO 25178-1:2016	Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 1: Indication of surface texture
ISO 25178-2:2021	Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 2: Terms, definitions and surface texture parameters
SAE AS291F-2014	Surface Texture, Roughness, Waviness and Lay (Stabilized: Sep 2014)

*Contains additional information beyond definitions, such as measurement methods, instrument classification, etc.

There are numerous methods available for measuring the texture of a surface, including non-contact and contact approaches. **Present standard test methods and guides for measuring surface finish** are listed in the table below. These are applicable to a variety of materials, though none are specific to those produced via AM.

Validation of surface finish may be particularly difficult on wire-like features. The list below will likely apply to planar or wide surfaces; thin wires do not lend themselves to stylus techniques, and other methods may be required.

Standard	Title
ASME B46.1-2019	Surface Texture (Surface Roughness, Waviness, and Lay)
ASTM D4417-21	Standard Test Methods for Field Measurement of Surface Profile of Blast Cleaned Steel
ASTM D7127-17	Standard Test Method for Measurement of Surface Roughness of Abrasive Blast Cleaned Metal Surfaces Using a Portable Stylus Instrument
ISO 8503-2:2012	Preparation of steel substrates before application of paints and related products - Surface roughness characteristics of blast-cleaned steel substrates - Part 2: Method for the grading of surface profile of abrasive blast-cleaned steel - Comparator procedure
ISO 21920-3:2021	Geometrical Product Specifications (GPS) - Surface Texture: Profile - Part 3: Specification Operators
ISO 25178-3:2012	Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 3: Specification operators
ISO 25718-6:2010	Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 6: Classification of methods for measuring surface texture
MPIF Standard Test Method 58	Method for Determination of Surface Finish of Powder Metallurgy (PM) Products
SAE AMS 03-2C-2020	Cleaning and Preparation of Metal Surfaces
SAE J911	Surface Texture, Roughness (Ra), Peak Count (Pc), and Mean Profile Spacing, (Rsm) Measurement of Metallic Coated and Uncoated Steel Sheet/Strip to be Formed and/or to be Painted

- Additionally, ISO 25178-601, -602, -603, -604, -605, -606 and -607 define nominal characteristics of various types of instruments for surface texture measurement. ISO 16610-1, -20, -21, -30, -31, and -40 define various methods for filtering data.
- ASME B5 Technical Committee 65 on Micromachining also is working on post-processing.
- To physically achieve a specific surface texture, there are numerous methods available. These include mechanically abrasive techniques, electro-chemical polishing, micro-machining, chemical and thermal techniques.
- Mechanical techniques such as shot peening or media blasting (e.g., ASTM B851-04(2020) and F1330-91(2018), respectively and SAE AMS2430U:2018, *Shot Peening, Automatic*) can likely be applied easily to AM materials, but may require investigation into their effects on fatigue life when the work hardening effects become significant.
- Non-abrasive methods, such as electropolishing, chemical etching, or chemical-mechanical polishing may also be applicable to AM materials, as these are more dependent on material chemistry. The specifications available for these methods are extensive, and the individual standards will not be listed here; see publications from ASTM Committee B08 and ISO/TC 107, both on metallic and inorganic coatings, for more information.
- Solvent vapor smoothing may be applied to some polymeric AM materials. The process is highly dependent on the solvent and material chemistry. Vapor smoothing can address many geometries that abrasive methods cannot, however it can cause warping in thin areas of the piece.
- Organic coatings, (primers, paints, dyes, etc.) can be employed to improve the aesthetics, or provide enhanced textures such as rubberized painted. There are currently no standards associated with these finishing properties.
- Requirements for surface finish in ASTM standard specifications (e.g., ASTM F2924-14(2021), F3001-14(2021), F3055-14a(2021), and F3056-14e1(2021)) leave surface finish to agreement between the component supplier and purchaser and lack specific recommendations.

In-Development Standards

- AMPP TR21522, Corrosion Testing for Additive Manufacturing
- ASTM WK66682, Evaluating Post-processing and Characterization Techniques for AM Part Surfaces (initiated 01-22-2019)

Gap P4: Surface Texture (Surface Finish). Unique features, such as helixes, spirals, lattice structures, and internal surfaces and cavities, can be manufactured using AM versus subtractive machining. However, the applicability of current measurement methods to the surface of these features is not clear or captured in standards. For example, features such as helixes or lattices may produce wire-like structures that are not as easily measured using stylus instruments as flat surfaces.

Also, the suitability of current specification methods must be investigated for AM.

- ASME Y14.36-2018, *Surface Texture Symbols* may be sufficient, but further investigation is required to determine if AM-specific symbols are necessary (e.g., to control stair-stepping or allowable surface porosity).
- Furthermore, although there are methods available for finishing AM materials, many lack standard practices. Some methods require material removal, such as chemical polishing or abrasive techniques, and it is not known at this time how to accommodate this in AM product specifications in a standard form. Other methods require the addition of material, such as electroplating and coatings but it is also unknown how to accommodate these into AM standards.
- Lastly, as the effects of surface finish on performance become more apparent, material specification recommendations must go beyond "supplier and purchaser agreement," specifically for as-built, non-machined surfaces.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Project 1802 (WK66682) addresses AMSC gap P4.

- Standards for reliable NDT, such as XCT, for evaluation of internal passages
- Guidance for validation of surface finish on complex features (such as wires or non-planar surfaces). This is a big gap. How is the surface finish or residual stress determined on a surface that is not accessible?
- Investigation of mechanical techniques such as shot peening or media blasting and their effect on fatigue life for AM materials. There is some work already performed in this area. As expected, compressive stresses are beneficial with respect to fatigue life/limits and corrosion resistance. This is a subject that is being addressed in the AMPP TR21522 report with respect to corrosion fatigue.

Recommendation: Verify if there are certain measurement methods more appropriate to AM-unique features than a stylus approach such as optical 3D scanning. If so, they should be reviewed for their use on AM materials and appropriate standards written.

- The applicability of existing surface texture symbols to AM materials should be investigated.
- Available finishing methods should be reviewed for their effects on final material properties, and improved with standardized practices or guidelines where none exist.
- An AM standard is needed to improve the surface roughness of very complex internal passages like heat exchanger cores but also for uniform material removal of the internal passages to remove partially melted particles and surface asperities.

Priority: ☐High; ☒Medium; ☐Low

Organization: ISO/ASTM; ASME (B46 project team 53 on surface finish), IEEE-ISTO PWG, NIST

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☒Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green for R&D (metals); ☐Yellow; ☐Red; ☒Not Started; ☒Unknown for Standards (metals and polymers); ☐Withdrawn; ☐Closed; ☐New.

V3 Update: The ASME B46 committee, through their project team on Surface Finish for AM (PT53), continues to assess the latest research, knowledge gaps, and industry needs as they evolve with the rapidly growing AM technologies. The latest edition of the ASME B46.1 standard, which was approved by ANSI in 2019, contains subsection B-5 "Surface Texture of Parts Fabricated by Additive Manufacturing" as part of Nonmandatory Appendix B focusing on control and production of surface texture. Current priorities for PT53 are clarifying terminology in the B46.1 standard to create a better measurement and data handling procedures when working with AM surfaces, educating the research community on the methods described, and increasing the range of measurement instruments described (e.g., x-ray computed tomography (XCT)).

2.2.3.5 Machining (metals, polymers)

The specifications and standards for machining of AM parts are comparable to those for machining other semi-finished parts such as castings. This being the case, existing standards are adequate for machining AM parts. As new "designed for AM" parts become a reality, standards may require modification or new ones may have to be written. No gaps have been identified at this time.

2.2.3.6 Post-curing Methods (polymers)

Some AM processes produce cured polymers that require a secondary post-cure operation to further advance crosslinking and reduce outgassing (thermal vacuum stability) and offgassing (toxicity). The increased crosslinking from post-curing can result in improved properties of polymer parts. These include increased stiffness, better chemical resistance, higher temperature stability, reduced toxicity (due to reduction of unreacted constituents), or increased strength. The reduced outgassing of the polymer parts influences their dielectric properties (e.g., relative permittivity and loss factor) by directly influencing plastic density, ion viscosity, or increasing dipole relaxation.

Unlike the many traditional polymer processing methods AM cures the deposited plastics selectively layer by layer using various methods such as heated jets, binders, focused ultraviolet radiation, or laser heating. In these processes the polymerization reaction can be incomplete affecting the final part performance (i.e., degradation or warpage), especially if these materials are exposed to sunlight or other radiation sources during use or storage.

Before post-curing, polymer parts are often rinsed to remove unreached resin from the surface. Typically, this is done to improve the surface finish and remove “sticky” resin, making the parts safer to handle. The effect of the rinse, due to the absorption of solvent on mechanical properties and dimensional accuracy, is unknown, and insufficient post-rinse drying is known to affect dimensional accuracy.

In addition, an evaluation of the toxicity resulting from uncured reagents in liquid resins used during processes such as Vat Photopolymerization (e.g., SLA) would also be warranted to ensure product and environmental safety during and after production.

Ultimately, these unique risks warrant special post-cure considerations for polymers produced using AM.

The Methods

Post-curing methods ultimately depend on the underlying chemical processes (photo polymerization, thermosetting) used to initiate polymerization. Manufacturers commonly provide recommendations for post-cure conditions, which are based on the cure kinetics of the polymer and desired end properties.

While it is desirable to measure the total degree of cure and hence the cross-link density of the finished part, almost all methods (physical, chemical, mechanical and dielectric) depend on a destructive sampling scheme. These methods include glass transition temperature (Tg), differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), thermomechanical analysis (TMA), dynamic mechanical analysis (DMA), and dielectric response. Many of the standards applicable to the traditional polymer industry are also applicable to AM. These are listed in the following section.

For a non-destructive testing of the cured state of the manufactured part, optical density measurements or surface fourier transform infrared (FTIR), as used in certain cases of cross-linked polymers, may be applied. Optical measurements would also help to characterize voids and void density and entrapments. A full implementation of this technique, however, would depend on the overall thickness/diameter of the parts and requires further R&D.

Published Standards and Guidance Documents

Methods for measuring the above properties are listed below. Often, these methods require a reference standard for comparison to gauge cure completion. Also included are methods aimed at the storage of plastics that undergo photopolymerization, which may impact the handling of AM materials.

Committee	Standard	Title
ASTM D01	ASTM MNL45-EB	Radiation Curing of Coatings (Koleske JV)
ASTM D01.55	ASTM D3732-82(2017)	Standard Practice for Reporting Cure Times of Ultraviolet-Cured Coatings
ASTM D01.55	ASTM D5403-93(2021)	Standard Test Methods for Volatile Content of Radiation Curable Materials
ASTM D09.12	ASTM D150-22	Standard Test Methods for AC Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulation
ASTM D09.12	ASTM D257-14(2021)e1	Standard Test Methods for DC Resistance or Conductance of Insulating Materials
ASTM D20.10	ASTM D4473-08(2021)	Standard Test Method for Plastics: Dynamic Mechanical Properties: Cure Behavior
ASTM D20.10	ASTM D638-22	Standard Test Method for Tensile Properties of Plastics
ASTM D20.30	ASTM D3795-20	Standard Test Method for Thermal Flow, Cure, and Behavior Properties of Pourable Thermosetting Materials by Torque Rheometer
ASTM D20.70	ASTM D4526-20	Standard Practice for Determination of Volatiles in Polymers by Static Headspace Gas Chromatography
ASTM D30.04	ASTM D7028-07(2015)	Standard Test Method for Glass Transition Temperature (DMA Tg) of Polymer Matrix Composites by Dynamic Mechanical Analysis (DMA)
ASTM E21.05	ASTM E595-15(2021)	Standard Test Method for Total Mass Loss and Collected Volatile Condensable Materials from Outgassing in a Vacuum Environment
ASTM E21.05	ASTM E1559-09(2022)	Standard Test Method for Contamination Outgassing Characteristics of Spacecraft Materials
ASTM E37.01	ASTM E2160-04(2018)	Standard Test Method for Heat of Reaction of Thermally Reactive Materials by Differential Scanning Calorimetry
ASTM E37.01	ASTM E2550-21	Standard Test Method for Thermal Stability by Thermogravimetry
ASTM E37.01	ASTM E2602-22	Standard Test Methods for the Assignment of the Glass Transition Temperature by Modulated Temperature Differential Scanning Calorimetry
ASTM E37.10	ASTM E1356-08(2014)	Standard Test Method for Assignment of the Glass Transition Temperatures by Differential Scanning Calorimetry

Committee	Standard	Title
ASTM E37.10	ASTM E1545-22	Standard Test Method for Assignment of the Glass Transition Temperature by Thermomechanical Analysis
ASTM E37.10	ASTM E1640-18	Standard Test Method for Assignment of the Glass Transition Temperature By Dynamic Mechanical Analysis
ASTM E37.10	ASTM E1824-19	Standard Test Method for Assignment of a Glass Transition Temperature Using Thermomechanical Analysis: Tension Method
ASTM F04.11	ASTM F2042-18	Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II – Crosslinking and Fabrication
ISO/TC 51/SC 12	ISO 14322:2018	Plastics - Epoxy Resins - Determination Of Degree Of Crosslinking Of Crosslinked Epoxy Resins By Differential Scanning Calorimetry (DSC)
ISO/TC 138/SC 5	ISO 10147:2011	Pipes And Fittings Made Of Crosslinked Polyethylene (Pe-X) - Estimation Of The Degree Of Crosslinking By Determination Of The Gel Content

Published Standards that are specific to additive manufacturing include:

- ASTM F3091/ F3091M-14(2021), Standard Specification for Powder Bed Fusion of Plastic Materials
- ISO/ASTM 52903-1-20 Additive manufacturing — Material extrusion-based additive manufacturing of plastic materials — Part 1: Feedstock materials
- ISO/ASTM 52903-2-20 Additive manufacturing — Material extrusion-based additive manufacturing of plastic materials — Part 2: Process equipment

No in-development standards have been identified.

Gap P5: **Use of Post-cure to Reduce Toxic Gases from Uncured Polymer Feedstock.** An evaluation of the toxic gases resulting from uncured reagents in liquid resins used during processes such as Vat Photopolymerization (e.g., SLA) would be warranted to ensure product and environmental safety during and after production.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Augment existing standards with AM-specific recommendations for processes that utilize liquid resins. Evolved gas analysis, an analytical method by which the amount and characteristics of the volatile products released by an AM-built part under controlled temperature variation, is recommended for finished product safety and toxicity. To analyze evolved gas quantitatively, parameters such as sample chamber volume, thermal/vacuum conditions for releasing/analyzing the volatiles and the techniques for the analysis need to be specified.

Priority: ☐High; ☐Medium; ☒Low

Organization: ASTM D20, ISO/TC 261/ASTM F42

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☒Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Standards that have been published or reapproved since the release of version 2 are noted in the text.

Gap P6: Guidelines for Post-curing AM Plastics to Address Outgassing and Offgassing. Guidelines for evaluating the degree of polymerization and outgassing in AM parts, its effect on part properties, and the effects of post-polymerization treatments on them, have not been established specifically for AM materials. The voids and entrapments that can form in these technologies likely warrant greater testing or modified procedures compared to traditional methods.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Standard procedures for measuring the degree of polymerization and outgassing (thermal vacuum stability) and performance data for some materials may be archived in NASA's Materials and Processes Technical Information System (MAPTIS). In space systems, materials typically undergo outgassing testing for use in external environments and offgassing testing for use in crewed environments.

Recommendation: Extend existing methods with AM-specific recommendations.

Priority: ☐High; ☐Medium; ☒Low

Organization: ASTM E21.05, ASTM D20, ISO/TC 138, ISO/TC 261/ASTM F42

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided

2.2.3.7 Environmental, Health, and Safety (EHS) Hazards of Post-Processing

It is unknown whether there are any environmental, health, or safety hazards that are unique to additive manufacturing post-processing tasks.

Published Standards

While there are some existing general standards for health and safety (e.g., machine guarding), it is unknown if these are sufficient to cover environmental, health, and safety issues related to any unique post-processing tasks.

In-Development Standards

- ISO/ASTM FDIS 52931 Additive manufacturing of metals — Environment, health and safety — General principles for use of metallic materials. This standard that deals with metal powder addresses limited aspects of post-processing tasks for PBF processes.

New Gap P8: EHS Hazards Related to Post-Processing Tasks. In general, there are some existing general standards for health and safety (e.g., machine guarding), but it is unknown if these are sufficient to cover environmental, health, and safety issues related to any unique post-processing tasks encountered in additive manufacturing.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Detailed hazard assessments are needed for all post-processing tasks to determine whether there are environmental, health, and safety issues for post-processing tasks that are unique to additive manufacturing.

Recommendation: Conduct post-processing task hazard analyses and determine the need to develop standards for any hazards that are unique to additive manufacturing.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): Gov't agencies: NIOSH, EPA (for R&D). ASTM F42.06, ISO TC 261 (for standards).

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☒New

2.2.4 Finished Material Properties

2.2.4.1 Introduction

Finished materials properties characterization for AM parts is necessary in order to meet the required performance. This final characterization stage is focused on the result of significant due diligence employed in every aspect of the AM process chain (i.e., precursor material, process control, post-processing). As such, establishing standards to quantify the final products' properties/performance is crucial for the wider implementation of AM technology. The expected deployment of AM to produce low volumes of complex products emphasizes the need for standards that are less dependent on large-scale testing, the assumptions of homogenous location-specific properties, or isotropic material behavior. Rather, embracing the inherent heterogeneities in AM and developing standards that can quantify various properties and such heterogeneities before and after post-processing is key and enables wider utilization of the unique characteristics of AM parts/components. Towards this goal, the discussion in this section identifies various areas that can be used to define the characteristics of finished AM parts/components and hence provide recommendations for future standards development through a gap analysis.

The following topics are addressed within this section: material properties, component testing; biocompatibility of medical AM parts; removal of AM feedstock from medical AM parts; chemistry; material allowables; microstructure; and AM defect structures.

2.2.4.1.1 Finished Material Properties Terminology

The terms Material Allowable and Design Value are used throughout this section of the roadmap. Below are some definitions of how these terms are defined for **in key aerospace industry documents**.

For metals, the following definitions have been approved by the MMPDS General Coordination Committee for inclusion in MMPDS Volume II, Appendix A, targeted for publication on/about 1 July 2024.

> ***Material Allowable*** *—A bulk material property derived from the statistical reduction of data from a stable process. The amount of data required to derive these values is governed by the statistical significance (or basis) and methods defined in Chapter 9. Application of material allowables may require additional considerations for use in design.*
>
> ***Design Value*** *—A material property that is established to represent the finished part property. These numbers are typically based on material allowables and adjusted, using building block tests as necessary to account for the range of part geometric features (e.g., holes, notches, surface finish) and in-service environmental conditions (e.g., temperature, moisture, and fluid.) Design values are used in analysis compute structural design margin (i.e., margin of safety.)*

Influence Factor *—Use-case specific factors that affect the mechanical performance of a material. Examples include, but are not limited to, build direction, load orientation, surface condition (as-built, machined, shot peened, surface finish, et.al.) temperature, humidity, coating (anodized, plated, et.al.), etc. Volume II will publish information and guidance on specific Influence Factors similar to the precedent of MMPDS Volume I. Some documents call this a Scale Factor.*

Similarly, the following definitions appear in the Aerospace Industries Association's Recommended Guidance for Certification of AM Components (February 2020) which deals with metal AM components fabricated using PBF and DED:[18]

Material Allowable: *Material values that are determined from test data of the bulk material on a statistical basis. Allowable development approaches are established via industry standards such as MMPDS or company specific methodology and are based on testing conducted using accepted industry or company standards.*

Design Value: *Material properties that are established from test data on a statistical basis and represent the finished part properties. These values are typically based on material allowables and adjusted, using building block tests as necessary, to account for the range of part specific features and actual conditions. Design values are used in analysis to compute structural design margin (e.g., margin of safety).*

For non-metallic and composite materials, CMH-17 does not have the same set of definitions as MMPDS but generally agrees on them. Currently, CMH-17 has adopted the following definitions (Volume 1, revision H, 2022):

Allowables *– Material values that are determined from test data at the laminate or lamina level on a probability basis (e.g., A or B basis values, with 99% probability and 95% confidence, or 90% probability and 95% confidence, respectively). The amount of data required to derive these values is governed by the statistical significance (or basis) needed.*

CMH17 Clarifying Note: The definition presumes a stable and repeatable fabrication process. Further, the percentage probability, for a given statistical distribution, defines the percentage of the population that will fall above the calculated allowable value. The confidence percentage is based on the number of observations (test data points) available to

[18] Aerospace Industries Association, Recommended Guidance for Certification of AM Component, AIA Additive Manufacturing Working Group, February 2020, Appendix A, page 36, Accessed 2/16/2023 https://www.aia-aerospace.org/wp-content/uploads/AIA-Additive-Manufacturing-Best-Practices-Report-Final-Feb2020.pdf

determine the distribution. In general, the more observations, the more confidence there is in the derived allowable, and therefore the higher the calculated allowable value.

Design Values – *Material, structural elements, and structural detail properties that have been determined from test data and chosen to assure a high degree of confidence in the integrity of the completed structure. These values are most often based on allowables adjusted to account for actual structural conditions and used in analysis to compute margins-of-safety.*

<u>CMH17 Clarifying Note</u>: This definition presumes that structural configurations, damage, and environmental criteria that are program-unique are also covered.

It is recognized that there are differences in how terms are used between industry sectors and some sectors (e.g., medical) may not use these same terms at all.

For purposes of this roadmap, a **Material Allowable** is *the result of analyzing data for bulk material based on test coupons* and a **Design Value** *is the number that is used to compute the final margin of safety and includes all the application specific Influence Factors.* Design Values are a function of Material Allowables and Influence Factors.

New Gap FMP6: Finished Material Properties Terminology. There is inconsistency in how terms (e.g., material allowable, design value, material strength properties) are defined and used to describe design decisions that will inform finished material properties for metallic and non-metallic additively manufactured parts across industry sectors.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Encourage greater consistency in terminology used to establish finished material properties for metallic and non-metallic additively manufactured parts in future revisions of industry standards and guidance materials. The MMPDS and CMH-17 handbooks are accepted industry resources for the aerospace sector.

Priority: ☐High; ☐Medium; ☒Low

Organization: SDOs

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☒Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified.

V3 Status of Progress: Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒ New

2.2.4.2 Material Properties

Introduction

Mechanical properties include: yield strength, ultimate tensile strength, reduction in area, elongation, Young's modulus, compression strength, shear strength, bearing strength, fracture toughness, fatigue strength, fatigue crack growth rate, creep strength, and many others. Depending on the geometry of the component, a difference in properties between the test piece and the component may exist. The load bearing capabilities of a part/component must meet certain mechanical properties limits for certain applications. Most commercial forms of wrought metal products and composites are manufactured to specifications that require lot-release minimum mechanical properties, while most plastics have typical mechanical properties reported by their manufacturers. Because properties of plastics are not guaranteed, typical design practice uses a larger safety factor for plastic parts than for metal. Therefore, for AM parts it would be ideal to have standards with guaranteed mechanical properties rather than with typical properties. However, determining guaranteed properties usually requires an assumption of uniform chemistry, uniformity of bulk material structure, uniformity of post-processing, and the variation in the microstructure. Defects (percentage, distribution, and morphology) in AM metal deposits defies these typical assumptions of uniformity in the bulk material. The material chemistry and AM processing conditions (including post-processing) drives the microstructure and defect levels, and the microstructure and defect levels drive the properties. The processing conditions of each individual build can be unique, based on variations associated with feedstock, AM system design, AM system software, AM system parameter settings, AM build layout (location and number of parts on the build platform), and the individual parts' build geometries. In many instances, adequate access to the details of these processing conditions is not available. A thorough, industry-wide understanding of the processing conditions and resulting materials is difficult to achieve but is needed. Because of this, performing enough testing of the finished materials – so that proper statistics can be applied to the test data to ensure a low probability of the actual material properties being less than those guaranteed in a specification – is extremely difficult, and in some cases may be unachievable. In some cases, the ability for a given AM material to achieve minimum mechanical properties may need to be demonstrated for each unique AM system/AM build geometry combination. More information can be obtained in the section on material allowables and design values below.

Mechanical properties such as fracture toughness, fatigue strength, and fatigue crack growth are typically not listed as guaranteed minimums in specifications, even those for metals. Instead, typical data are determined and it is the responsibility of the design engineer to add the appropriate safety factors to ensure that the part will have a low probability of failure in service. The more typical data that exists, the more accurate will be the determined probability of failure of the part, so that, in general, the more testing that is done, the better.

Thermal properties, including thermal expansion, thermal conductivity and specific heat capacity, of additively manufactured materials are often required for applications. Reliable thermal properties should be available to the end user to allow for an accurate assessment of the thermal conductivity and specific heat capacity of the material after manufacturing. Data are generally available on the powder thermal properties, but limited data are available on the anisotropic nature of thermal properties.

Corrosion properties are also a concern. Additional information appears under the Test Methods section below.

For the medical device sector, biocompatibility and toxicology are concerns. See section 2.2.4.2.

2.2.4.2.1 Specification Content Requirements

Public specifications often include numerical values for "minimum" properties; however, the method for determining these numbers is inconsistent across SDOs. Not all specifications include statistically-based minimums. Note: In aerospace, regulators do not generally accept specification minimum properties as meeting requirements for design.

Published Standards

SAE AMS recently revised SAE AMS AM Metals General Agreement Data Submission Guidelines (12/3/2022).[19] All SAE AMS AM Metal specifications include lot-release minimum mechanical properties based on data analyzed by Battelle Memorial Institute to be compatible with MMPDS, Volume II, Section 9.2.2. There is a separate SAE AMS Data Submission Guideline for Non-metal AM specifications. Note: CMH-17 and MMPDS are considered by the FAA, DoD, and NASA as the primary sources for both static allowables and methods for allowables generation for non-metals and metals, respectively, in aerospace.

In-Development Standards

ASTM WK78636 – Additive Manufacturing – General Principles – Standard Practice for Creating Data Sets Used in Metal Additive Manufacturing Standards in ASTM F42.07. The work item as presented in

[19] These Guidelines are available to AMS-AM committee members in conjunction with developing SAE standards.

the most recent ballot may produce lot-release minimum values that may be considered inadequate for aerospace users.

New Gap FMP7: Material Properties: Specification Content Requirements. Specifications for materials and processes intended for a particular audience need to include minimum material properties that meet that industry's basic requirements. They also need to consider other requirements such as macro/microstructure for metals, and porosity for polymers. In aerospace, the SAE AMS AM data submission requirements are aligned with the primary material allowable references (CMH-17 and MMPDS) to ensure that material submitted to those programs support aerospace regulations and requirements. At least within an industry, specification content requirements would simplify the material selection process knowing that the framework for specification development is consistent and the output from different specifications are comparable.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Review existing data generation and analysis methods and document appropriate standard practices at an industry level for minimum material properties, and for microstructure. This could include a literature survey to review the approaches across different industries. R&D is needed to establish what test should be done as a lot release in AM. (Machined ASTM E8 bars are not sensitive to many LPBF specific processes failures.)

Recommendation: Coordinate activity between SDOs, including the AM data generation and/or data management consortia groups SAE-ITC Additive Manufacturing Data Consortium (AMDC) and ASTM Consortium for Materials Data Standardization (CMDS), so that specifications for specific industries produce comparable content. Each industry may need to have its own standard. The aerospace industry generally complies with CMH-17 and MMPDS.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM International, SAE AMS, CMH-17, MMPDS for aerospace, defense, and space.

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☒Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Each user must verify that a public specification meets the requirements of cognizant regulators. This can be cost prohibitive, restricting the opportunities for use of AM.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.2.4.2.2 Metals

Defining a set of minimum properties for AM products is difficult because properties are dependent on the process, the process parameters, the direction of the test sample relative to the build direction, the location on the build plate, the type of machine used for the build, the geometry, the post-AM thermal processes, and the operator, among other factors. Since the relationship between these variables and properties is not currently well known, and since the method of qualifying minimum properties may be application dependent, developing a well-supported set of minimum properties is a challenge. Standards that contain minimum properties for AM parts are primarily for specific metals produced by laser powder bed fusion and directed energy deposition. These do so by leaving the method of qualification up to an agreement between the purchaser and the supplier. Many other factors, not all of which are currently known or understood, can interact in a way that creates highly complex processing conditions. To get test data that are valid for a given process, all process parameters must be fixed under controlled conditions, including post-build treatments. The resultant data are then only useful for that specific process. Standardizing an optimized process therefore significantly lowers the amount of testing required to determine guaranteed mechanical properties, but this standardization is likely to be machine-specific, at least in the near future. Any major change to the fixed process requires the substantiation that the critical mechanical properties do not detrimentally change. See the section below on material allowables and design values.

Published Standards (Metals)

There are several specifications for metal AM materials that cover the manufacturing process and state minimum properties of specific materials produced primarily by powder bed fusion, with standards for other processes beginning to emerge. In many cases, these properties are currently derived from metal casting properties.

ASTM F42

- ASTM F2924-14(2021) - Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
- ASTM F3001-14(2021) - Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion

- ASTM F3055-14a(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion
- ASTM F3056-14(2021) Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
- ASTM F3184-16, Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion
- ASTM F3302-18 Standard for Additive Manufacturing – Finished Part Properties – Standard Specification for Titanium Alloys via Powder Bed Fusion
- ASTM F3318-18 Standard for Additive Manufacturing – Finished Part Properties – Specification for AlSi10Mg with Powder Bed Fusion – Laser Beam

ASTM F42/ISO TC 261

- ISO/ASTM 52909:2022, Additive manufacturing of metals — Finished part properties — Orientation and location dependence of mechanical properties for metal powder bed fusion

SAE AMS-AM

- SAE AMS4999A, Titanium Alloy Direct Deposited Products 6Al - 4V Annealed (2016-09-26)
- SAE AMS7000A, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion- and Heat-Resistant, 62Ni - 21.5Cr - 9.0Mo - 3.65Nb Stress Relieved, Hot Isostatic Pressed and Solution Annealed (2022-05-16)
- SAE AMS7004, Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate, Ti-6Al-4V, Stress Relieved (2019-01-31)
- SAE AMS7011, Electron Beam-Powder Bed Fusion (EB-PBF) Produced Preforms and Parts, Titanium Alloy, 6Al - 4V, Hot Isostatically Pressed (2022-11-22)

In-Development Standards (Metals)

There are several new standards under development that discuss minimum properties for metal AM parts of specific materials produced by powder bed fusion or other processes as listed below, although they may not state exactly how to determine these properties.

ASTM F42

- ASTM WK65929, Specification for Additive Manufacturing-Finished Part Properties and Post Processing - Additively Manufactured Spaceflight Hardware by Laser Beam Powder Bed Fusion In Metals
- ASTM WK65937, New Specification for Additive Manufacturing -- Space Application -- Flight Hardware made by Laser Beam Powder Bed Fusion Process
- ASTM WK66637, Specification for Additive Manufacturing -- Finished Part Properties -- Specification for 4340 Steel via Laser Beam Powder Bed Fusion for Transportation and Heavy Equipment Industries

- ASTM WK77186, New Specification for Additive Manufacturing -- Finished Part Properties -- Specification for Niobium-Hafnium Alloy UNS R04295 via Laser Beam Powder Bed Fusion for Spaceflight Applications
- ASTM WK78636, New Practice for Additive Manufacturing -- General Principles -- Standard Practice for Creating Data Sets Used in Metal Additive Manufacturing Standards
- ASTM WK82659, New Specification for Additive manufacturing -- Powder bed fusion -- Standard specification for maraging steel (UNS K93120)

ASTM F42/ISO TC261

- ISO/ASTM DIS 52924, Additive manufacturing of polymers — Feedstock materials — Qualification of materials for laser-based powder bed fusion of part

SAE AMS-AM

- SAE AMS7009, Additive Manufacturing of Titanium 6Al4V with Laser-Wire Deposition - Annealed and Aged (2018-01-06)
- SAE AMS7016, Laser-Powder Bed Fusion (L-PBF) Produced Parts, 17-4PH H1025 Alloy (2018-10-24)
- SAE AMS7024, Inconel 718 L-PBF Material specification (2019-06-19)
- SAE AMS7028, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Titanium Alloy, Ti-6Al-4V Stress Relieved, and Hot Isostatic Pressed (2020-01-31)
- SAE AMS7030, Laser- Powder Bed Fusion (L-PBF) Produced Parts of AlSi10Mg (2020-02-19)
- SAE AMS7036, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Steel, Corrosion and Heat Resistant 17Cr – 13Ni – 2.5Mo (316L), Hot Isostatic Pressed (2021-03-09)
- SAE AMS7038, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion and Heat-Resistant -52.5Ni - 19Cr - 3.0Mo - 5.1Cb (Nb) - 0.90Ti - 0.50Al - 18Fe Stress Relieved, Hot Isostatic Pressed (2021-03-02)
- SAE AMS7039, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Steel, Corrosion and Heat Resistant 17Cr – 13Ni – 2.5Mo (316L), Stress Relief and Anneal (2021-04-19)
- SAE AMS7046, Laser Powder Bed Fusion Produced Parts, Aluminum Alloy, 5.3Zn – 3.3Mg - 1.7Zr – 1.6Cu (Composition Similar to 7A77.60), SR + HIP + T7 (2022-01-14)
- SAE AMS7047, Low Alloy, Medium Carbon Steel Powder for Binder Jet Additive Manufacturing, 1.0Cr – 0.20Mo – 0.30C (Composition Similar to UNS G41300) (2022-01-14)
- SAE AMS7048, Binder Jet Additive Manufacturing (BJAM) Produced Parts, Steel, 1.0Cr – 0.20Mo – 0.30C, As-Sintered (Composition Similar to UNS G41300) (2022-01-14)
- SAE AMS7049, Binder Jet Additive Manufacturing (BJAM) Produced Parts, Steel, 1.0Cr – 0.20Mo – 0.30C, Austenitized, Quenched and Tempered (Composition Similar to UNS G41300) (2022-01-14)
- SAE AMS7050, Binder Jet Additive Manufacturing (BJAM) Produced Parts, Steel, 1.0Cr – 0.20Mo – 0.30C, Hot Isostatic Pressed, Austenitized, Quenched and Tempered (Composition Similar to UNS G41300) (2022-01-14)

- SAE AMS7051, Binder Jet (BJAM) Printed Parts, Precipitation Hardenable Steel Alloy, Corrosion and Heat-Resistant, 16.0Cr - 4.0Ni - 4.0Cu - 0.30Nb Solution Annealed and H900 Aged (2022-06-20)
- SAE AMS7051/1, Binder Jet (BJAM) Printed Parts, Precipitation Hardenable Steel Alloy, 16.0Cr - 4.0Ni - 4.0Cu - 0.30Nb Solution Annealed and H900 Aged, Desktop Metal – Production System P-1 (2022-06-20)

Gap FMP1: Material Properties (Metals). Standards that address thermal properties, minimum mechanical properties, and degradation properties, and that also contain qualification procedures, are needed for metallic AM materials. Many metals used in aerospace applications will have standardized tables in MMPDS, Volume II when data is submitted to the program.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Developing these standards will require generating data that currently may not exist or may not be in the public arena. The ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE has several projects aimed at addressing this gap. A material specification, ASTM WK82659 for maraging steel, is under development in F42.05 and through an AM CoE project 2006.

Recommendation: Develop standards that identify the means to establish material properties and qualification procedures for metals made using a given AM process, set of parameters, and build design. Qualification requirements to establish minimum mechanical properties for AM parts need to be developed.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F42/ISO TC 261, SAE AMS-AM, MMPDS, NIST, ASME, ASTM AM CoE

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; New

V3 Update: ASME research project 0183 has been completed, and shows statistical correlations of some critical properties and property interactions with respect to the essential variables of ASME code case 3020. (ASME code case 3020 provides assumptions of which base metal can be compared to get other properties that weren't tested.) Round robin testing by multiple parties is ongoing. Results from ORNL have been received and the data needs to be incorporated into a report.

The National Center for Advanced Materials Performance (NCAMP) and Joint Metals Additive Database Definition (JMADD) qualification program funded by America Makes and FAA, led by Wichita State University National Institute for Aviation Research (NIAR) is working to develop material property data for Ti-6-4 on laser powder bed fusion process. The program started in early 2021.

2.2.4.2.3 Non-Metals

Published Standards (Non-Metals)

SAE AMS-AM

- SAE AMS7100/1, Fused Filament Fabrication Process - Stratasys Fortus 900mc Plus with Type 1, Class 1, Form 1, Grade 0 Natural Color Material for (2022-07-06)
- SAE AMS7101/1, Fused Filament Fabrication, Type 1, Class 1, Form 1, Grade 0, Natural Color Material for (2022-07-06)
- SAE AMS7101A, Fused Filament Fabrication, Material for (2022-07-08)

In-Development Standards (Non-Metals)

ASME

- ASME is working to form a Working Group on this topic for polymers.

SAE AMS-AM

- SAE AMS7100/1A, Fused Filament Fabrication Process - Stratasys Fortus 900mc Plus, with Type 1, Class 1, Form 1, Grade 0, Natural Color Material for (2022-10-04)
- SAE AMS7100/3, Fused Filament Fabrication Process – Stratasys F900 with Type 3, Class 1, Form 3, Grade 3CNT, Black Color Material for (2022-07-11)
- SAE AMS7100/4, Fused Filament Fabrication Process – Stratasys F900 with Type 3, Class 1, Form 3, Grade 0, Natural Color Material for (2022-07-11)
- SAE AMS7101/2, 1Fused Filament Fabrication Process- Markforged X7 with Onyx FR-A a Type 1 Form 1 PACF15FR15 filament (2021-10-21)

- SAE AMS7101/3, Fused Filament Fabrication, Type 3, Class 1, Form 3, Grade 3CNT, Black Color Material for (2022-07-11)
- SAE AMS7101/4, Fused Filament Fabrication, Type 3, Class 1, Form 3, Grade 0, Natural Color Material for (2022-07-11)
- SAE AMS7101B, Fused Filament Fabrication, Material for (2022-07-11)
- SAE AMS7103, Material for High Performance Laser Sintering (2019-01-15)
- SAE AMS7104, Continuous Fiber Reinforced Fused Filament Fabrication
- SAE AMS7104/1, Continuous Fiber Reinforced Fused Filament Fabrication Markforged
- SAE AMS7105, Continuous Carbon Fiber Reinforced Fused Filament Fabrication - Markforged
- SAE AMS7105/1,Continuous Carbon Fiber Reinforced Fused Filament Fabrication, material Carbon Fiber FR-A

New Gap FMP8: Material Properties (Non-Metals). Standards that address thermal properties, minimum mechanical properties, and degradation properties, and that also contain qualification procedures, are needed for non-metallic AM materials. Non-metals are addressed in CMH-17 Volume VII.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Developing these standards will require generating data that currently may not exist or may not be in the public arena.

Recommendation: Develop standards that identify the means to establish material properties and qualification procedures for non-metals made using a given AM process, set of parameters, and build design. Qualification requirements to establish minimum mechanical properties for AM parts need to be developed.

Priority: ☒High; ☐Medium; ☐Low (Polymers) / ☐High; ☐Medium; ☒Low (Ceramics)

Organization: ASTM F42/ISO TC 261, SAE AMS-AM, CMH-17, NIST, ASME

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☒Ceramic; ☒Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒ New

V3 Update: The NCAMP Polymer AM qualification program includes HexPEKK and Markforged continuous fiber composite material. Both programs started in 2020. NCAMP released public specifications and a material property database of ULTEM 9085/Fortus 900MC in 2018.

The CMH-17 Non-Metallic Additive Manufacturing Coordination Group was formed in October 2018. A CMH-17 committee is drafting tables of material properties to be included in the first release of the non-metallic handbook. Properties are based on NCAMP qualification of ULTEM 9085**.**

2.2.4.2.4 Test Methods (Metals and Non-Metals)

There is currently a need for standards on mechanical property test methods that are specific for AM parts.

Published Standards

There is currently a guide for determining the types of existing mechanical tests that should be used for evaluating mechanical properties of AM materials (ASTM F3122-14(2022), and a standard on how to report data (ASTM F2971-13(2021)). MMPDS (metals) and CMH17 (non-metals) include a listing of thermal and mechanical tests.

In-Development Standards

AMPP

AMPP TR21522, Corrosion Testing for Additive Manufacturing, was formed in July 2021 with the goal of assessing the state of the art with respect to corrosion testing of additive manufactured materials and preparing a summary report with recommendations. A group of about 35 subject matter experts were assembled to accomplish the goals. An assessment of the open literature resulted in the selection of about 340 relevant references that were evaluated with respect to corrosion mechanism, material and additive manufacturing process.

The corrosion mechanisms investigated included general and localized corrosion, environmental cracking (such as SCC, SSC and HISC) and high temperature oxidation. The scope is limited to metallic materials of construction.

As of November 2022, the assessment of the open literature is complete and the compilation of the gems gleaned from the literature is largely complete. TR21522 has started drafting the report with

Scope and Introduction sections completed. The timeline for completion of the report and submittal for peer review has been updated to June 2023. See new gap QC28.

ASTM F42

- ASTM WK66029, Guide for Mechanical Testing of Polymer Additively Manufactured Materials
- ASTM WK70164, Practice for Additive Manufacturing -- Finished Part Properties -- Standard Practice for Assigning Part Classifications for Metallic Materials
- ASTM WK71391, Guide for Additive Manufacturing -- Static Properties for Polymer AM (Continuation)
- ASTM WK71395, New Practice for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process
- ASTM WK73340, Test Method for Additive Manufacturing – Dynamic Properties of Polymer Additive Manufacturing
- ASTM WK75901 Test Method for Additive Manufacturing -- Test Artifacts -- Miniature Tension Testing of Metallic Materials
- ASTM WK78224, Test Method for Additive Manufacturing -- Vat Photopolymerization -- Next Generation Tensile Test Method

MPIF

The Metal Powder Industries Federation (MPIF) is working on material standards MPIF Std 35 for Metal AM Components. MPIF has completed tensile testing for SS-316L and 17-4PH annealed condition from binder jet and LPBF processes. MPIF has out for testing 17-4PH H900 for both processes. Upon completion of the 17-4PH H900 testing a standard will be issued (Spring 2023). Samples are tested per MPIF Test Std 74 or 75 and samples are from 3 to 6 commercial process vendors. Data will include tension min and typ., properties, typ. hardness, typ. density and chemistry limits. MPIF Test Stds 74 and 75 describe the exact geometry and method of producing the tension bars.

New Gap FMP9: Material Properties: Test Methods (Metals and Non-Metals). Existing mechanical test methods for traditionally-manufactured parts are used as needed for AM, and are acceptable for many purposes. Unique testing standards that take into consideration characteristics that are unique to AM parts such as those that use multiple materials (i.e., heterogenous/nonhomogeneous), gradients in composition and/or microstructure, and anisotropy are needed.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Developing these standards will require generating data that currently may not exist or may not be in the public arena.

Recommendation: Develop standards on mechanical property test methods that are specific for AM parts

Priority: ☒High; ☐Medium; ☐Low (Metals, Polymers) / ☐High; ☐Medium; ☒Low (Ceramics)

Organization: ASTM F42/ISO TC 261, SAE AMS-AM, CMH-17, MMPDS, NIST, ASME, AMPP, MPIF

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒ New

2.2.4.3 Component Testing

Introduction

Component testing using currently available test methods needs to consider the problem with building standard coupon geometries that are then machined to dimensions. Any post-processing or machining of the key areas could influence the results of mechanical testing (for example, machining (?) all the material processed with contour parameters) and as a result may not be representative of a part that is put into service in the as-built condition or only lightly finished.

Additive Part Qualification: Aerospace Perspective

Once form and fit have been established, the end user of an AM component must validate the systematic functionality of the AM component. In addition to basic, foundational knowledge about fundamental material properties and production processing effects, reasonable component level destructive tests and nondestructive testing methods performed by ISO/IEC 17025 accredited testing laboratories should be used to qualify the AM component function.

Examples of component-level destructive tests could include: part cut-ups to validate dimensional and critical material morphology, static or fatigue/damage tolerance strength evaluations from a configured part, lug or crippling strength/stability evaluations, etc. Non-destructive examples could include X-ray/computed tomography, pressure, eddy current, etc.

Note that these non-destructive functionality tests may evolve into a statistically-based plan for ongoing validation of AM part quality in production.

Additive Part Qualification: Medical Device Perspective

Mechanical properties testing for components and coupons is integral to the qualification and approval process. For any given part, different aspects may be critical to its function. In the medical field, AM devices can be used to match a patient's anatomy or create an implant that would otherwise be impossible to manufacture. Some applications require long fatigue life and strength as the primary mechanical properties (e.g., a hip implant). Others require flexibility, and the ability to degrade over time in a way that maintains geometric stability (e.g., a tracheal splint).

In medicine, the diversity of applications and complexity of geometric shapes means there are many different aspects that may be tested for any given part. It is often difficult to determine what can be tested with coupons and what must be tested on the part. In addition, the quality of the part can be strongly influenced by the other parts in the build volume or positioning of parts in the space, meaning that careful coupon planning is imperative. Clear guidelines are not yet available for these aspects of coupon use in AM for the medical field; however, some general guidelines do exist.

Published Standards

Guidelines for validation methods for manufacturing methods are available from the FDA through the Quality System regulations and current Good Manufacturing Practices documentation. Other industries have similar practices. These sets of documents provide a framework to help manufacturers establish internal methods for verifying a production process, determining the appropriate quality controls, and validating it to reduce testing burden over time.

In terms of published standards, the requirements for testing and validation are described in FDA's Design Control Guidance for Medical Device Manufacturers (relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001) and also in ISO 13485. Other published standards include ASTM F3127-22, Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices. General testing standards can also be applied.

2.2.4.4 Biocompatibility of Medical AM Parts

It is generally thought that biocompatibility standards such as ANSI/AAMI/ISO 10993-1:2018 have already been developed to address a broad range of materials and therefore should still be sufficient to assess the biocompatibility of AM materials. Biocompatibility is done on a final, finished, sterilized device. The final finished device is extracted in polar, mid-polar and non-polar solvents and substances identified by analytical tests and the biocompatibility of these substances determined through testing in biocompatibility assays. Depending on the patient contact site and duration of exposure to a device, it might also be necessary to conduct animal testing for biocompatibility.

Published Standards and Guidance

- ANSI/AAMI/ISO 14971:2019, Medical devices – Application of risk management to medical devices
- ANSI/AAMI/ISO 10993-1:2018, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
  - Use of International Standard ISO 10933-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process," Guidance for Industry and Food and Drug Administration Staff (September 2020)
- ISO 10993-18:2020, Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
- ISO 18562-4:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate

No gaps have been identified with respect to biocompatibility.

2.2.4.5 Removal of AM Feedstock from Medical AM Parts

It can be very difficult to clean parts of remaining raw AM material. Cleaning protocols can vary significantly between AM technologies and between manufacturers because of the wide range of materials and applications combinations that are possible. Several nondestructive measurement techniques such as computed tomography (CT) or ultrasound scans are already being adopted by part producers. A potentially small number of measurement and evaluation techniques could likely assess a large proportion of AM parts.

Published Standards

- ASTM F3127-22, Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices
- ASTM F3208-20, Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
- ASTM F3275-22, Standard Guide for Using a Force Tester to Evaluate Performance of a Brush Part Designed to Clean the Internal Channel of a Medical Device
- ASTM F3335-20, Standard Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder Bed Fusion
- ISO 19227:2018, Implants for Surgery - Cleanliness of Orthopedic Implants- General Requirements
- ISO/TS 19930:2017, Guidance on Aspects of a Risk-Based Approach to Assuring Sterility of Terminally Sterilized, Single-Use Health Care Product That Is Unable to Withstand Processing to Achieve Maximally A Sterility Assurance Level Of 10-6

- [United States Pharmacopeia-National Formulary (USP-NF), General Chapter 788 Revision, *Particulate Matter in Injections*]

In-Development Standards

- [ASTM WK82776 - Additive Manufacturing for Medical - PBF - Assessment of Residual Powder]

Gap FMP3: Removal of AM Feedstock from Medical AM Parts. Like many medical devices, medical AM parts must be cleaned of manufacturing residues and contact materials prior to packaging or final use. The cleaning process should ensure that AM materials such as powder are removed before use. Residual AM feedstock left on the parts may include but is not limited to cooling fluids or AM materials (powder or uncured monomer), that may be stuck within small geometric features or lattice structures. There is a need to reproducibly measure and evaluate the residual AM feedstock of a part with relevant, risk-based acceptance criteria.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to establish standards which discern clean from uncleaned parts in terms of AM residual feedstock; specifically, to reliably distinguish unsintered, unmelted, and uncured material from the intended part.

Recommendation: Develop standard test methods, metrics, and acceptance criteria for measuring cleanliness of complex 3D geometries that are based on existing standards but focus on AM-specific considerations. ASTM F42 already has work in progress.

Priority: ☒High; ☐Medium; ☐Low

Organization: AAMI, ASTM F04, ASTM F42/ISO TC 261, ISO/TC 150, ISO/TC 194, ISO/TC 198

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: A number of ASTM F04.15 (material test methods) standards have been updated.

2.2.4.6 Chemistry

Introduction

Chemistry of materials (i.e., chemical composition) is the foundation that drives material performance such as mechanical properties and corrosion resistance. Ensuring the proper chemical composition of materials throughout the manufacturing process is essential in the certification of products used in industry. It is essential for product specifications to contain rigorous chemistry requirements as well as standard chemical analysis test methods to ensure that delivered product meets the intended design requirements. Most additive manufacturing processes rapidly melt and solidify materials, thus having the ability to lead to unusual behavior in some material systems compared to traditional manufacturing methods. Some unusual behavior has been noted in changes from pre-build chemistry to post-build chemistry. Therefore, it is essential for additive manufacturing standards to contain chemistry requirements and standard chemical analysis test methods for both feedstock (precursor) materials and as-built parts (finished materials).

Published Standards

There are several specifications for metal AM parts fabricated using powder bed fusion that have requirements for chemical composition of the as-built part. Generally, these specifications require both the feedstock (precursor) material and the as-built part to meet required chemical composition requirements defined in the specification.

There are currently well-established standards for chemical analysis test methods for metal materials (examples include ASTM E34, E353, etc.).

Existing Specifications Including Chemical Composition Requirements for AM Parts

Committee	Standard	Title
ASTM F42	F2924-14(2021)	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
	F3001-14(2021)	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
	F3055-14a(2021)	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion

	F3056-14e1(2021)	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
	F3184-16	Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion
	F3213-17	Standard for Additive Manufacturing – Finished Part Properties – Standard Specification for Cobalt-28 Chromium-6 Molybdenum via Powder Bed Fusion
	F3318-18	Standard for Additive Manufacturing – Finished Part Properties – Specification for AlSi10Mg with Powder Bed Fusion – Laser Beam
SAE AMS-AM	AMS7000A	Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion and Heat-Resistant, 62Ni – 21.5Cr – 9.0Mo – 3.65 Nb Stress Relieved, Hot Isostatic Pressed and Solution Annealed (2022-05-16)
	AMS7004	Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate, Ti-6Al-4V, Stress Relieved (2019-01-31)
	AMS7011	Electron Beam-Powder Bed Fusion (EB-PBF) Produced Preforms and Parts Titanium Alloy, 6Al - 4V Hot Isostatically Pressed (2022-11-22)

In-Development Standards

Specifications in Development Including Chemical Composition Requirements for AM Parts

Committee	Work Item Number	Title
SAE AMS-AM	AMS7009	Additive Manufacturing of Titanium 6Al4V with Laser-Wire Deposition - Annealed and Aged

While no gaps have been identified, SDOs (e.g., ASTM, SAE, etc.) should continue to include chemical composition requirements in AM part (finished materials) specifications. Standards also should continue to require both the feedstock (precursor) material and as-built part (finished material) to conform to their specific chemistry requirements unless otherwise determined necessary.

2.2.4.7 Material Allowables

Material allowables are statistically derived static material properties based on a defined set of data and statistical analysis methods. Users must apply appropriate influence factors to material allowables in order to compute design values that are accepted by government procuring and/or certification agencies for the development and manufacture of aerospace products. Design values, although critical for certification, are typically highly proprietary and application dependent and therefore are not expected to be published in standards. Public standards may identify some possible influence factors to consider, but they will not include any design values. For the widespread adoption of AM for the aerospace industry, reliable material allowables must be developed which can be used by industry to compute design values that may be considered for acceptance by the various procuring and certification agencies.

The development of standard test methods, specifications, and best practice guides will allow for the standardization of additively manufactured materials property data that can be used to generate material allowables, which are needed for computing design values for acceptance by government procuring and certification agencies. The data obtained through these standards and specifications can be used for statistical analysis of material allowables (typically T90 or T99 values). Once these material allowables are established, the application of AM components can be accelerated.

For metals, MMPDS has approved data generation and analysis procedures for calculating material allowables that may be adopted for metallic additive manufacturing. See section 2.3.2.3 in the Q&C chapter for more details on MMPDS.

For polymers, CMH-17 has approved data generation and analysis procedures for calculating material allowables that may be adopted for non-metallic additive manufacturing. The user remains responsible for determining influence factors that satisfy their customer. See section 2.3.2.3 in the Q&C chapter for more details on CMH-17.

Although several material specifications have been published for use with AM materials, they are not sufficient enough in detail to support the development of material allowables. The minimum mechanical properties values may not always be statistically derived and, therefore, cannot be used to develop S-basis, T90, and T99 values. In many cases, these properties are currently derived from metal casting properties.

The standard terminology, practices, and guides may be of some use in developing a standard method to describe various AM processes and testing methods.

An alternative to the allowables approach for additive processes is documented in the NASA standard NASA-STD-6030. Rather than a one-time, comprehensive allowables development campaign that attempts to account for all future variability in one large sampling, the method of NASA-STD-6030 requires a lower initial investment that is bolstered by continuous statistical process control. For additive manufactured materials there is heightened concern for future variability that may not be captured in the one-time sampling effort of the traditional methodology. Ongoing quality and performance evaluations are required on a build-to-build basis to maintain material consistency (equivalence from an engineering perspective), which includes periodic review and confirmation that newly produced materials continue to perform equivalent to the materials originally used to develop the properties. As documented in the standards, this methodology is unique as it involves sustained engagement and interaction of engineering and production to monitor the process and confirm that controls are adequate for produced parts to meet the design value assumptions.

In applications using ASME boiler and pressure vessel code (B&PVC) as a basis, the addition of AM materials into the stress and physical properties tables in ASME Section II Part D represents the most direct path to widespread adoption of AM materials in B&PVC applications. In order to add AM materials to the data tables, test data of representative additively manufactured parts must be correlated to the material properties and allowables in ASME Section II, Part D to determine applicability; and if not applicable, new data must be generated for addition to the Part D tables. While other adoption methods may be necessary due to process variability, this effort would likely be undertaken during establishment of ASTM material specifications as part of a larger adoption effort of ASTM additive material specifications into ASME Section II.

Gap FMP4: Material Allowables. Several material and process specifications are now available for use in material allowables programs. In addition, there are multiple public allowables development programs in progress. For metallic additively manufactured material, the MMPDS General Coordination Committee has approved guidelines, definitions, specification content, data generation, data analysis, and presentation guidelines for users. MMPDS continues to work toward compiling the first edition of MMPDS, Volume II. The target release is tentatively forecasted to be July 1, 2024. For polymer based additively manufactured materials, an FAA sponsored research program developed allowables that are currently under consideration for a future publication of CMH-17.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Recommended R&D required to fill this gap includes expansion of current allowables activities and further guidelines to support these activities.

Recommendation: Leverage research to improve existing guidelines as follows:

- Expand on allowable programs in progress
- Develop additional guidelines for best practices
- Expand allowables programs with additional AM processes and alloys
- Additional machine types for a given alloy
- Statistical methodology assessment and validation
- Acceptance and equivalency protocol development and validation

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F42/ISO TC 261, SAE AMS-AM, AWS, NASA, ASME BPVC, MMPDS, CMH-17, NIST

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: Proprietary methods are being used in lieu of industry standards.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As described in the text.

2.2.4.8 Microstructure

Microstructure is a multiscale subsurface structure of a metallic alloy that can be viewed by either surface treatments that reveal the subsurface structures (e.g., etching) or by recording the subsurface response to external stimuli (e.g., electron beam, X-ray, etc.).

For metallic alloys, subsurface structures include phase-based features (e.g., laths, grains, etc.) and defects (e.g., cracks, porosities). Both identification and quantification of various microstructure features are needed to link them with the additively manufactured part's performance. For phase-based features, both morphology and crystallography of various phases need to be identified and quantified; these are dependent on the alloy system and the thermomechanical pedigree. Defects morphology, which is dependent on processing pedigree, also needs to be identified and quantified. Due to the heterogeneous nature of the AM process, microstructure quantifications should account for the 3D spatial variability of various microstructure features that often results in 3D spatial heterogeneity in material properties.

Microstructure has a direct impact on an AM part's performance because it affects its location specific material properties under static and dynamic loading conditions. Thus, understanding the microstructure characteristics (spatial variability of crystallography and morphology) leads to accurate estimates of the part's in-service performance and further optimization of post-processing heat treatments to control the location of specific material properties and, hence, the part's in-service performance.

For metallic alloys to be included in MMPDS, micrographs and other relevant data and metadata will be required. Some of that information will be available to users to support regulatory reviews. Industry and government experts are evaluating options for this new approach to commodity material acceptance. Specification content requirements for AM require that the SDO and specification sponsor consider what microstructure controls are needed for a particular alloy. Users can impose application specific requirements above and beyond what is included in the specification of MMPDS.

Test Methods or Best Practice Guides for Microstructure of AM Parts

The nature of vertically building parts in AM causes directionality in the thermal gradient that is complicated by the variability in a part's geometry and the resultant heterogeneous microstructure that is characterized by 3D spatial variability. Thus, microstructure identification and quantification in AM should consider microstructure heterogeneity as the norm and homogeneity as the special case. Fast cooling rates from the melt combined with thermal gradients can result in submicron scale microstructure features (e.g., martensite needles or alpha laths in alpha/beta titanium) within millimeter scale features (e.g., prior beta grains in titanium alloys or large gamma grains in TiAl). Thus, microstructure identification and quantification methods should account for multiscale 3D microstructure spatial heterogeneities that span to tens of millimeters while having the resolution of sub-micrometers. While the physics of traditional casting and welding processes are different than the one associated with metallic additive manufacturing, established standards for microstructure identification and quantification in both techniques can be used as a start towards standards for AM. However, they often focus on the morphology of phases with limited standards for crystallography and no standards for spatial distribution.

Published Standards

The following test standards are published for microstructure morphology quantification:

Committee	Test Standard Number	Title	Notes
ASTM Subcommittee: A04.21	ASTM A247-19	Standard Test Method for Evaluating the Microstructure of Graphite in Iron Castings	This can be a guide to image-based evaluation of microstructures due to the similarity in heterogeneity of graphite in iron to various phases of heterogeneities in AM alloys
ASTM Subcommittee: E04.01	ASTM E3-11(2017)	Standard Guide for Preparation of Metallographic Specimens	
ASTM Subcommittee: E04.01	ASTM E407-07(2015)e1	Standard Practice for Microetching Metals and Alloys	The procedures in this standard can be followed for inspecting AM metals
ASTM - Subcommittee: E04.08	ASTM E112-13(2021)	Standard Test Methods for Determining Average Grain Size	Does not account for heterogeneous microstructure
ASTM - Subcommittee: E04.08	ASTM E930-19	Standard Test Methods for Estimating the Largest Grain Observed in a Metallographic Section (ALA Grain Size)	Does not account for spatial location of ALA grain and the alignment relative to the build direction

Committee	Test Standard Number	Title	Notes
ASTM - Subcommittee: E04.08	ASTM E1181-02(2015)	Standard Test Methods for Characterizing Duplex Grain Sizes	It may partially work for TiAl alloys but not for the gradient from surface to core of AM parts
ASTM - Subcommittee: E04.11	ASTM E2627-13(2019)	Standard Practice for Determining Average Grain Size Using Electron Backscatter Diffraction (EBSD) in Fully Recrystallized Polycrystalline Materials	Not suitable for AM grain structure
ASTM - Subcommittee: E04.14	ASTM E562-19	Standard Test Method for Determining Volume Fraction by Systematic Manual Point Count	Partial use in AM because volume fraction is not enough
ASTM Subcommittee: E04.14	ASTM E1268- 19	Standard Practice for Assessing the Degree of Banding or Orientation of Microstructures	Not suitable for AM. While banding is a sort of heterogeneity, in AM there is size heterogeneity in addition to orientation banding
ASTM - Subcommittee: E04.14	ASTM E1382-97(2015)	Standard Test Methods for Determining Average Grain Size Using Semiautomatic and Automatic Image Analysis	An average is not suitable for AM
ISO/TC 202	ISO 13067:2020	Microbeam analysis - Electron backscatter diffraction - Measurement of average grain size	It does not address the size of EBSD scan to have reliable statistics of grains in AM material

In-Development Standards

- ASTM WK65929, Specification for Additive Manufacturing-Finished Part Properties and Post Processing - Additively Manufactured Spaceflight Hardware by Laser Beam Powder Bed Fusion in Metals
- ASTM WK65937, New Specification for Additive Manufacturing -- Space Application -- Flight Hardware made by Laser Beam Powder Bed Fusion Process

Gap FMP5: Microstructure. There is an inherent heterogeneity in the microstructure of metallic alloys made by AM that requires a standard for identification and quantification of the spatial variability of various microstructure features.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Develop Calphad databases suitable for non-equilibrium solidification. ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Projects 1804/1907 (WK65937, WK65929) address AMSC gap FMP5.

Recommendation: Develop a standard for characterization and acceptance criteria of AM microstructures (both identification and quantification).

Priority: ☒High; ☐Medium; ☐Low

Organization: NIST, ASTM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☒Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.2.4.9 AM Defect Structures

All manufacturing processes invariably produce some level of defect structures. Some of the defect types are unique to additive and not observed in traditional materials processing. Defects are in general discontinuities in the material and can negatively influence the performance that is offered by the base material microstructure. AM defects can form in the bulk, near the surface, and can also be associated with the external surfaces formed during the material consolidation process. AM defects are also highly material and process dependent, i.e., polymer-based processes produce different types of defects than the metal fusion processes. Where similarities exist, they tend to be within specific types of material and process combinations, for example, metal-based laser powder fusion processes tend to produce similar types of defect structures. The diversity in AM has in general precluded concentrated evaluation of defect structures resulting in limited qualitative and weak quantitative understanding regarding the nature of AM defects, how they influence material performance, and what levels should be accepted.

Internal defects may include inclusions and oxides but in general involve voids and interfaces that form as additional material is added to the preceding deposit. These defects may be influenced by characteristics of the feedstock and are also highly dependent on the localized process conditions at the point of consolidation. Process and material specific maps can be constructed to identify defect regimes, but these provide little guidance on specifics such as volume fraction, size, morphology, and in particular, their quantitative effect on material performance. For example, 3 types of defects are commonly recognized in laser powder bed fusion including lack-of-fusion, keyholing, and balling. They also are known to generally occur in certain regions of the process window. But details regarding size morphology and specific impact on performance is generally unquantified.

Some bulk (internal to the material) and subsurface defects can be mitigated or “healed” through subsequent thermal processing. For example, HIP is commonly used to address residual voids left by the laser powder bed fusion process. The effectiveness of such treatments, however, can depend on starting material condition, the alloy, and of course HIP conditions. HIP effectiveness is generally determined on a case-by-case basis and done so experimentally.

Similarly, surface defects may be mitigated by machining, abrasive and /or chemical milling, peening and or other surface treatments. The effectiveness of milder surface remediation methods are also very process and material specific and determined empirically. Simple measures of surface roughness as provided by 2D stylus and even 3D optical interferometry are not sufficient to fully characterize the nature of some of the surface topology generated in AM processes. For example, deep surface crevices that can be left by the metal laser and e-beam powder bed fusion processes that are well beyond the line of sight of the 3D optical methods.

Guidance on how the industry might begin to address some of the above may come from prior industrial and academic experiences. The metals casting industry defines and grades materials into classes based on defect size and frequency. If a link between defect characteristics and material performance can be established, a similar microstructurally based grading scheme may be possible for AM. Fracture mechanics and the extended empirical methods of Murakami, Kitagawa-Takahashi and others have been used to link idealized defects to material performance – in particular fatigue. Process specific characterization of AM defects might lead to useful assessments of material performance using such methods.

Gaps –

1. Catalogs of process specific defect types – process and material specific
2. Qualitative and quantitative models that link defect structures to material performance

Additional detail follows below. There is a broad need to share knowledge on acceptance criteria for typical defect structures. See a similar gap: Gap NDE8: NDE Acceptance Criteria for Fracture Critical AM Parts. The two identified gaps below need to be accomplished prior to establishing consensus on acceptance criteria which are application specific.

Published Standards and Related Materials

In a review of existing documents, the following was noted:

- The ISO/ASTM 52900-21 reference standard on terminology only mentions porosity. It does not mention flaw, defect, cracks, discontinuity, etc. AWS D20.1M:2019 also does not define terminology for defects. ASTM guides on AM processes also do not provide catalogs of process specific defects.

Documents that may be more closely applicable include the following:

- ASTM E3166-20e1, Standard Guide for Nondestructive Examination of Metal Additively Manufactured Aerospace Parts After Build
- ISO/ASTM TR 52906:2022, Additive manufacturing — Non-destructive testing — Intentionally seeding flaws in metallic parts

In-Development Standards

- ISO/ASTM DTR 52905, Additive manufacturing of metals — Non-destructive testing and evaluation — Defect detection in parts
- ASTM WK75329, New Practice for Nondestructive Testing (NDT), Part Quality, and Acceptability Levels of Additively Manufactured Laser Based Powder Bed Fusion Aerospace Components

New Gap FMP10: Catalogs of process specific defect types. Catalogs of process defects would be useful for diagnosing and correcting an AM process or choosing an appropriate post-processing step to eliminate or minimize the deleterious effect of defects on the final part performance. Such catalogs are not generally available for AM processes. See also gap NDE1 on Terminology for the Identification of AM Anomalies Interrogated by NDE Methods.

R&D Needed: ☒Yes; ☐No; Maybe

R&D Expectations: R&D is required to correctly diagnose the cause of defects for some processes and materials.

Recommendation: Develop catalogs of process specific defects

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM, AWS, SAE, potentially other SDOs, NIST, national labs, DoD, NASA

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap FMP11: Assessment of models linking defect structures and material performance. Structure-property models for AM defects are needed to support acceptance criteria for part qualification. Guidance and technical reports are needed on the use of existing models and the development of new models.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop guides and technical reports on current structure-property models for defects and the development of new models. Publish high fidelity, pedigreed datasets for structure-property model validation.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM, AWS, SAE, potentially other SDOs, NIST, national labs, DoD, NASA

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.3 Qualification & Certification

2.3.1 Introduction

Each section in this roadmap discusses various issues and relevant standards at some point in the lifecycle of an AM part. The goal of this chapter is to look at those issues in the context of applicable qualification and certification (Q&C) procedures. Ultimately, all of the gaps identified in this roadmap relate in some respect to Q&C.[20]

Whereas AM produced components must be tested for performance much the same as traditionally manufactured items, there will be aspects unique to AM that must be addressed before such components are deployed. This is especially the case for mission and safety-critical components and applications. A critical part may be required to be built from qualified material, using qualified

[20] Accompanying this roadmap is a spreadsheet listing the identified gaps and applicable Q&C categories.

processes, etc. Suffice it to say that there are many types of qualifications that can be discussed within the scope of AM. As such, Q&C is a major area of focus for AM.

The first part of this section discusses Q&C terminology and a prescriptive versus a performance-based framework. The next part focuses on industry documents and related activities that provide guidance on suggested or necessary components of an acceptable qualification procedure. The third part discusses the approach to qualification and certification within different industry sectors and related issues, including where there is a need for further standardization work or guidance to address such issues. Lastly, there is a brief section on conclusions.

2.3.1.1 Q&C Terminology

Qualification is defined in ISO/ASTM 52900:2021, Additive Manufacturing - General Principles - Fundamentals and vocabulary as:

> **Qualification.** process of demonstrating whether an entity is capable of fulfilling specified requirements
>
> Note 1 to entry: In *additive manufacturing*, qualification typically involves *parts*, materials, equipment, operators and processes.

Certification is defined in ISO/IEC 17000:2020, Conformity Assessment - Vocabulary And General Principles as:

> **Certification.** third-party *attestation* related to an *object of conformity assessment*, with the exception of *accreditation*

A formal definitional distinction therefore is that certification describes something done by an authorized third party independent of the person or organization that provides the product, as well as the user or customer of the product.

One of the major issues in the discussion of Q&C in AM is the ambiguity of terms and their usage. For example, ISO 9000:2015, Quality management systems – Fundamentals and vocabulary, does not define qualification or certification, but defines verification and notes that qualification is sometimes used as a synonym for each:

> **Verification:** Confirmation, through the provision of *objective evidence*, that specified *requirements* have been fulfilled
>
> - Note 1 to entry: The objective evidence needed for a verification can be the result of an *inspection* or of other forms of *determination* such as performing alternative calculations or reviewing *documents*.
> - Note 2 to entry: The activities carried out for verification are sometimes called a qualification [emphasis added] *process*.

- Note 3 to entry: The word "verified" is used to designate the corresponding status.

Related terms defined in ISO/IEC 17000:2020 are:

> **Verification.** confirmation of truthfulness through the provision of objective evidence that *specified requirements* have been fulfilled
>
> Note 1 to entry: Verification can be applied to claims to confirm the information declared with the claim regarding events that have already occurred or results that have already been obtained.
>
> **Validation.** confirmation of plausibility for a specific intended use or application through the provision of objective evidence that *specified requirements* have been fulfilled
>
> Note 1 to entry: Validation can be applied to claims to confirm the information declared with the claim regarding an intended future use.

Terms may be defined in specific contexts. For example, verification and validation are defined and/or discussed in:

- ASME VVUQ 1 – 2022, Verification, Validation, and Uncertainty Quantification Terminology in Computational Modeling and Simulation
- DOT/FAA/TC-20/42, Model-Based Systems Engineering and Model-Based Safety Analysis: Final Report
- IEEE 1012-2016 - IEEE Standard for System, Software, and Hardware Verification and Validation

ASME VVUQ 50, Verification, Validation, and Uncertainty Quantification of Computational Modeling for Advanced Manufacturing, is being developed. It will cover procedures for verification, validation, and uncertainty quantification in modeling and computational simulation for advanced manufacturing. Four key areas where they wish to develop content are: additive manufacturing, subtractive manufacturing, uncertainty in manufacturing, and process control.

Aside from ambiguities in formal definitions, there are sometimes differences in how terms are used by industry sector. The aerospace industry utilizes SAE AS9100D, Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations. The defense industry approach to certification of parts/criticality of parts aligns with the aerospace industry practice except for terminology. The aerospace industry qualification procedure equates to what the defense industry describes as certification. Terminology within the medical community is defined in law or regulation.

In addition to the source documents already mentioned, the ISO Online Browsing Platform is a useful resource for researching how terms are defined in various standardization contexts.

Gap QC1: Harmonization of AM Q&C Terminology. One of the challenges in discussing qualification and certification in AM is the ambiguity of the terms qualification, certification, verification, and validation, and how these terms are used by different industrial sectors when describing Q&C of materials, parts, processes, personnel, and equipment.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Compare how the terms qualification, certification, verification, and validation are used by industry sector. Update as needed existing terminology standards to harmonize definitions and encourage consistent use of terms across industry sectors with respect to AM.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F42/ISO TC 261, AAMI, ASME, SAE

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: This is an ongoing effort.

2.3.1.2 Q&C Framework – Prescriptive versus Performance-based

To understand the Q&C methodology within an industry or when comparing approaches used by different industries, it is important to recognize that the framework used for Q&C often differs significantly. One useful metric in comparing Q&C frameworks is to note the degree to which the certifying entity dictates "how" a task is done versus only dictating "what" the outcome of the task must be. This consideration of “how” versus “what” establishes a range of possibilities for the Q&C framework, from fully prescriptive at one extreme telling the provider exactly how to proceed to being fully performance-based at the other extreme giving the provider only the performance requirements of the final product. Generally, the reality exists as a blend of the two philosophies falling somewhere between these extremes. Performance based Q&C offers the providers the most flexibility and provides a better environment for innovation. This arrangement requires trust between certifier and provider. This trust is usually enforced indirectly by significant financial or legal motivations on the provider to ensure the product meets its certification goals. In the opposite extreme, a prescriptive solution tends to reduce innovation in return for a better-defined process and product. A more prescriptive solution is common when the certifying agency has a direct stake in the product outcome, i.e., the certifier is also the customer. The prescriptive approach is often chosen when the situation offers limited consequences on the provider for not performing, other than not being compensated for that job, i.e., contract work. Therefore, the motivating factors on the provider tend to guide the Q&C framework. If the provider’s future business case relies heavily on providing a safe, reliable product at certification, performance-based Q&C is generally useful. When these motivations are not as strong or when the certifying entity has a direct stake in the outcome, the Q&C framework tends more toward prescriptive.

A microcosm reflecting this variety of Q&C framework is evident within the commercial sector. An Original Equipment Manufacturer (OEM) may be operating under largely performance-based rules to produce their device; however, when the OEM contracts to a provider to produce for them, the OEM serves as a “certifier” to the provider, and the OEM will typically be prescriptive in their engagement to ensure the product complies with their internal standards.

The Q&C framework employed can have an effect on the role of standards and type of standards that are most useful within the framework. Standards and guidance material may vary depending on where the Q&C framework falls in the spectrum from prescriptive to performance based. Within this chapter, there are perspectives from a variety of industry sectors. The approach used by each falls somewhere along this continuum. The reader will find certifying agencies that have a purely regulatory role such as the FDA and FAA leaning toward performance-based methods, whereas agencies that hold more a more direct stake in the products tend to be more prescriptive, such as NASA and cases within the DOD. However, in general, there is movement toward having government certification processes be less prescriptive and more performance-based across the board. The motivations and consequences will determine the correct balance in the Q&C framework through sometimes tough lessons learned.

Design Qualification vs Production Qualification

The FAA uses language of Type Certification (TC) for the approval of the design and Production Certification (PC) for the approval of the production supplier. When talking about qualification, it is important to understand that the design Q&C and the production Q&C are different types of Q&C. There are typically 3 agencies involved in TC and PC Q&C. The 3 agencies are the: (1) Regulator, (2) OEM or TC holder, and (3) manufacturer or PC holder. It is most common that these are 3 different organizations, but it is possible that a single organization is responsible for multiple agency roles. NASA, for example, can be responsible for both the regulator and OEM role and can sometimes also be the manufacturer.

Prescriptive and performance approaches are two different means of compliance for Production Q&C. There are pros and cons to using the either the prescriptive approach or the performance approach. Before a Q&C framework is established, an organization or agency must understand each and decide which is better suited for their situation. It has been demonstrated that both approaches can be used for Q&C of safety critical component manufacture. A comparison of the approaches follows below.

Prescriptive:	**Performance:**
Often used for composite and polymer manufacturing	Often used for other metals processes like castings and forgings
Best suited for short-run (small quantity) manufacturing	Establishes an "AM foundry" for both short-run and long-run manufacturing
Part or supplier-specific allowables established	One allowable set established for all parts, machines, and suppliers
Lower upfront costs	Higher upfront costs
Higher manufacturing costs	Lower manufacturing costs
Performance is the product of the prescribed process	The process is established to meet performance requirements
Machine & supplier specific	Machine & supplier agnostic
Risk: Process variation within prescribed process can result in different performance	Risk: Supplier knowledge required to control process to meet performance
Production part performance determined by organization prescribing manufacturing process (typically, the OEM)	Production part performance determined by manufacturing organization

AM Specific Considerations

When developing a Q&C framework, it is important to identify what within the AM process is unique as compared to other methods of manufacturing and what is common. Casting and forging Q&C is a common predicate to use when developing a metal AM framework. The performance-based Q&C approach is used for casting and forging and therefore a significant part of the AM qualification framework can be taken directly or by analogy for the metal AM process. It is often the case that AM has inherent opportunities to improve the Q&C as compared to traditional manufacturing; however, the priority should be focused on required unique AM elements. A common example is in-situ monitoring. The digital layer-by-layer nature of AM has inherent advantages for process monitoring as compared to casting and forging. It has been shown that human process controls are sufficient for AM in the same way that they are sufficient for castings and forgings. The addition of in-situ monitoring will have significant cost benefit, but is not a requirement for the Q&C of AM parts. In this example, in-situ is not a gap, but an opportunity when a metals performance-based approach is used.

Performance-based approach to Q&C

Section 2.3.2.8 describes the *AIA Recommended Guidance for Certification of AM Components* whitepaper. The whitepaper introduces a performance-based Q&C approach. The framework established in the whitepaper leverages medical industry language which aligns with a traditional casting and forging approach to Q&C. The approach is paraphrased below:

Installation Qualification (IQ) – Is the sight acceptance test (qualification) of the machine to ensure it meets the machine OEM specifications. In layman's terms, "the machine works."

Operational Qualification (OQ) – Is the qualification of the machine and process to ensure it consistently meets a material specification. Measure of performance are the requirements given within the material specification. Typical examples of performance requirements are chemistry, microstructure, minimum tensile strength, and porosity. In layman's terms, "the AM foundry is open for business."

Performance Qualification (PQ) – Is the qualification of the machine and process to ensure it consistently meets a part and/or part family level of requirements. These requirements are determined by the OEM or TC holder. The requirements are most often defined within the product definition and the OEM process qualification requirements. The method of meeting these requirements (how) is not defined, but the performance requirements are defined (what). This can involve additional material equivalency testing. In layman's terms, "the process is fully qualified." Operator training would come under PQ.

2.3.2 Identified Guidance Documents

Input was invited from all AMSC participants on relevant qualification procedures. What follows below reflects what was submitted for inclusion in this section in no particular order. In each case, authors were invited to provide background on the impetus for the document or initiative, what the group hoped to accomplish, and next steps.

2.3.2.1 U.S. Food and Drug Administration (FDA) Guidance on Technical Considerations for AM Devices

Additive Manufacturing (AM) is a rapidly growing technology in the medical field. Since 2010, the number of medical devices cleared each year by the FDA (Agency) has risen steadily. FDA noted the increase in AM devices in the fields of orthopaedics, dentistry, and oral and maxillofacial surgery, and began to investigate both AM applications and technologies. By gaining experience through independent research and careful evaluation of submissions, the Agency was able to clear over 250 AM-fabricated devices by the end of 2022.

In late 2014, FDA held a public workshop to discuss the technical considerations for AM medical devices (e.g., best practices, current challenges, opportunities for growth). Small and large medical device manufacturers, patient advocacy groups, scientists, standards development organizations (SDOs), and other medical industry stakeholders attended to discuss five broad themes: (1) materials; (2) design, printing, and post-printing validation; (3) printing characteristics and parameters; (4) physical and mechanical assessment of final devices; and (5) biological considerations of final devices, including cleaning, sterility, and biocompatibility. This constructive event catalyzed increased FDA outreach and stakeholder interactions, resulting in the production of a Draft Guidance (May 2016). After public comment, the Final Guidance on *Technical Considerations for Additive Manufactured Devices: Final Guidance for Industry and Food and Drug Administration Staff (AM Technical Guidance)* was published in December 2017.

FDA also recognizes that AM increases the role of clinicians (e.g., physicians, surgeons, therapists) in the creation of medical devices either by 3D printing patient-specific anatomic models (Models) from medical imaging at the point of care or directing engineers how to design a cleared patient specific implant that will be manufactured and shipped to them for a specific surgical procedure. In August 2017, FDA and the Radiological Society of North America (RSNA), an international clinical radiology society, held a jointly sponsored meeting on the topic of 3D Printed Patient-specific Anatomic Models. This meeting focused on clinically used Models to identify current best practices, levels of benefit vs. risk for different intended uses, and gaps in clinical evidence needed to perform effective regulatory review of those Models. The meeting underscored the need for continued education and development of standards and best practices in both the clinical and regulatory settings.

In 2022, the FDA and the Veterans Health Administration (VHA) held a Virtual Public Workshop – "3D Printing in Hospitals: Veteran's Health Administration's Experiences in Point of Care 3D Printing of Device and Implementing a Quality Management System" to share VHA's experiences using 3D printing/additive manufacturing in their hospitals. The workshop provided a forum for VHA and other stakeholders to present and discuss their experience for other healthcare facilities considering 3D printing medical devices to understand the requirements to implement a quality management system (QMS).

In 2021, FDA released a discussion paper titled "3D Printing Medical Devices at the Point of Care" which provided background information on 3D printing and proposed potential PoC manufacturing scenarios for public comment. Continued interaction between FDA and healthcare stakeholders will be key to ensuring safe and effective innovation across the industry and in clinical practice.

Goals and Results of the FDA AM Program

The FDA has three closely related goals with its AM program, including the AM Technical Guidance, informational videos, presentations and research publications, and FDA 3D Printing website.

Goal 1: Describe the type of technical information that may be required to meet regulatory requirements for clearance or approval and to meet post-market inspection and compliance requirements.

A Guidance document is used by FDA to provide the Agency's current thinking when an industry or technology is new to the market or to provide a groundwork for safety and effectiveness testing and metrics. The AM Technical Guidance is a cross-cutting document that adds to existing guidance documents that focus on a specific submission type or a single device category. The document describes recommendations, best practices, and advisories for different aspects of the additive manufacturing workflow; however, since the scope of the document is broad, it does not list specific acceptance criteria or prescriptive actions. The sponsor (company or person submitting a file to the FDA) must determine which recommendations and considerations are applicable to their medical device, process, and regulatory status. Resources such as CDRH Device Advice[21] and the FDA 3D Printing[22] websites also provide information that may help sponsors to make those determinations.

Unlike other regulatory bodies like FAA, the U.S. FDA does not "certify" any aspect of specific medical devices or their production. However, premarket clearance or approval from the FDA is necessary to market many medical devices in the U.S. Devices are reviewed using general risk-based criteria set by statutes and regulations[23] and clarified in process or device-specific guidance documents. The Agency aims to provide transparency about the information required or recommended for a given device or submission. This transparency is especially important with emerging technologies such as additive manufacturing.

Goal 2: Improve the introductory regulatory and technical information for the increasing number of stakeholders that are new to the medical device industry.

In addition to aiding traditional medical device manufacturers, the FDA anticipates that the AM program will help many research labs and early stage companies to identify potential challenges and incorporate established best practices, systems engineering approaches, and comprehensive quality systems into their processes. This may be important for research groups and laboratories that wish to begin clinical trials with AM devices and medical products made in house, but that would have previously required external manufacturing partners who would have assisted with the regulatory process.

Goal 3: Highlight best practices for the industry in an easy to understand manner that could be used by those who are allied to the medical device area but who make products that are not typically inspected or reviewed (i.e., Class I Medical Devices) and those who may not be traditional medical device manufacturers (e.g., researchers, clinical staff).

The FDA's AM Technical Guidance, website, and industry presentations represent the Agency's current thoughts on the best practices for AM design, manufacturing, and validation processes. Even if a particular medical product does not require clearance or approval before marketing, the Agency believes this information can be applicable to all types of medical product development and production workflows regardless of the regulatory requirements.

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[21] CDRH Device Advice: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/

[22] FDA 3D Printing Website: https://www.fda.gov/medical-devices/products-and-medical-procedures/3d-printing-medical-devices

[23] CFR for med devices (21 CFR 800-1099) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=800&CFRPartTo=1099

2.3.2.2 Nadcap Program

Nadcap is an industry managed program, administered by the Performance Review Institute (PRI), devoted to improving quality and reducing costs of critical process accreditations throughout the aviation, defense, and space industries.[24]

In October 2013, the Welding Task Group was assigned responsibility to assess the industry needs and develop audit criteria capable of assessing suppliers utilizing additive manufacturing technology. Analysis demonstrated that the Task Group would be best suited developing audit criteria to assess laser and electron-beam powder bed variants of the process. During the period 2014 to 2016, a sub-team of the Task Group, as well as invited industry experts, including equipment and powder manufacturers, developed and verified various drafts of audit criteria via trial audits. This culminated in the approval of the audit criteria AC7110/14, Nadcap Audit Criteria for Laser and Electron Beam Metallic Powder Bed Additive Manufacturing, which was released for use in early 2017.

Concurrent with the checklist development, existing welding auditors were theoretically and practically trained in the technology and then examined to qualify them to conduct audits to this new audit criteria. Audits already have been performed and suppliers accredited to the audit criteria.

The Task Group made an initial revision based on comments from users of the audit criteria. A further revision was subsequently made once industry standards became available, to ensure proper alignment with industry requirements.

The AC7110/14 audit criteria are available for downloading at no charge to any person registered in eAuditNet (www.eauditnet.com). Once registered, the audit criteria can be found via Resources / Documents / Audit Criteria / Welding. In addition to AC7110/14, AC7110, Nadcap Audit Criteria for Welding/Torch and Induction Brazing and Additive Manufacturing, should also be downloaded, as AC7110 is a core checklist required for all of the welding audit criteria.

Following approval by the Nadcap Management Council and subsequently the Board of Directors, a new Additive Manufacturing Task Group was launched at the June 2023 Nadcap meeting. This AM dedicated Task Group will initially transfer existing audit criteria from the Welding Task Group and then develop audit criteria for additional AM processes as needed by industry.

[24] More information on the Nadcap program can be found at https://p-r-i.org/nadcap/about-nadcap/

2.3.2.3 Composite Materials Handbook-17 (CMH-17) and Metallic Materials Properties Development and Standardization (MMPDS) Handbook

These two guidance documents are heavily used as part of the qualification process for metal and composite materials. These documents both are based in volunteer organizations that have been active for decades in rigorously reviewing data and statistical analyses for publication of material allowables.

As additively manufactured materials are expanding into regulated areas, these handbook organizations are developing new volumes that will include material allowables and qualification and certification guidelines. AM data are not currently available in either handbook; however, both organizations are considering including them in future revisions.

Composite Materials Handbook -17 (CMH-17)

History: CMH-17 has a long history beginning in 1943 with the initial publication of the Army-Navy-Commerce (ANC) Bulletin 17 Plastics for Aircraft (Air Force, Navy, and Civil Aeronautics Document). In 1959, the handbook "MIL-HDBK-17 Plastics for Air Vehicles" was first released utilizing content from the ANC Bulletin. In 1978, an industry and government group (Coordination Group) was formed followed by the release of MIL-HDBK-17B Volume 1 in 1988. Since that time, several revisions and volumes have been published including polymer matrix, metal matrix, ceramic matrix, and structural sandwich composites. In 2012, the Handbook name was formally changed from MIL-HDBK-17 to CMH-17 and is now published by SAE. There are currently 6 volumes in the series.

Since the first publication of the CMH-17, the goal has been to create, publish, and maintain proven, reliable engineering information and standards subjected to a thorough technical review, and to support the development and use of composite materials and structures. The Handbook has been successful in maintaining a volunteer organization of experts and publishing the information to the international composites community. Through training and tutorials, CMH-17 has extended its reach to suit user needs. Additional information is available at www.cmh17.org.

Role in Certification: CMH-17 is an accepted source for composite material allowables recognized by the FAA. FAA AIR100-2010-120-003 states that National Center for Advanced Materials Performance (NCAMP) allowables are acceptable for showing compliance with polymer matrix composites and they must be validated as being applicable for an applicant's application by the provisions listed in AIR100. Although CMH-17 is not specifically listed in AIR100, CMH-17 has adopted NCAMP procedures. The material values published in CMH-17 are not acceptable for design unless applicants follow the equivalency procedures provided in NCAMP and CMH-17 to validate that the published values are applicable for that applicant's product.

Content: CMH-17 is an evolving document that reflects the state of the art in composite materials. Periodic updates are made to maintain updated references to proven standards and engineering practices, as well as up-to-date reliable composites data. Current areas of development include application focused guidelines such as Engine Applications and Crashworthiness, as well as new data for adhesives, core, thermoplastics, repair, and other new materials data linked to publicly -available material and process specifications.

Non-Metallic Additive: In 2018, a new group under CMH-17 was formed to develop a seventh volume focused on non-metallic additively manufactured materials. The Additive Manufacturing Coordination Group is actively developing content through five Working Groups: Data Review, Design & Analysis, Materials & Processes, Statistics, and Testing. Initial guidelines and data are focused on polymer AM, primarily through available qualification data. As part of a Federal Aviation Administration (FAA) led effort, qualification data of a polymer AM material has been generated and submitted to CMH-17 for consideration. The Additive Manufacturing Coordination Group is currently reviewing this data set for publication in a future release of the handbook. Note: CMH-17 has historically been devoted to composite materials. Composites, as additively manufactured polymers, are considered "process dependent" materials. This being the case, material values published in CMH-17 are not acceptable for design unless applicants follow the equivalency procedures provided in CMH-17 to validate that the published values are applicable for that applicant's product. It is expected that values published for AM polymers will be subjected to these same procedures.

Metallic Materials Properties Development and Standardization (MMPDS) Handbook

History: MMPDS also has a long history beginning with ANC-5 published in 1937. The United States Air Force (USAF) assumed primary responsibility for continuing development of the Handbook in 1954, recruited Battelle Memorial Institute as secretariat and changed the program name to MIL-HDBK-5 in 1956. Battelle has maintained and published the Handbook since 1957, serving as an impartial agent to collect and analyze industry data and to publish statistically valid design allowables. In 1997 the Industrial Steering Group (ISG) was formed to supplement government funding. In 2003, the Federal Aviation Administration took over the government oversight role and changed the name of the document to the Metallic Materials Properties Development and Standardization (MMPDS) Handbook. The ISG is currently composed of 48 companies from 12 countries. The Government Steering Group (GSG) includes representatives of the FAA, U.S. Air Force, U.S. Army, U.S. Navy, Defense Logistics Agency, and NASA. Additional information is available at www.mmpds.org. Together, the ISG and GSG form the MMPDS Coordinating Committee.

Role in Certification: The MMPDS Handbook is an accepted source for metallic material and fastener system allowables for conventional metals recognized by the FAA, all departments and agencies of the Department of Defense (DoD), and the National Aeronautics and Space Administration (NASA) within the limitations of the certification requirements of the specific government agency. Per FAA Memorandum PS-AIR-MMPDS: (Subject: Metallic Material Properties Development and Standardization (MMPDS) Handbook) A and B-basis design values are acceptable for compliance for material strength properties and design values for aircraft certification and continued airworthiness without further showing of compliance. A-/B-/S-Basis material allowables are often accepted as the basis for design values for engine certification. Users are responsible for evaluating influence factors such as temperature, surface treatments, etc., to compute design values for their specific application. Chapter 9

(Guidelines) are widely used by aerospace companies to develop proprietary material allowables for materials that are not included in the MMPDS Handbook.

Content: The Handbook contains design information on the mechanical and physical properties of metallic materials and joints commonly used in aircraft and aerospace vehicle components and structures. Chapter 9 (Guidelines) documents the test standards, data requirements, and statistical algorithms required for consideration for each type of property reported. For example, A-/B-Basis static strength values require no less than 100 tests with material drawn from 10 heats/10 lots of metal fitted with three-parameter Weibull or Pearson Type II probability distribution functions or 299 tests using a non-parametric method. Test data generated by industry suppliers and users are submitted to Battelle for analysis using guidelines documented in MMPDS Chapter 9. Results are reviewed at twice yearly MMPDS General Coordination Committee (GCC) meetings for approval. These coordination meetings are open to the public. Each year, new alloys are added, guidelines are updated, and revisions are made to existing sections after ISG and GSG review and approval.

Additive Metals: MMPDS has had limited exposure to additive manufacturing materials. Data for SAE AMS 4999 (LAM Ti 6-4) was submitted in 2003 but the GCC decided that the data submitted did not meet the existing requirements to support publishing material properties in MMPDS. Beginning in 2011, the Emerging Technology Work Group (ETWG) was organized and began a focused effort to develop guidelines appropriate for data generation, analysis, and publication of material allowables for process intensive metals, including AM alloys. An interim report, *Guidelines for Emerging Materials and Technologies* documented the progress but was closed in the spring of 2016 at the Government Steering Group's (GSG) request because the underlying technology and supporting infrastructure was considered not mature enough to publish generic material properties. Industry had produced few public specifications, a major barrier to admission into the Handbook, and there were concerns that the variability of material being produced was too great, and the sources of that variability insufficiently understood.

The ETWG continued to engage with government, industry, and SDOs to support technology improvements. In the last five years, the GCC decided that process intensive materials and joining technologies (such as AM metals and friction-stir welding) should be published as a separate volume rather than as new sections of the existing Handbook. Between 2018 and 2022, the GCC approved 16 agenda items documenting guidelines, definitions, specification content, data generation, data analysis, and presentation guidelines for users. The GCC continues to work toward compiling the first edition of MMPDS, Volume II. The target release is tentatively forecasted to be July 1, 2024.

The new volume will define the minimum requirements for the GCC to consider creating an entry. The first edition will not include any material allowables. Because the guidelines remain undefined, most businesses consider the risk due to possible changes too great to justify the investment in data generation. MMPDS repeatedly warns the user that the Secretariat, the GCC, the GSG, and regulators may require more information. This has always been the case, even for conventional product forms.

There are known gaps in the new volume. However, the data submission guidance is sufficient for generating data in support of creating those future tables. Static material allowables will be labeled C/D-Basis rather than A/B-Basis to remind users that additional effort will be required by regulators at the FAA, DoD, and NASA. A new chapter has been added that will be expanded to assist users in that process. The MMPDS program will solicit input from industry and government and continue to expand and improve along with the science and engineering.

2.3.2.4 AWS D20

The American Welding Society (AWS) formed a standalone committee for the creation of an AM standard in 2013 and published AWS D20.1/D20.1M:2109, Specification for Fabrication of Metal Components Using Additive Manufacturing, in 2019.

The AWS D20 committee has created a comprehensive document that identifies requirements for AM machine qualification, procedure qualification, and machine operator qualification, as well as fabrication and inspection requirements for AM components. The D20.1 standard includes requirements for both powder bed fusion and directed energy deposition metal AM processes. A graded approach is being taken, with three different component classifications that determine the level of qualification and inspection requirements.

The D20 committee is currently working on two documents, a revised D20.1 that would apply only to processes with powder feedstock for either powder bed fusion or directed energy deposition and a new D20.2 that would apply to processes with wire feedstock for directed energy deposition. Both documents will continue to focus on qualification, with such application issues as component classification, material chemical composition, build design, and acceptable mechanical properties not specified by the standard.

2.3.2.5 NASA Standards for Additively Manufactured Spaceflight Hardware

Motivations

NASA human rated spaceflight programs have quickly embraced the promise of AM to benefit design flexibility, cost, and schedule challenges of system development and manufacture. Each of NASA's current human spaceflight programs – the Artemis program with the Space Launch System, Human Landing System, and Orion Spacecraft, as well as the Commercial Crew Program – is developing AM hardware and establishing a significant future role for AM in these systems. In many cases, the timeline for qualification of this early AM hardware and certification of its associated systems has been condensed compared to the typical introduction of new manufacturing technology.

The primary motivation for NASA-STD-6030, Additive Manufacturing Requirements for Spaceflight Systems, and NASA-STD-6033, Additive Manufacturing Requirements for Equipment and Facility control, is the same as the predecessor documents (MSFC-STD-3716 and MSFC-SPEC-3717): to provide an overall framework for the qualification, control, and implementation of AM processes for spaceflight hardware over a range of criticalities. NASA-STD-6030 establishes basic policy for AM at the Agency level and extends its applicable scope to more processes and material systems than its predecessors. The intent of these documents is to provide a semi-prescriptive framework for AM implementations to successfully achieve certification through tailoring the requirements to meet the unique needs of the project and the provider's environment.

NASA continues to work with many of the SDOs developing various types of standards products for the AM ecosystem. These products continue to develop and are now frequently providing appropriate direction for controlling specific aspects of the overall AM process. What has yet to evolve from the SDOs is a clear, overarching, framework of standards that provides a common engineering practice to govern the full AM production life cycle; therefore, NASA considers these standards necessary to define a basic engineering practice for implementing the overall AM process in the context of NASA's overarching standards for materials, structures, and fracture control.

Objectives and Content

As stated, the primary objectives of NASA-STD-6030 and NASA-STD-6033 are to provide an overarching framework of methodologies to meet the intent of existing NASA requirements in materials, structures, and fracture control for AM parts. The standards were released in April of 2021 and are public documents available on the internet at https://standards.nasa.gov .

The following principles guided the new NASA standards in their development and philosophy:

- Define a manageable, systematic, and consistent approach to AM to allow the Agency to evaluate risk and make consistent decisions regarding the certification of designs and hardware.
- Integrate the AM process in a manner compatible with existing governing Agency standards.
- Enforce discipline and systematic rigor throughout the AM process, from design to part.
- Avoid defining the specifics of AM processes; instead define methodologies for qualifying and controlling the processes.
- Accommodate the use of internal and open industry standards as appropriate.
- Provide NASA with opportunities for insight to gauge quality, completeness, and rigor through a well-defined and predictable set of reviewable products governing the AM process.

To accomplish these goals, the NASA standards provide a framework of requirements for foundational process controls and part production controls. The foundational controls begin with the implementation of a Quality Management System (QMS) and the development of an AM Control Plan (AMCP). The AMCP documents all tailoring of the requirements as agreed to for the AM implementation and replaces the NASA standards as the governing document. Further foundational controls are established regarding the qualification of AM material processes, establishing control of AM machines and facilities (through NASA-STD-6033), and the systematic development and substantiation of AM material properties for use in design and statistical process control. Only once these foundational controls are in place do the part production controls get implemented to produce AM parts to a qualified process. The following describes key products produced while establishing a qualified AM process and part production:

Foundational Controls

- Equipment and facility Process Controls (NASA-STD-6033)
    - An AM Equipment and Facility Control Plan (EFCP) is established to formalize AM equipment process controls including feedstock management, contamination control, digital data control and security, prerequisite machine calibration requirements, preventive maintenance requirements, machine health tracking, and so forth.
- Baseline AM material and process qualifications (NASA-STD-6030)
    - Feedstock material, AM machine, and the AM process are indelibly linked in this concept. Once fully defined, this combination is set as a "candidate AM material process."
    - After successful evaluation of the candidate process, a Qualified Material Process (QMP) is newly established (or shown equivalent to an existing QMP) for each individual AM machine.
- Material property development
    - The development of AM material properties and their integration into the AM ecosystem for use in part design, statistical process control, and the concept of engineering equivalency demonstrate compatibility of material performance across characterization activities and part implementations.

Part Production Controls

- Design Evaluation
    - A part classification system for evaluating risk is based on consequence of failure, structural margins, and risks associated with the physics of the AM build process.
- Part Process Control
    - There is a requirement for a Part Production Plan (PPP) that outlines the cradle-to-grave process for producing the AM part, including establishing the part integrity rationale through process controls, nondestructive inspections, and proof testing.
    - There are requirements for a formal Preproduction Article evaluation (PPA) and Manufacturing Readiness Review (MRR), leading to a locked and Qualified Part Process (QPP).

The resulting products of these controls (AMCP, EFCP, QMP, PDP, QPP) provide a consistent and quantifiable set of deliverables for the Agency to reliably evaluate the implementation of AM parts.

2.3.2.6 ASME Y14.46

ASME Y14.46, Product Definition for AM, is a subcommittee formed by the ASME Y14 Engineering Product Definitions and Related Documentation Practices Committee. The Y14.46 document addresses Product Definition requirements that are specific to AM as well as requirements not specific to, but elevated because of, AM. The sections reflect four main topics: 1) Part Definition, 2) Process, 3) Verification and Conformance, and 4) Data Package Requirements.

The Verification and Conformance Section provides guidance on conformance to specifications for AM products, in particular manufacturing imperfections meeting acceptable ranges, specified key characteristics, and identification of acceptance criteria specific to using AM processes and the associated level of reliability.

Surface finish specifications and inspection methodologies (including NDE, laser, non-contact, etc.) will continue to be developed by both the ASME B89 Dimensional Metrology Standards Committee and ASME B46 Classification and Designation of Surface Qualities Standards Committee.

The Y14.46 standard was published on June 8, 2022. This is an ANSI approved standard established following review of comments received on the draft standard for trial use issued in 2017.

2.3.2.7 Underwriters Laboratories (UL)

Underwriters Laboratories (UL) is accredited by the American National Standards Institute (ANSI) as an audited designator. UL promulgates the standard for safety ANSI/UL746C, Standard for Polymeric Materials – Use in Electrical Equipment Evaluations, Seventh Edition, dated February 5, 2018, ANSI approved June 30, 2022. This standard is maintained by the UL746C Standards Technical Panel composed of various interests including: authorities having jurisdiction, commercial/industrial users, producers, consumers, supply chain, testing/standards organizations, and general interests.

Standard

ANSI/UL746C contains requirements for parts fabricated from polymeric materials used to construct electrical equipment. The standard describes test procedures for fabricated polymeric parts in specific applications to evaluate specific criteria. The standard's scope includes parts made by additive manufacturing technology.

End-Product Evaluations

ANSI/UL746C specifies that end-product parts, or test specimens cut from the end-product parts, be subjected to various tests, or application of historical data, for qualification. The following properties may be addressed at the end-product level evaluation:

- Thermal endurance
- Electric strength / Volume resistivity
- Impact resistance
- Flammability
- Tracking resistance
- Resistance to electrical ignition sources
- Permanence
- UV & water/weathering resistance
- Dimensional stability

Pre-Selection Data

UL also conducts material certification for preselection purposes. ANSI/UL746C specifies test specimens printed, or cut from a printed part, in the specified dimensions may represent the end-product applications where identical production parameters are used.

UL also administers a component recognition program category for plastics used for additive manufacturing entitled: “[Plastics - Component] Plastics for Additive Manufacturing – Component (QMTC2).” Materials certified under this category are identified by the material manufacturer and grade designation.

Process parameters that are also specified, dependent on process, typically include:

- Printer make & model
- Build plane
- Layer thickness
- Hatch spacing
- Post process method(s)
- Infill
- Raster angle
- Print speed
- Laser power
- Air gap
- Scan strategy

2.3.2.8 AIA Recommended Guidance for Certification of AM Components

In 2016, the Federal Aviation Administration (FAA) requested the Aerospace Industries Association (AIA) to create a document outlining the considerations that should be made before utilizing Additive Manufacturing in aerospace parts production. The AIA sponsored a technical working group comprising technical leaders from over a dozen Original Equipment Manufacturer (OEM) airframe and powerplant manufacturers, who worked for several years to create a best practices document. The document was developed based on a gap analysis of the perceived needs versus technical realities and the missing regulatory framework, which aimed to provide guidance on how to address and close those gaps.

The AIA Working Group for Additive Manufacturing report specifically addressed the unique aspects of certifying AM components for aerospace applications. The resulting paper provided guidance for compliance to specific Federal Aviation Regulations (14 CFR 2x.603, 2x.605, 2x.613, 23.2260, 33.15, and 35.17) for metal powder bed fusion (PBF) and directed energy deposition (DED) additive processes. The final report also discussed current industry best practices and considerations for material/process development, part/system qualification, and development of material allowables and/or design values. The authors of the report were experienced aerospace industry design approval holders (DAH) and users of state-of-the-art additive equipment, thus providing a qualified and knowledgeable perspective on these issues.

The final document was published in 2020. Since its initial publication, the document has been frequently referenced by other standards bodies and used as an important reference document by numerous aerospace OEMs and suppliers. However, the original version of the document did not provide guidance on the use of AM in the maintenance, repair and operations (MRO) context and the use of AM in fatigue and fracture critical situations. Therefore, the AIA has requested the working group to continue their work on those two topics, and updates to the best practices document in those areas will be forthcoming over the next two years. The updates will also include additional input on suggested areas of research and development focus and investment for industrial, governmental, and standards development organizations.

2.3.2.9 EASA Certification Memo (CM-S-008) on Additive Manufacturing

The purpose of the European Union Aviation Safety Agency (EASA) Certification Memorandum CM-S-008 is to "provide guidance regarding the introduction and use of Additive Manufacturing (AM) technologies across a broad range of Products (Aircraft, Rotorcraft and Propulsion) and Parts and Appliances subject to EASA Type Certification, including CS-22, CS-VLA, CS-23, CS25, CS-VLR, CS-27, CS-29, CS-E, CS-P, CS-APU, or equivalent requirements."

"EASA Certification Memoranda clarify the Agency's general course of action on specific certification items. They are intended to provide guidance on a particular subject and, as nonbinding material, may provide complementary information and guidance for compliance demonstration with current standards."

2.3.2.10 European Cooperation for Space Standardization (ECSS) Processing and Quality Assurance Requirements for Metallic Powder Bed Fusion Technologies for Space Applications

This Standard ECSS-Q-ST-70-80C (30 July 2021) defines requirements for processing and quality assurance of powder bed fusion technologies for space applications.

Within this standard a set of phases are specified, each to be followed when defining, verifying and manufacturing parts using metallic powder bed fusion technologies. In addition, requirements for operating and supervision personnel and equipment facilities are described.

This Standard does not aim to prescribe process parameters relevant to the fabrication using metallic powder bed fusion technologies.

Although this standard is developed for powder bed fusion based techniques, its principles can also be used as a reference for other metal-based and polymer-based processes. These include Wire Arc

Additive Manufacturing (WAAM), , Stereolithography (with metals), Binder Jetting, but also Selective Laser Sintering (SLS), Stereolithography (with polymers), Fused Deposition Modelling (FDM), and others.

2.3.2.11 United Kingdom's Military Aircraft Structures Airworthiness Advisory Group (MASAAG) Guidance on the Qualification and Certification of AM Parts for Military Aviation

The aim of the MASAAG Paper 124 Issue 2 is to provide "guidance on the qualification and certification of additive manufactured (AM) parts for use in military aviation. This guidance is aimed at the Regulator, Type Airworthiness Authorities (TAA), Design Organizations (DO) and AM Part Suppliers. This paper covers metallic and polymeric parts for aircraft structures (Grade A parts), engines (Critical parts) and systems. Within the paper, the existing military and civil regulatory material, relevant to AM parts, has been reviewed (Chapters 3, 4 and 5). In addition, a significant proportion of the paper (Chapters 6 and 7) has been devoted to describing the various methodologies used for AM part design and build. This has been included to explain the sources of variation in performance of AM parts and to underpin the recommendations made to minimize, measure and account for these performance variations. Where appropriate, existing standards for AM or other relevant manufacturing or test methods have been identified and are referenced within this paper."

The 116 recommendations made are divided into those affecting regulation, Acceptable Means of Compliance (AMC) and Guidance Material (GM). The background to each recommendation has been explained within the relevant section and the recommendations have been collated into cross-referenced summary tables in Chapter 9.

2.3.2.12 Naval Sea Systems Command (NAVSEA) Requirements and Guidance on the Use of Additive Manufacturing

The Department of the Navy has identified the impact that additive manufacturing can have on cost, schedule, and sustainment, and has stood up a Technical Authority at NAVSEA to oversee the implementation of this emerging manufacturing capability into the fleet. NAVSEA 05T was designated as the technical authority that has cognizance over the use of the additive manufacturing, excluding nuclear applications and strategic weapons systems. A defined and repeatable process was identified as a need to ensure that safe and quality components were manufactured for shipboard applications, so NAVSEA 05T produced the *Ser OST/2018-024 Guidance on the Use of Additive Manufacturing* document. The document covers terminology, the decision process, recording/approval forms for AM components, AM processes and post-processing guidance, AM materials guidance, and Technical Data Package (TDP) information needed to utilize AM for critical and non-critical Navy applications. The document is currently being revised into a Technical Manual to incorporate lessons learned from operational experience with the original guidance document.

Components with severity assessments of a certain level, as defined by the *Guidance on the Use of Additive Manufacturing* document, may invoke additional requirements generated by NAVSEA to ensure that sufficient objective quality evidence is generated to provide confidence in the AM material for critical applications. The most frequently invoked types of documents are:

- Material Selection Requirements (MSR) - T9074-AX-GIB-010/100, Material Selection Requirements, is a NAVSEA Technical Publication that defines the metallic MSR that must be met by each design activity responsible for the selection of metallic materials for ships and their systems. Additively manufactured materials are treated as "New Material Applications" and follow the process flow as defined in the document to demonstrate that the application and environmental requirements are met. Appendix A of the document outlines the material selection considerations that must be identified and technically rationalized for component approval. NAVSEA is also currently working to generate an alternative approach to MSR for AM components that scales the amount of testing required based of the results of a severity assessment.

- AM Process Specific Technical Publications – NAVSEA has currently published two AM process specific technical publications, *S9074-A2-GIB-010/AM-PBF Requirements for Metal Powder Bed Fusion Additive Manufacturing* and *S9074-A4-GIB-010/AM-WIRE DED Requirements for Metal Directed Energy Deposition Additive Manufacturing,* that cover general requirements, provisions for quality assurance and Process Control Plans, test procedures, and instructions for preparation for delivery of critical metal AM components. These documents are intended to ensure that an activity's AM procedures demonstrate a sound process, the process is capable of producing the component, the component performance is suitable for the application, and repeatable work processes are in place to ensure consistency.

  The existing process technical publications are currently being updated to streamline qualification and reduce the procedure for qualification testing to better align with process variability and defer in-depth material testing/characterization based on application specific requirements and the operational environment. They also allow for the use of additional power sources such as electron beam for powder bed fusion and electron beam and laser-wire for directed energy deposition. Additionally, requirements documents similar to the initially released AM process-specific technical publications are being generated for critical polymers, blown-powder directed energy deposition, and metal fused filament fabrication.

NAVSEA's major push is to now implement these documents and establish qualified vendors in the U.S. industrial base who can deliver the cost, schedule, performance, and sustainment benefits that AM offers to impact the Naval Fleet.

2.3.3 User Group/Industry Perspectives on Q&C

Whereas the prior section addressed focused efforts underway to develop guidance documents on qualification and certification, this section endeavors to tie perspectives together by industry sector. Philosophies and needs of the following sectors are discussed and gaps are identified: aerospace (spaceflight, civil and defense aviation), defense, electronics, energy (nuclear, oil and natural gas), and medical. In the case of the automotive and construction sectors, content was invited but not provided.

2.3.3.1 Aerospace Industry

2.3.3.1.1 Civil/Commercial Spaceflight Industry

Intent and motivation of each of Q&C guidance and standard documents

Within the realm of NASA spaceflight activities, NASA has provided standards with requirements and guidance over the past five years. The first documents released in 2017 were MSFC-STD-3716 and MSFC-STD-3717. In 2021, NASA-STD-6030 and NASA-STD-6033 were released, essentially replacing the MSFC standards. See section 2.3.2.5 for a more complete description of these documents. These standards provide an overall framework to the implementation of AM and include requirements for all aspects of material and process control, material property development, part planning and production. A core feature of these standards is that they require the development of an Additive Manufacturing Control Plan (AMCP) that tailors the requirements to the needs of the program or project and adapts the requirements to a best fit to the methods of the organization serving as the cognizant engineering authority and the AM production entity. The expectation is that the intent of the requirements will be met as appropriate to the project and the AMCP, once approved, replaces the standard as the governing requirements document.

Other spaceflight related activities, such as commercial satellite production and launch and similar ventures, do not have an open, consensus Q&C standard that creates a common methodology. In these sectors of spaceflight, internal company practices are independently reviewed and accepted by the purchaser, similar to scenarios common in performance-based environments.

Description of prescriptive versus performance-based aspects of Q&C in the industry

Activities within the NASA spaceflight sector can span the range of prescriptive to performance-based requirements frameworks depending upon the program. The intent within NASA is to move toward adoption of NASA-STD-6030 methodologies across most AM implementations. The NASA-STD-6030 methods are most accurately described as prescriptive, given there are numerous “shall” statements that need to be evaluated for compliance to their intent. This methodology is not prescriptive to a detail level that includes design methods, AM parameter sets, or methods of part inspection. Rather, it is prescriptive in requiring defined expectations for material and process control, acceptable levels of material quality, minimum activities for material property characterization, etc. In general, a well-controlled AM process operating rigorously under a quality management system needs only modest adaptation to meet the intent of the NASA-STD-6030. The process of adjudicating the prescriptive requirements into a tailored, mutually acceptable AMCP to control the AM process requires an open-minded, collaborative effort. Currently, the resulting AMCP relies most heavily on proprietary documents. This trend has started to moderate in cases of smaller entities toward the available open standards that have been developed with sufficient control and specificity to be used in an environment compliant with NASA-STD-6030.

Role of AM Part Classification in the requirements and standards framework

The NASA spaceflight sector has adopted a part classification system that permeates the Q&C framework. The primary part classes are based on consequence of failure [A (high), B, and C (low)] and are influential in many aspects of the AM value chain including machine and process qualification, AM process control requirements for witness testing and surveillance, material allowable and design value rigor, and part inspection requirements, to name a few.

Summary of framework of requirements (or trends in development thereof) in the "Life Cycle Areas" described below

- **Materials – Feedstock material controls, Final material quality controls, Material allowables and design value substantiation**

The scope of feedstock controls is defined at a very high level in NASA-STD-6030, primarily identifying the minimum aspects of controls expected to be enforced. Most commonly, larger entities follow internal corporate feedstock specifications; however, the use of open industry standards has increased recently as many of the SDO products provide controls expected within the NASA framework.

In NASA-STD-6030, the expectations for controls on final material quality are primarily defined at the establishment of the Qualified Material Process. This allows for adaptation for part class and other variables to be considered. The definition required for final material quality, including material microstructure evolution in heat treatment (metals) is sufficient to form a basis for understanding material equivalence in the AM process. The adoption of the standards portfolios of the AM SDO community is hindered in this sector by the lack of definition of acceptable final material quality criteria at a level sufficient to ensure continued material consistency and determine material equivalence.

The definition and substantiation of material allowables and design values continues to be a significant standardization challenge. NASA-STD-6030 provides a framework for the development of these values and a required process control methodology that is intended to ensure the ongoing validity of these properties throughout production as applied to specific parts. The NASA standard does not purport to be the correct or final policy for the development of AM allowables and design values. NASA continues to support the SDOs such as MMPDS and CMH-17 in their activities in this regard. There remains a philosophical difference of opinion across the sector regarding the development and implementation of AM material allowables and design values. The contrasting views are not easily articulated but can be fairly summarized into two basic camps: 1) AM properties should be developed through mostly traditional policies under the assumption that a qualified process following a published, public industry standard will sufficiently control the process such that a one-time sampling of sufficient lots and specimens can be used to define allowables in the traditional sense. In this methodology, there is an expectation that there will be a "further showing" rationale provided by AM users to demonstrate their process is compliant to the standard. Or, 2) AM properties are to be developed on defined, qualified processes that are characterized sufficiently to provide a broad basis of information used to demonstrate continuous material engineering equivalency is maintained by process controls throughout the AM value chain from qualification criteria, to allowables and design values, to process witness testing, through to part first article evaluations. This approach allows for potentially smaller up-front characterization scope in exchange for the on-going controls that ensure the process of each AM machine is producing material that is consistently equivalent in an engineering sense. The NASA-STD-6030 subscribes to this latter methodology. The prevailing approach will be dictated by the demonstrated reliability of the AM process over time. The first, traditional approach requires significant assumptions in the current reliability of the process.

- **Process/Procedures – Process or Procedure Qualification, Process control and Statistical Process Control (SPC)**

The method of qualifying AM processes and machines remains poorly defined in the SDO space as related to this sector, with a scattering of standards addressing various aspects of the AM qualification process. One particular challenge in this regard is a lack of standard terminology related to qualification of AM machines and processes. Confusion persists about what is machine qualification and what is process qualification, how the two are related, and what represents adequate scope of the required qualification evaluations. With respect to regulatory expectations in this sector, there does not appear to be a clear convergence across the SDO space in this regard. Within NASA activities, NASA-STD-6030 attempts to put sufficient definition to these topics to permit a common understanding and a basis for conversation and negotiation. The NASA standard separates machine calibration and confirmation of functionality as a separate precursor activity to the qualification process. The qualification process is viewed as an affirmation that a defined machine and process parameter combination produces material of appropriate quality for the application. This is referred to as a Qualified Material Process (QMP). The qualification activities required are generally more comprehensive than what appears in currently available SDO offerings. Evaluations of resulting material are required in as-built and final states for microstructure and defect state, including key operations within the process, e.g., in powder bed fusion: contour interfaces, “stitching” zones, etc. Evaluations of rendered surface quality and detail resolution are required as are evaluations of mechanical properties that probe a variety of failure modes such as tensile, fatigue, and toughness. In cases where qualification methodologies exist within internal corporate policies, negotiation is generally required to strike an appropriate balance for AM process qualification intent.

The range of realized process control methodologies is broad across this sector with limited degrees of consensus on what is most effective and minimally required to achieve the expected part reliability. The fixed process control documentation (PCD) is generally the core basis of control across the sector. These PCD approaches most always utilize a minimalistic, single-point process witness methodology to confirm process/part acceptance. Though required by some SDO production standards as well as the NASA-STD-6030, the implementation and acceptance of genuine statistical process control (SPC) methodologies remains uncommon. Where SPC is implemented, it is often segregated from actual part acceptance and used for “engineering information” only. This remains a significant standardization challenge. Even within the SPC implementation, there are differing opinions about whether SPC should apply to machine key process variables, the outcome of the final material performance, or both. It is not clear that standardizing SPC implementation in AM has the priority it needs withing the SDO community.

- **Machine/Equipment - Equipment control**

AM equipment control has recently made some modest gains in the standardization process within the SDOs; however, a consistent and standardized implementation of AM machine and equipment control remains elusive in this sector. The approach and extent to how machines and their facility environments are controlled varies greatly from instance to instance, often based on past practices or level of understanding of AM at a given entity. The NASA-STD-6033 provides a broad description of expectations of AM machine and facility control, primarily in the requirement of a plan for such control along with key aspects of controls expected to be addressed by the control plan. An SDO standard that attempts to define the minimum aspects of AM machine and facility control either does not yet exist or has failed to achieve consensus within this sector.

While there are unique aspects to AM equipment and facilities that require specific care and control, from a regulatory perspective there have not been any expectations of unique regulatory activities needed in this regard in the sector. The regulatory acknowledgement that such controls need to be defined and exist is considered adequate. Standards to assists in the implementation of machine and facility controls would make the regulatory aspect of accessing the adequacy of such controls easier and more consistent.

- **Part/Devices – Part classifications, if used, and what they affect in Q&C, Design, Part and/or Product Qualification, Difference in regulatory requirements by product type, Technical Data Package expectations**

The intent and implementation of part classifications remains very inconsistent across the sector. NASA-STD-6030 has provided a system of part classification that ranks parts first by consequence of failure into three primary classes, high to low (A, B, C), and sub-classes (1-4) based on risk criteria within classes A and B. Within the NASA spaceflight portion of the sector, NASA pushes hard for the use of these standard classifications, but there is limited consensus. The reality is that within any regulated sector, AM parts are likely to be pressed into a variety of service conditions that vary in criticality, usually based on safety or perhaps on liability or expense. Though some limited activity has occurred recently in the SDO community regarding standardizing AM part classifications, the vast majority of standards do not invoke the concept of AM part classification. As a general rule, SDO standards are written to a “lowest-common-denominator” that will pass a committee vote. When combined with the absence of classifications to segregate levels of control, the SDO products end up in a state considered inadequate for critical applications within the sector due to lack of specific controls that would need to be added in through extensive customer agreements in the purchase contract.

- **Personnel/Suppliers - Personnel training**

Training of personnel currently has minimal structure to it in this sector, even though proper training is a prerequisite for ensuring process control. While there are efforts underway to help train engineers and technicians in the variety of jobs related to AM, the predominant means of training continues to be on the job experience anchored by training offered by AM equipment manufacturers. The NASA requirements acknowledge the evolving training environment and recognize that many providers will prefer to have their staff internally trained. The requirement for training is that a formal method exist with documentation and that staff have clear understanding of what aspects of the AM process are covered by their training credentials.

- **Framework for enabling AM suppliers**

In the civil spaceflight sector, there continues to be a steady move toward the adoption of external AM suppliers. For this discussion, the scenario of an AM supplier exists when the producer of the AM parts is separate from the design entity and/or the "cognizant engineering organization." This creates a challenge regarding establishing requisite engineering equivalence of AM materials and processes between the design and production entities so that part performance is assured to meet the assumptions used in design. The NASA standards do not specify how external AM suppliers are qualified or enabled. Rather, they hold that the foundational process control and required material engineering equivalency is established and maintained through equipment and facility controls, qualification of materials and processes, statistical process controls, and so forth. In other words, it is incumbent on the cognizant engineering organization to ensure the supplier process is in full compliance with the base requirements and that the engineering equivalency of the material performance is ensured.

2.3.3.1.2 Civil and Defense Aviation Industry

Intent and motivation of each of Q&C guidance and standard documents

The primary public guidance and standard documents influencing the aviation industry today are:

- AIA Recommended Guidance for Certification of AM Components
- SAE AMS7000A, Laser-Powder Bed Fusion (L-PBF) Produced Parts, Nickel Alloy, Corrosion- and Heat-Resistant, 62Ni - 21.5Cr - 9.0Mo - 3.65Nb Stress Relieved, Hot Isostatic Pressed and Solution Annealed
- SAE AMS7001 – Nickel Alloy, Corrosion And Heat Resistant, Powder For Additive Manufacturing, 62Ni-21.5Cr-9.0Mo-3.65NbSAE AMS7002A – Process Requirements For Production Of Metal Powder Feedstock For Use In Additive Manufacturing Of Aerospace Parts
- SAE AMS7003A – Laser Powder Bed Fusion Process
- SAE AMS7004, Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate Ti-6Al-4V Stress Relieved
- SAE AMS7005, Wire Fed Plasma Arc Directed Energy Deposition Additive Manufacturing Process

Description of prescriptive versus performance-based aspects of Q&C in the industry

The performance-based approach is the recommendation of the aviation industry given in the *AIA Recommended Guidance for Certification of AM Components* whitepaper. It is the consensus that this is the preferred approach for both civil and defense metal AM parts for use within the Aviation industry. The basis of the following responses is a performance-based approach.

Materials

Material standards for aviation fall into 4 categories: (1) feedstock requirements, (2) final material requirements, (3) process control requirements, and (4) material allowables. SAE has separated the first three into separate specifications while ASTM has combined the first three into one specification. The last data category, for the most part, does not exist in a publicly accessible location like MMPDS to date. Historically, airframe metal allowables are published in MMPDS while engine metal allowables have most often been published in proprietary OEM databases.

Where metal AM specifications exist today, there remains gaps in the data. For example, both SAE and ASTM contain language which require porosity requirements to be provided by the purchaser. Significant manufacturing and materials engineering is required by each OEM to determine the appropriate porosity requirements. (See new gap FMP7 in 2.2.4.2.1.)

The current pace of material standards development for all four categories will not meet the required industry demand for material standards. Building an entirely new manufacturing process for a full suite of alloys will require a different approach than the historical consensus approach. There will be a significant material data and standards gap for aerospace applications until development is significantly accelerated.

New Gap QC17: AM Part Material Development Timeline. Building an entirely new manufacturing process for a full suite of alloys requires a different approach than the historical consensus approach so that industry timelines can be met.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Current state of technology does not allow material data set required. Use predictive modeling to replace testing, for example.

Recommendation: Develop standards, specifications, and allowables in concert to provide the industry a more robust material standards ecosystem.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM, SAE, MMPDS, CMH-17

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion;☐Material Jetting; ☐Powder B d Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Process/Procedures and Machine/Equipment

Machine/equipment Q&C is a subset of the overall AM process/procedure Q&C. Therefore, these are combined in the response to the "User Group/Industry Perspectives" questions.

Material standards (with noted deficiencies on specific limits) define what is required for AM qualification. An organized approach of following IQ/OQ/PQ qualification has been proven to meet aviation part requirements.

Traditionally, in all manufacturing processes, the manufacturing know-how to meet the defined requirement set is often held as a supplier trade secret. For a quickly expanding manufacturing technology like AM, the part manufacture learning is too slow to keep pace. The gap is therefore in publicly available information to help suppliers much more rapidly develop AM know-how. To use the 80/20 rule for illustrative purposes, AM Q&C is something like 80% process control and 20% machine capability. This means the Q&C primary gap is in OQ/PQ manufacturing know-how.

New Gap QC18: OQ/PQ Process Know-How. Public research is required to demonstrate in a serial production environment the Key Process Variables (KPVs) and the required process controls to maintain stability. To date such work primarily has been developed privately and is held as a trade secret.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: See recommendation

Recommendation: Carry out research to demonstrate in a serial production environment the KPVs and required process controls to maintain stability.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): Research institutes, universities, SDOs

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion;☐Material Jetting; ☐Powder B d Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Parts/Devices

Part Families

- Within the performance-based Q&C approach, part families and part classification are relatively straight forward. OQ part families is simply a combination of the additive method and material specification. For example, Inconel 625 LPBF would be an OQ part family. The PQ part family may be the same as the OQ family or may be a subset. For example, thin wall Inconel 625 LPF may require additional thin wall qualification.
- Part application or level of risk typically is NOT a reason to create a different part family. The manufacturing process for both the low-risk part and the high-risk part are likely the same. The difference between the two will be the level of quality control and inspection required.

Part Criticality and Risk

- Part criticality and risk level is a very important when determining the Q&C requirements. In order to ensure that part criticality is appropriately included within Q&C, it is important to understand the differences in similar (and often confused) terms. Criticality, Risk, and Failure Mode & Effects Analysis (FMEA) Risk Priority are related but different measures.

- **Part Criticality** is the severity or the consequence if a failure were to occur. Typical criticality levels are: (1) cause maintenance or repair, (2) reduced performance, and (3) possible loss of life or injury. Criticality levels are defined by the regulator. FAA, NASA, USAF, NAVAIR, NAVSEA, AMCOM, DEVCOM, engines, airframes, nuclear, etc. all have different definitions and requirements within regulatory and service branch documents. Part criticality levels are manufacturing process agnostic. Consequence of a part failure is NOT affected by whether the part is a casting, forging, or AM part.
- **Risk Level** is the combined effect of part criticality and the likelihood of a given failure mode. Of the two factors, part criticality is defined by the regulator, and the likelihood or probability of the failure is determined by the OEM or TC holder. The manufacturing method WILL affect the probability of a failure and therefore AM guidance would be useful to make this assessment. This is currently a gap.
- **FMEA Risk Priority** is worth understanding when discussing criticality and risk. A Failure Mode and Effects Analysis (FMEA) Risk Priority Number (RPN) is determined using three factors: (1) criticality severity or consequence, (2) probability or likelihood of a failure, and (3) detectability. Detectability refers to an operational failure of a part, and is manufacturing process agnostic. For example, detecting a broken oil tube relates to the part function and not the part manufacturing method. Detectability is determined by the OEM or TC holder. Well documented processes exist for this assessment.

Gap QC2: AM Part Risk Classification System for Consistent Qualification Standards. A part classification system is used to describe the **level of risk** associated with a part and may therefore be used as a metric to gauge appropriate qualification requirements. The risk level is determined by two factors: (1) the part criticality as defined by the regulator, and (2) the likelihood or probability of the failure as determined by the OEM. A standard is needed to define common AM failure modes and a method for each failure mode to determine qualitative failure likelihood or quantitative failure probability. In most cases, this will provide guidance related to manufacturing variation effect on design margin.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Projects 1804/1907 (WK65937, WK65929) address AMSC gap QC2.

Recommendation: Develop a standard to define common AM failure modes and a method for each failure mode to determine qualitative failure likelihood or quantitative failure probability. A technical report describing existing risk classification systems for AM parts also would be useful. It could include the recommended minimum process and part qualification requirements commensurate with part risk for each classification level.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F42/ISO TC 261, AWS, DoD, NASA, SAE

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Published standards since the last roadmap iteration include ASTM F3572-22, Standard Practice for Additive Manufacturing – General Principles – Part Classifications for Additive Manufactured Parts Used in Aviation which we understand will be referenced by EASA.

Part Performance

For design (FAA TC) Q&C, an engineering method standard work approach applies. This will define requirements for the creation of material allowables and the engineering methods used to determine design margins. It often includes an FMEA to identify and mitigate failure modes. This is manufacturing method agnostic and should follow a standard approach.

For production (FAA PC) Q&C, the part performance requirements are defined within the product definition. Additive parts do not require any unique product definition. All metal parts include: (1) dimensions and tolerances, (2) specifications, and (3) inspection requirements (part performance requirements). If a 3D CAD model is not part of the product definition package, it must be created from the 2D definition by the part producer. These elements are referred as Technical Data Packages (TDPs) by the DoD.

Following a performance-based Q&C approach, the following testing is required to ensure part performance:

1. Material testing to establish material specs and material allowables
2. OQ material spec testing
3. PQ material testing and inspection
4. First Article testing and inspection

5. Serial production witness coupon testing and inspection
6. Part performance testing, if required (e.g., pressure test)

Personnel/Suppliers - Personnel training

Today, training for operators, engineers, and certifying agencies is being performed as mostly on-the-job (OJT). A gap exists to in workforce training. Once publicly available manufacturing know-how with identified KPVs is developed, workforce training will need to be establish to support industry growth. Research institutes and universities must play an important role in workforce training.

New Gap QC19: Workforce Training. Publicly accessible OQ and PQ process know-how must first be developed and then be provided to the industry through workforce training programs. Research institutes and universities must play an important role in workforce training.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: For OQ and PQ (see prior gap QC18).

Recommendation: Develop publicly accessible OQ and PQ process know-how as the basis of workforce training programs.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): Research institutes, universities, SDOs

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion;☐Material Jetting; ☐Powder B d Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Framework for enabling AM suppliers

Today, the majority of aviation industry flight certified parts have been manufactured by the OEMs. However, the aviation industry largely depends on a healthy supply chain of independent production shops. Three items are required for independent production shops to be qualified:

1. OQ and PQ stable process know-how
2. Workforce training
3. Certifying agencies with established KPVs

Gaps have been identified for **OQ/PQ process know-how** and **Workforce training.** Item 3, certifying agency KPVs is related to items 1 and 2, but is itself a gap. Certifying agencies need public access to serial production data such that a supplier Q&C checklist can be established against known process KPVs. It is important that these KPVs are grounded in true production data so that the certifying agent can confidently provide supplier certification. The performance-based approach using established KPV performance metrics is a machine and supplier agnostic approach. It provides the freedom and innovation of machine OEMs and suppliers to meet the defined requirements.

New Gap QC20: Certifying Agency KPV Checklist. Publicly accessible OQ and PQ process know-how must first be developed and KPVs identified and supported with production data. These KPVs can then be used to establish certifying agency checklists.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: For OQ and PQ (see prior gap QC18).

Recommendation: Develop publicly accessible OQ and PQ process know-how based on production data to establish certifying agency checklists

Priority: ☐High; ☒Medium; ☐Low

Organization(s): Research institutes, universities, SDOs

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion;☐Material Jetting; ☐Powder B d Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Requirements Integration

Very few industry based requirements integration documents exist today. The *AIA Recommended Guidance for Certification of AM Components* whitepaper provides a high level overview of a performance-based approach. A gap exists that there is a need for a more detailed requirements integration for each technical area. Publishing such a document would provide a means of compliance to the regulatory requirements.

New Gap QC21: Detailed Requirements Integration Document. Publicly accessible OQ and PQ process know-how must first be developed and then be published in a detailed requirements integration document.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: For OQ and PQ (see prior gap QC18).

Recommendation: Develop publicly accessible OQ and PQ process know-how and publish it in a detailed requirements integration document.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): Research institutes, universities, SDOs, regulators

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion;☐Material Jetting; ☐Powder B d Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Quality Assurance

The performance-based Q&C approach uses the same quality and inspection methods used for castings and forgings. . AM parts can provide unique challenges as compared to castings and forgings for CT scan and surface inspection. A potential QA gap was identified for tailoring NDE techniques – to define methods and defect size requirements tailored to AM processes for CT scan and surface inspection – but the WG was unable to reach a consensus on this topic.

2.3.3.2 Automotive Industry

This industry sector may be at a more nascent stage in its use of AM and content was not provided for the roadmap.

The process control WG has noted this nearly published standard: ISO/ASTM DIS 52945, Additive manufacturing for automotive — Qualification principles — Generic machine evaluation and specification of key performance indicators for PBF-LB/M processes.

2.3.3.3 Construction Industry

This industry sector may be at a more nascent stage in its use of AM and content was not provided for the roadmap.

2.3.3.4 Defense Industry

For aircraft flight applications, refer to 2.3.3.1.2, Civil and Defense Aviation Industry.

The defense industry does not have a certification program like the FAA or NASA as a standard requirement across the industry. So, the certification and qualification of material, machine, process, and build is not exactly the same from company to company or even across the defense agencies. In some ways qualification of a part for a Defense Acquisition remains very similar to standard parts. Anything going onto a ship, aircraft, submarine, ground vehicle, or otherwise employed by our military forces goes through varying levels of Q&C prior to deployment. Even commercial or non-developmental items have to be tested to make sure they meet the technical and performance requirements demanded by the platform. Depending on the rigor required for the part usage, it is evaluated at a component and system level. Rigor is dependent on class classification of parts. A common evaluation for AM and non-AM parts are class classification. Different groups rate their class classification differently, but they all evaluate an overall understanding of application, characterizing the risk (from low to high) and the probability of failure. For example, any new aircraft undergoes rigorous developmental and operational testing before fielding, no matter the origin of the item on the platform. Components are tested individually, as part of a system, perhaps integrated into an avionics suite or green weight airframe as appropriate, then flight tested as appropriate before a decision is made for full rate production. This happens regardless of how that part is manufactured.

As industry standards and specification are created, groups are starting to add them into their standard process, but it is slow for two reasons. One, groups have already created and started to qualify to their own internal specs. Two, it is hard to find suppliers that can meet the requirements of the industry standards and specifications currently. There is a movement towards them, but it is slow. Future state may have some groups heavily using them and others remaining primarily only with their internal specs. While standards are being developed for many applications, there is still a need for defense industry specifications to capture unique requirements and materials for the military.

Different groups leverage different allowable[25] tools and requirements. Both MMPDS and CMH-17 are developing a framework of methodologies and policies for additive processes. These frameworks as well as internally developed allowables are being used. Some groups go beyond traditional allowable recommendations because of the variability of the AM process; some qualify by machine-to-machine and others go to a wide variety of suppliers to get a larger variability.

The U.S. Department of Defense (DoD), through its Joint Defense Manufacturing Council released the Department of Defense Additive Manufacturing Strategy (January 2021). DoD is working with the Defense Logistics Agency (DLA), and the Office of Safety & Defense (OSD) on a Joint AM Acceptability (JAMA III) initiative**.** The JAMA project is the result of the DoD Instruction (DoDI) 5000.93, Use of Additive Manufacturing in the DoD, which became effective on 10 June 2021. The goal of JAMA III is to "Generate frameworks for a *common AM part qualification process* for the DoD and industry stakeholders to facilitate *commercial integration of AM vendors* into the DoD supply chain, while maintaining quality standards."[26]

DLA has expressed strong support for use of AM for acquisition, particularly in manufacturing decades old legacy parts that no longer have a supporting industrial base. However, the technical data associated with these parts is specific to casting, forging, and other traditional processes usually found as 2D blueprints, thus requiring a conversion to AM specific models. In addition to the added cost of this

[25] See discussion of terminology ("material allowable" and "design value") in section 2.2.4.1.1 of this roadmap.
[26] Presentation slides from January 18, 2023 JAMA III AM Standards & Specifications Discussion. Contact dlarddeloittejamateam@deloitte.com for more information.

process, current methods of converting to AM tech data introduces changes which require requalification.

On June 6, 2023, the Defense Advanced Research Projects Agency (DARPA) posted a Request for Information (RFI) seeking new ideas on *revolutionary* approaches to transform today's arduous process of part qualification. The intent of the RFI is to shape a potential future DARPA program in this area to test concepts that are very different from how things are done today. High-level DoD interest in this area is to accelerate and enable widespread U.S. industrial base participation for potential future surge production needs. DARPA is also planning a workshop in Arlington, VA on August 15, 2023 (by invite only) to brainstorm new concepts based on the RFI responses received. Additional information is available at https://sam.gov/opp/bc5c3d4a79414d768421201181e16f28/view.

DOD Technical Data Package (TDP)

A TDP is defined in MIL-STD-31000B, Military Standard: Technical Data Package (TDP) (31-OCT-2018), section 3.1.40 as:

> *The authoritative technical description of an item. This technical description supports the acquisition, production, inspection, engineering, and logistics support of the item. The description defines the required design configuration and/or performance requirements, and procedures required to ensure adequacy of item performance. It consists of applicable technical data such as models, engineering design data, associated lists, specifications, standards, performance requirements, quality assurance provisions, software documentation and packaging details.*

A TDP is used to contract out for the procurement of parts and components for DoD assets. The goal of developing a TDP is to encompass all the necessary data to allow for competitive bidding for parts to be additively manufactured, while ensuring that there is enough detail and information within the TDP to produce the same exact part with the same properties that fall within the specified tolerances and requirements from any vendor. The development of an AM TDP will not be possible without specifications and standards that can be invoked to guide the manufacturing process.

As TDP's are developed, there is a push for an increased awareness of digital thread for all parts, but especially AM parts, capturing data from design, analysis, build files, manufacturing plans, etc. One of the biggest hurdles in this area is software capability.

There are a number of cooperative research & development agreements (CRADAs) between defense agencies and defense contractors to help align and build a common understanding, and to bring both group knowledge of AM up and have the same understanding and requirements for TDPs.

Navy efforts have included developing a part- and process- agnostic TDP format that will aid in the overall process for manufacturing components via additive manufacturing (regardless of criticality). It is understood that there are a number of challenges associated with developing a process-agnostic TDP.

See the discussion in section 2.1.5, Design Documentation, of this roadmap and gap DE17 on contents of data packages.

Neutral build files are the desired end state for build files that can be ported between different types of machines/processes. See also gap DE20 on neutral build file format.

Harmonizing Q&C Terminology for Process Parameters

Each machine manufacturer has their own set of terms that they use to describe the processing parameters within their machine. Often, two identical process parameters will have different terms associated with that parameter if you directly compare two machines made by different manufacturers.

Published Standards

- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing
- ISO/ASTM 52900:2021, Additive Manufacturing - General Principles - Fundamentals and vocabulary
- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05)

In-Development Standards

- ASTM WK65929, Specification for Additive Manufacturing-Finished Part Properties and Post Processing - Additively Manufactured Spaceflight Hardware by Laser Beam Powder Bed Fusion In Metals
- ASTM WK65937, New Specification for Additive Manufacturing -- Space Application -- Flight Hardware made by Laser Beam Powder Bed Fusion Process

Gap QC3: Harmonizing Q&C Terminology for Process Parameters. In order to enable full understanding of the given processes and to include this type of information in a process-agnostic TDP, and for purposes of qualification and/or certification, there must be standardization of process parameter terminology across machine manufacturers.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Projects 1804/1907 (WK65937, WK65929) address AMSC gap QC3.

Recommendation: Develop standardized terminology for process parameters for use across all AM equipment. Incorporate terms as appropriate into ISO/ASTM 52900:2021, Additive manufacturing - General principles – Fundamentals and Vocabulary. See also gap PC5 on parameter control.

Priority: ☐ High; ☒Medium; ☐Low

Organization: ASTM F42/ISO TC 261 JG 51, AWS D20, SAE AMS-AM, IEEE-ISTO PWG

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

Process Approval for DoD-procured Parts

For a lot of defense agencies and contractors, before a vendor can supply a component, that vendor must be qualified to manufacture that part with an AM specific process, machine, and sometimes serial number (S/N) of machine. Q&C necessarily is applied to the actual manufacturer, not a third party that may act as a middleman or distributor. For every Source Approval Request (SAR) package, a vendor must demonstrate manufacturing standards, first article test, and requisite performance testing within their capacity to do so. The manufacturing methods for the part must be specified by the vendor along with any other critical processes through the end of post-processing. This would include all of the parameters needed to qualify or certify the final part. Depending on the use, the defense agency often requires additional environmental testing, be it flight, seaworthiness, or electromagnetic compatibility. As AM continues to rapidly mature, especially in the near term, it may be challenging to keep up with the pace. Therefore, industry and government will have to work together to understand the nuances of different AM methods, and what needs to be qualified, tested, and demonstrated by an AM produced component. ASTM has begun to populate the landscape with some standards, such as ASTM B962-17, Standard Test Methods for Density of Compacted or Sintered Powder Metallurgy (PM) Products Using Archimedes' Principle, which has already undergone several revisions.

Certification of parts is governed by regulations for criticality and safety criteria based on the application. Responsibility for certification of the components for the intended application needs to be agreed to between the customer (DoD) and the supplier/manufacturer of the AM component.

Identified published standards include: ASTM B962-17 noted above, ASTM E384-22, Standard Test Method for Microindentation Hardness of Materials, and ASTM F3213-17, Standard for Additive Manufacturing - Finished Part Properties - Standard Specification for Cobalt-28 Chromium-6 Molybdenum via Powder Bed Fusion.

Gap QC4: Process Approval for DoD-procured Parts. As multiple methods of AM continue to mature, and new AM techniques are introduced, the government will need to fully understand the ramifications of each of these techniques, of what they are capable, and how certain AM procedures might lend themselves to some classes of parts and not others. Thus, not only must the government understand the differences, but how they should be assessed and tested, and what additional checks must be made on the end product before it can be qualified for use in a military platform. High pressures, temperatures, and other contained environments could impact the performance or life of safety-critical parts in ways that are not understood. More research is required to determine the delta between traditional and AM methods.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Starting with the most mature technologies, such as laser powder bed, there is a need to develop standards that assess required checks for levels of criticality and safety as part of the DoD procurement process. DoD should participate in the development of such standards and specify the certification requirements needed.

Priority: ☐ High; ☒Medium; ☐Low

Organization: ASME, ASTM F42/ISO TC 261, DoD, Industry, SAE, Service SYSCOMS

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☒Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

Machine Operator Training and Qualification in the DOD Framework

Training and qualification are not standardized across the defense industry, since many AM processes do not have standards to address them, and many users rely on internal requirements for training and qualification. All potential users of an AM machine, auxiliary equipment, and related software need to undergo appropriate training for their responsible areas. There may be different levels of operator training required. AM machine operator competencies may include: feedstock material storage, safety, and setup; machine calibration and maintenance; machine setup and operation; build cycle monitoring; and interruption recovery. Re-training at some frequency also may be required. An internal training database should be maintained and used to reflect operator competencies on each responsibility and to ensure any changes in machine operation are accounted for in training updates. Periodic audits may be used to validate that operation steps are being followed.

Published Standards

ISO/ASTM 52942:2020 Additive manufacturing — Qualification principles — Qualifying machine operators of laser metal powder bed fusion machines and equipment used in aerospace applications (aka ASTM F3471-20, was ASTM WK73170)

The SAE 7000 series also addresses training. There is also SAE ARP 1962B-2019, Training and Approval of Heat-Treating Personnel, though it is not AM-specific.

AWS D20.1 contains a Clause 6 on requirements for AM machine operator performance qualification. It requires that the AM machine operator undergo training, written examination, practical examination, and a build demonstration in order to become qualified.

in-Development Standards

- ASTM WK65937, New Specification for Additive Manufacturing -- Space Application -- Flight Hardware made by Laser Beam Powder Bed Fusion Process
- ASTM WK72458 New Specification for Additive Manufacturing -- Qualification principles -- Qualification of coordinators for metallic parts production
- ISO/ASTM DIS 52926-1, Additive manufacturing of metals — Qualification principles — Part 1: General qualification of operators (see also ASTM WK71375 /F3500)
- ISO/ASTM DIS 52926-2, Additive manufacturing of metals — Qualification principles — Part 2: Qualification of operators for PBF-LB (see also ASTM F3466)
- ISO/ASTM DIS 52926-3, Additive manufacturing of metals — Qualification principles — Part 3: Qualification of operators for PBF-EB (see also ASTM F3467)

- [ISO/ASTM DIS 52926-4, Additive manufacturing of metals — Qualification principles — Part 4: Qualification of operators for DED-LB (see also ASTM WK71378 / F3468)]()
- [ISO/ASTM DIS 52926-5, Additive manufacturing of metals — Qualification principles — Part 5: Qualification of operators for DED-Arc (see also ASTM WK71379 / F3469)]()

Underwriters Laboratories (UL), in cooperation with industry SMEs, for example, has developed a multi-tiered program covering comprehensive introductory knowledge, technical and business competencies, and hands-on application-based learning. The University of Louisville is host to UL's advanced hands-on training focused on metals. The program emphasizes the safe implementation of AM and in collaboration with Tooling-U SME, includes the industry's first Professional Certification. ASME is also exploring machine operator training curriculum.

Gap QC5: Machine Operator Training and Qualification. There is a need for standards or guidelines outlining AM training requirements. AM training programs include but are not limited to those offered by OEMs and other third-party organizations.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop AM operator training and qualification standards or guidelines. The provision of equipment-specific training is the purview of OEMs. At a high level, SDO training materials are aimed at covering the various AM materials and processes available in the market and are performance based to ensure consistent AM part quality. Develop additional standards for artisanal levels of competency and experience, delineating an individual's expertise in the field or subsets of the AM field.

Priority: ☐High; ☐Medium; ☒Low

Organization: NASA, SAE, AWS, OEMs, UL, ASTM F42/ISO TC 261, AAMI

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

Concerns also include training for enlisted personnel, training tailored for specific AM machines (or categories thereof), and materials as needed to complete mission requirements. Such a training course should include:

Qualification

- Software and CAD file preparation
- Knowledge of machine and material limits
- Machine calibration and maintenance (whether performed by the operator/vendor or the machine OEM)
- Proper material handling
- Proper waste recycling/containment
- Monitoring of the fabrication process
- Part separation from the build plate
- Post-processing (if performed by the operator/vendor)
- Inspection/testing (if performed by the operator/vendor)
- Safety precautions for AM machine and material use

Certification

- Reading all applicable standards and supplements on AM certification (when developed)
- Testing in accordance to these standards
- Completing an AM performance qualification test at an accredited test facility
- Submitting a completed application for certification
- Submitting maintenance of AM certification prior to expiration, which verifies that all the AM processes were used

Material Certification Within the DOD Framework

Precursor materials will have to meet certain specified requirements in order to be used for AM processes. The current specifications and standards along with the gaps that exist for precursor materials can be found in the Precursor Materials section of this document. Due to the nature of how parts are made, and how differences in orientation, build plate location, or AM processes are being used, the buildup of stresses and resulting material properties may vary between machines and build plates. Responsibility for verification and testing of the material properties (including test coupons/artifacts) and for compliance with the performance requirements of the components needs to be agreed to between the customer (DoD) and the supplier/manufacturer of the AM component.

Qualification and Certification Testing of Final Parts Within the DOD

As previously mentioned, the certification of final parts for use will be a significantly more difficult process for AM components as a result of the lack of allowables for AM materials and the lack of consistency between AM parts made via different AM processes and even parts made via the same process using different equipment. The challenges associated with the gaps in standards and specifications for finished materials are addressed in the Finished Material Properties section of this document.

2.3.3.5 Electronics and Electrical Products Industry

This industry focuses on producing electrified products for use in residential, commercial, and industrial applications including homes, retail/hospitality establishments, public spaces, offices, and factories/warehouses. The category can be subdivided into indoor and/or outdoor applications. Furthermore, the category is sometimes further divided into home and/or professional applications. Typically, such products are qualified and verified as part of a product certification to demonstrate compliance with recognized product safety and performance standards. Also, since these products may become permanent or semi-permanent elements of built structures, or structures themselves, they are required to comply with installation and use requirements of relevant electrical or building codes and regulations. Some electronic components are also used in other industries covered by other sections of this chapter. This section is not covering Q&C requirements in those other industries.

Use of Additive Manufacturing

AM has been in regular use to produce prototypes for physical examination, fit/function analysis and test sample purposes. AM has also been used to produce tooling or jigs for mechanical product manufacturing purposes.

Previously, there has been an industry shift toward an interest in using AM to produce mechanical parts for targeting proof-of-concept, prototype, and volume applications. Recently a new industry started to evolve which additively creates traditional electronic printed circuit board (PCB) assemblies with either formed and/or unpackaged/prepackaged components, known as Additively Manufactured Electronics (AME). These substrates merge component and electrical data from mechanical and electrical CAD systems (MCAD and ECAD, respectively). For example, a wire wound inductor shape is created in MCAD, loaded into an ECAD PCB layout, given electrical properties, and embedded into the schematic and layout, then additively formed within the circuit board. This is also including AM created semiconductor devices. Functionally-graded materials for both dielectrics and conductors are being introduced which are compatible with AM processes to supplant traditional PCB materials, for example nano particle inks for printing methods. Multiple trade organizations and academic research institutions have begun to examine the advantages of AM and are promoting its adoption for these applications. The AME assemblies cross into all application domains.

Qualification and Certification

Since electrical and electronics products are typically required to be qualified and certified to existing product safety and performance standards, the use of an equivalent AM built component or full product should also conform to the practice of standards. Many of the applicable standards contain type-test based evaluation criteria which allow parts to be qualified based on their physical and electrical properties. Accordingly, type-testing of AM parts is an option. These standards also contain prescriptive requirements based on historical data. The application of these prescriptive requirements could require reconsideration of applicability to parts fabricated by AM. Certifications generally require ongoing verification in production to ensure consistency between production parts and parts subject to prescriptive and/or type-test qualification. Variations in parts due to different AM processes or parts made using different equipment must be addressed. To address some of these variables, standards have been developed for polymeric materials as described in the Identified Guidance Documents section of this document.

Currently there are no industry qualification or certification standards for AME technology. A significant amount of investigation and testing is required due to the significant physical difference between existing PCB and PCB assemblies, which use copper plated mechanically drilled, or laser ablated, holes to connect between layers of horizontally etched traces, versus additively created X,Y,Z interconnect structures.

Since products in this category often also need to conform to installation requirements contained in codes and regulations, consideration must be given to the application of AM parts in this context. Such codes and regulations can focus on criteria such as fire resistance, smoke generation, structural integrity and toxicity. As AM and AME mature as methods of manufacturing general purpose electronic and electrical products, there is a need to understand the possible ramifications on compliance with product safety/performance standards and regulations. An understanding of differences between traditional manufacturing techniques and AM regarding end-product performance is needed.

Published Standards: None identified

In-Development Standards

The following new IPC projects are planned to start in 3Q2023 and be released by 4Q2025.

- IPC-6905 Qualification and Performance Specification for Additively Manufactured Electronics (AME)
- IPC-6911 Acceptability of Additively Manufactured Electronics (AME)
- IPC-B Additively Manufactured Electronics (AME) Coupons

New Gap QC22: Additively Manufactured Electronics (AME). No qualification, acceptability, and coupon standards currently exist for 3D AME substrates where traditional AM electrically functional components are created within an electrical PCB-like substrate. See also roadmap section 2.6.2.9 on AME data transfer format and gap DA7.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Reliability and qualification standards with validating research is required for all industries.

Recommendation: Develop standards for AME technology.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): IPC, IEC

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☒Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: The current alternative is to manufacture AME substrates by extrapolating reliability and qualification requirements from existing IPC printed circuit board specifications and test methods.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.3.3.6 Energy Sector

2.3.3.6.1 Nuclear Industry

Introduction

The U.S. Nuclear Sector is similar to other energy and industry sectors in experiencing challenges with qualification and certification of components produced via additive manufacturing (AM). From the U.S. Department of Energy's (DOE) Office of Nuclear Energy (NE): Advanced Materials and Manufacturing Technologies (AMMT) Program:

> *Certification and qualification of processes and/or parts produced through advanced manufacturing presents a significant challenge for the nuclear power industry. Current approaches rely on extensive post-build evaluations and often require several build iterations to demonstrate convergence of part build quality and variability. In situ data (e.g., data about the component or part collected during the AM process) is used to confirm or highlight potential issues, but it has not yet been used as a surrogate or to supplant traditional quality evaluations.*

The U.S. nuclear industry is undergoing a new renaissance.[27] Traditional methods of manufacturing and construction are now being revolutionized by AM. AM offers new complex, geometric builds in various materials and alloys which enables advanced and optimized designs not previously possible. The acceptance and certification of AM components must also be a priority. Technological advances allow for a digitally certified component build that may assure that quality aspects are met. There remain some gaps that must be addressed to fully exploit the use of AM, as further discussed in the gaps section below.

Industry Governance

The U.S. nuclear energy industry (i.e., entities that use nuclear fission or will use nuclear fusion to produce electricity)is governed, regulated, and/or licensed by a combination of government agencies including the Nuclear Regulatory Commission (NRC), Department of Defense (DOD), National Aeronautics and Space Administration (NASA), and the Department of Energy (DOE). According to the U.S. General Accounting Office (GAO), DOE seeks to advance nuclear energy through research and

[27] Hochman, Thomas and Nate, The New Atlantis, "A Nuclear Renaissance? Stalled for decades, U.S. atomic power seems set for a comeback. Here's what it'll take to get it right this time." (Fall 2022). Accessed 6/23/2023 https://www.thenewatlantis.com/publications/a-nuclear-renaissance

development activities. It is also responsible for siting, building, and operating a geologic repository to dispose of high-level nuclear waste.

The NRC's approach to AM is to identify the safety-significant differences between AM and conventional manufacturing to focus limited resources on the areas of greatest importance (M. Hiser et al., J. Nuclear Materials 546 (2021). The NRC is actively regulating and monitoring the use of AM parts within nuclear applications.

The NRC licenses and oversees the safe operation and security of commercial nuclear power plants, research reactors, and other nuclear production and utilization facilities. The NRC, in conjunction with state and local regulatory agencies, is responsible for all U.S. commercial nuclear plants (93 licensed power reactors), research and test reactors (31 operational), and private isotope facilities. Nuclear fuels and fuel cycle facilities in the U.S. are also regulated and licensed by the NRC and include additional regulatory processes defined in Title 10 to the Code of Federal Regulations (10CFR) 10CFR70 and others. NASA works in conjunction with the NRC and DOE in researching, overseeing, and regulating U.S. nuclear space applications.[28]

The DOE serves much of the research role for the public and private nuclear industry while also regulating research reactors and isotope production facilities residing on DOE sites, namely at national laboratories. Examples of these include the isotope research and production facilities and the High-flux Isotope Reactor (HFIR) residing at Oak Ridge National Laboratory (ORNL) and the Advanced Test Reactor at Idaho National Laboratory (INL). There are a total of approximately six operating reactors and numerous nuclear facilities under DOE oversight and regulation.

The DOE National Nuclear Security Agency (NNSA) is also responsible, in conjunction with the DOD, for the nuclear weapons stockpile readiness, production, and disposition. The Naval Nuclear Propulsion Program provides militarily effective nuclear propulsion plants and ensures their safe, reliable, and long-lived operation. NNSA's Naval Reactors Program provides the design, development, and operational support required to provide militarily effective nuclear propulsion plants and ensures their safe, reliable and long-lived operation.

Various departments within the DOE are involved in material and qualification research into general additive manufacturing including the Advanced Materials and Manufacturing Technology Office (AMMTO) and the Industrial Efficiency and Decarbonization Office (IEDO) taking over responsibilities for the Advanced Manufacturing Office (AMO). For nuclear applications, the DOE's Office of Reactor Fleet and Advanced Reactor Deployment has established the AMMT program, specifically focused on material research and qualification for nuclear applications. Both of these DOE efforts include participation by

[28] https://www.nrc.gov/docs/ML2021/ML20210M302.pdf

research entities, faculty, resources, and personnel from U.S. academia and the DOE national laboratories.

Nuclear part fabrication, qualification, and certification processes are unique. The highest levels of quality, material specifications, and requirements are applied. The parts must be able to withstand and perform their safety functions while being exposed to potentially long-term and high levels of radioactivity and exposure to potentially corrosive environments. To support these safety functions, additional specifications and testing of nuclear parts are performed to ensure the radiation and corrosion effects do not alter the performance of the component materials and parts. Parts sourced from commercial vendors, if serving a nuclear safety function, must be dedicated for their function using nuclear quality assurance (QA) programs according to 10 CFR Parts 50 and 52 and/or the American Society of Mechanical Engineers (ASME) NQA-1 quality assurance standards. Additionally, DOE regulations also require compliance with 10 CFR 830, Nuclear Safety Management, and DOE Order O-414.1D, Quality Assurance, among others.

Use of Additive Manufacturing

The current NRC regulatory framework allows the review of submittals involving the incorporation of AMT-fabricated components. As shown in Table 1, the NRC has published both generic technical bases and draft technology-specific guidelines for specific AM processes. The NRC has developed draft guideline documents for PBF-L, DED-LB, and cold-spray (CS) to assist the staff with reviewing potential submittals. The NRC has developed a document for implementing the 10 CFR 50.59 "Changes, Tests, and Experiments" process pertaining to AMTs.

Action Plan Reports

Subject	ADAMS Accession No.
AMT Action Plan, Rev. 1	ML19333B980
Draft review guidelines	ML21074A037
Implementation with 10 CFR 50.59 process	ML21155A043
Assessment of regulatory guidance	ML20233A693
NDE gap analysis	ML20349A012
Modeling gap analysis: microstructure	ML20269A301
Modeling gap analysis: performance	ML20350B550

	Technical Letter Report/ Technical Assessment	Draft Guidelines Documents
LPBD	ML20351A292	ML21074A040
L-DED	ML21301A077	ML22143A951
CS	ML21263A105	ML22143A952
EBW	ML22143A927	*future work—as industry projects are completed*
PM-HIP	ML22164A437	

Table 1. Reports NRC published to provide more insight into the use of advanced manufacturing technologies for reactor applications (https://www.nrc.gov/reactors/power/amts.html).

The DOD and NASA have issued standards and guidance for the use of safety components, systems, and structures, while being fairly silent on their use in nuclear applications. The NRC reviews and utilizes commercial standards to the extent practicable, such as ASME, ASTM International, the American Welding Society (AWS), and the International Organization for Standardization (ISO), to provide the AM material, process, and qualification standards required to be used in nuclear applications. The NRC's approach to AM is to identify the safety-significant differences between AM and conventional manufacturing. AM fabricated stainless-steel components recently installed in the nuclear fleet include a thimble plugging device placed in service in Byron, Unit 1 in 2020 and fuel channel brackets which were placed in service in 2021 in Browns Ferry, Unit 2. .

AM techniques, especially binder jetting technologies, are actively being used to research and produce a new ceramic high-temperature fault-tolerant nuclear fuel called TRi-structural ISOtropic (TRISO) which is actively being prototyped for production by several private nuclear companies. These fuels were originally developed in the 1960s at Los Alamos National Laboratory (LANL), INL, ORNL and other labs. Recent technological advances in AM and fuel process now allow full-scale production and implementation.

AM part production may include rapid design iteration and novel geometries and design optimizations not possible with traditional manufacturing methods. The use of intelligent AM machines allows integration of advancements in embedded sensors, artificial intelligence, and machine/system learning technologies that lend themselves to real-time understanding of fabrication quality and performance. These technologies allow fabricators to know more about a completed part than previously. They may be brought to bear in complex and higher quality applications like the nuclear sector. Areas of interest for future research include: material science, AM techniques, finishing improvements, testing methods, and inspection, including non-destructive evaluation (NDE), to address surface finish, complex geometries, dimensional tolerances, powder residue and reuse, and closed cavities.

Relevant Programs and References

DOE NE AMMT 2022 Roadmap

The Advanced Materials and Manufacturing Technologies (AMMT) program will develop cross-cutting technologies in support of current fleet and next-generation advanced nuclear reactor technologies and maintain U.S. leadership in materials and manufacturing technologies for nuclear energy applications. The overarching vision of the AMMT program is to accelerate the development, qualification, demonstration, and deployment of advanced materials and manufacturing technologies to enable reliable and economical nuclear energy. This roadmap identifies key research needs, challenges, and opportunities; outlines strategic research priorities; and provides a detailed five-year plan to realize the mission and vision of the AMMT program.

The major goals of the AMMT program are (1) to develop advanced materials and manufacturing technologies that have cross-reactor impacts, (2) to establish a comprehensive framework for rapid qualification of new materials made by advanced manufacturing, and (3) to accelerate *commercialization of new materials and manufacturing technologies through demonstration and deployment.*

Electric Power Research Institute (EPRI) Advanced Nuclear Technology (ANT) Program

The ANT program's mission is to reduce the risk and uncertainty of constructing and operating new nuclear power plants. The program reviews existing technologies from inside and outside the nuclear industry in order to evaluate and adapt those technologies best suited for use in nuclear power plants. This is done by finding, defining, and extending useful and valuable existing technologies; performing necessary R&D to determine the efficacy of those technologies in nuclear applications; and working with codes and standards organizations to potentially enable effective use of the new technologies. The program also performs R&D to help address new plant design challenges in the areas of construction, operations and maintenance that can lead to optimized performance, during and after construction. ANT also collaborates with various industry organizations to further the reach and impact of the program's research, including IAEA, WANO, and NEI.

EPRI funds private research into AM technologies for use in the nuclear energy sector.

EPRI presented the "Vision of Advanced Manufacturing Technology (AMT) Use in the Nuclear Industry," at the NRC Workshop on Advanced Manufacturing Technologies for Nuclear Applications, December 7-10, 2020

Nuclear Energy Institute (NEI)

From the NEI Website:

> *NEI's mission is to promote the use and growth of nuclear energy through efficient operations and effective policy.*
>
> *NEI accomplishes this by providing a unified industry voice before Congress, the executive branch, state and local legislatures, and federal regulators, as well as international organizations and venues, on key policy issues.*

From the Roadmap for Regulatory Acceptance of Advanced Manufacturing Methods in the Nuclear Energy Industry, prepared by the NEI, May 13, 2019:

> *Advanced manufacturing methods (AMM) have the potential to transform the nuclear industry by producing high quality components faster and cheaper, and enhancing the performance of current operating plants and advanced reactors. AMM could also be used to quickly supply replacement parts for obsolete components and to reduce warehouse inventories.*
>
> *A number of companies are preparing to use AMM to fabricate components for current operating plants and future advanced reactors. However, a lack of clarity on the regulatory pathways, and on*

the ability to gain timely regulatory approval (if it is needed), for AMM fabricated nuclear components are potential barriers to their use.

Nuclear Regulatory Commission (NRC)

As shown in Table 1, the NRC has published both generic technical bases and technology specific guidelines for initial AMTs as part of the AMT Action Plan (ML19333B980). A useful overview perspective is presented by J. Nuclear Materials 546 (2021) "Regulatory Research Perspective on Additive Manufacturing for Nuclear Component Applications." Work is continuing on additional AMTs, NDE methodologies, and technology gaps.

Gaps

- Summary of Q&C standardization gaps identified:
  - **New Gap QC23**: Production and Incorporation of AM Parts in Nuclear Applications and Facilities.
  - **New Gap QC24**: Nuclear AM Component In-service Performance.
  - **New Gap QC25**: Nuclear Industry Use of Artificial Intelligence (AI) and Machine/System Learning Technologies
  - **New Gap QC26**: Nuclear Industry Use of Material and Production Data Combined with Digital Analysis and Diagnostic Informed Qualification of AM Components
  - **New Gap QC27**: Use and Qualification of AM Non-metallic Advanced Materials in Support of New or Advanced Nuclear Fuel and High-temperature Reactor Applications.

New Gap QC23: Production and Incorporation of AM Parts in Nuclear Applications and Facilities. More research and guidance would likely result in improved AM production capabilities in the nuclear sector including the ability to control grain structures, apply novel geometries, and rapidly produce parts for repair, replacement, and/or production while meeting the requirements of applicable standards and codes under radiological conditions.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: DOE, NRC, and EPRI have solicited research and inputs on the use of AM parts in nuclear applications. DOE Nuclear Energy (NE) has formed a program called the Advanced Materials and Manufacturing Technology (AMMT) to continue work begun under the Transformational Challenge Reactor (TCR) and other similar DOE laboratory programs that began the process of testing materials and designs for nuclear applications, especially utilizing stainless steel. Additional research should include the expansion of materials to include high-heat ceramics, embedded sensors, in-situ monitoring, stainless and other steels, including radiological effects on them, and the qualification of AM materials and related parts.

Recommendation: Additional guidance and research is required to support codes and standards development, qualification, certification, implementation, disposition, and licensing of nuclear AM parts.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): NRC, DOE (i.e., AMMT), NEI, EPRI, ASME, ASTM

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☒Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☒Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☒Material Extrusion; ☒Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☒Other (specify)

Current Alternative: Individual efforts to incorporate AM parts through regulatory processes may require additional testing and qualification.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap QC24: Nuclear AM Component In-service Performance. Monitoring the performance of AM parts, when installed in nuclear applications depends on the component's intended function, location and access. Due to the mechanism of layering powder in AM systems like Powder Bed Fusion and Directed Energy Deposition, in-situ monitoring systems can be embedded within the parts during the production process that allows real-time monitoring of part and reactor performance. The process of embedding sensors within AM parts has been tested with some success at the national laboratories, but additional research is needed to mature the process to production scale and initiate testing within the U.S. nuclear fleet. The embedding process and equipment maintainability should be considered during the design process before incorporating this technology.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Both DOE and the NRC have solicited research and inputs on the use of in-situ monitoring of AM components in nuclear applications. DOE Nuclear Energy (NE) has formed a program called the Advanced Materials and Manufacturing Technology (AMMT) to continue work begun under the Transformational Challenge Reactor (TCR) and other similar DOE laboratory programs that began the process of testing in-situ monitoring combined with ex-situ examination techniques as inputs into AI and machine learning algorithms to rapidly detect potential quality anomalies during the manufacturing process and monitor in-service performance.

Recommendation: Additional guidance and research is required to ensure the development, qualification, certification, implementation, disposition, and licensing of nuclear AM parts utilizing advanced monitoring and intelligent systems combined into a digital platform to help inform the quality of AM parts.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): NRC, DOE, NEI, EPRI, ASME, ASTM, AMMT

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☒Automotive; ☐Construction; ☒Defense; ☐Electronics; ☒Energy; ☐Medical; ☒Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☒Other (specify) Combines computer controls, in-situ monitoring, and artificial intelligence.

Current Alternative: Traditional in-service part monitoring may require costly techniques and processes or removal from service for inspection.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap QC25: Nuclear Industry Use of Artificial Intelligence (AI) and Machine/System Learning Technologies to Qualify AM Parts. There is a need for additional research, guidance, and standards on the use of Artificial Intelligence and Machine/System Learning technologies and techniques to rapidly inform AM part qualification and acceptance for high quality and safety applications in the nuclear industry. AM part design and production allows for real-time monitoring of AM machine performance and part quality that can inform production and quality personnel of potential issues with the machine, build, and part performance. The use of modern intelligent computer and system learning applications to rapidly identify potential AM quality and conformance issues has begun development and testing in the national laboratories and private industry but needs additional support and research to mature for application and acceptance by regulatory bodies, standards organizations, and quality organizations.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Both DOE and the NRC have solicited research and inputs on the use of AI and machine learning in AM nuclear applications. DOE Nuclear Energy (NE) has formed a program called the Advanced Materials and Manufacturing Technology (AMMT) to continue work begun under the Transformational Challenge Reactor (TCR) and other similar DOE laboratory programs that began the process of testing in-situ monitoring combined with ex-situ examination techniques as inputs into an AI and machine learning algorithms to rapidly detect potential quality anomalies during the manufacturing process. Additional support and research are needed to mature application and acceptance by regulatory bodies, standards organizations, and quality organizations.

Recommendation: Additional guidance and research is required to ensure the development, qualification, certification, implementation, disposition, and licensing of nuclear AM parts utilizing advanced monitoring and intelligent systems combined into a digital platform to help inform the quality of AM parts.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): NRC, DOE, NEI, EPRI, ASME, ASTM, AMMT

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☒Other (specify) Combines digital twin, computer controls, in-situ monitoring, and artificial intelligence.

Current Alternative: Traditional part qualification may require additional testing and qualification processes.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap QC26: Nuclear Industry Use of Material and Production Data Combined with Digital Analysis and Diagnostic Informed Qualification of AM Components. There is a need for additional research, guidance, and standards on the use of analysis and diagnostic tools to analyze AM materials and build data combined with AM digital twin, in-situ monitoring, Artificial Intelligence and Machine/System Learning technologies, and techniques to rapidly inform AM part qualification and acceptance in the nuclear industry. AM technologies and processes produce a significant amount of build and potential performance data and information. Mining and analyzing this data from in-situ and ex-situ sources, material properties, testing, and quality inputs can introduce a much more efficient system for identification of part issues, rapid qualification decisions, and future references under a digital twin model. Additional work on digital platforms/systems that can rapidly assimilate, mine, analyze and store AM part data is needed.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Both DOE and the NRC have solicited research and inputs on the use of AM parts in nuclear applications. DOE Nuclear Energy (NE) has formed a program called the Advanced Materials and Manufacturing Technology (AMMT) to continue work begun under the Transformational Challenge Reactor (TCR) and other similar DOE laboratory programs that began the process of integrating material and test data combined with production data into AI and machine learning algorithms in a digital platform to rapidly detect potential quality anomalies during the manufacturing process.

Recommendation: Additional guidance and research is required to ensure the development, qualification, certification, implementation, disposition, and licensing of nuclear AM parts utilizing advanced monitoring and intelligent systems combined into a digital platform to help inform the quality of AM parts.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): NRC, DOE, NEI, EPRI, ASME, ASTM, AMMT

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☒Other (specify) Combines digital twin, computer controls, in-situ monitoring, and artificial intelligence.

Current Alternative: Traditional part qualification may require additional testing and qualification processes.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

New Gap QC27: Use and Qualification of AM Non-metallic Advanced Materials in Support of New or Advanced Nuclear Fuel and High-temperature Reactor Applications. The new line of advanced reactors for potential application in the U.S. nuclear energy fleets may operate at a much higher temperature than the current U.S. fleet. The nuclear industry (and other industries) can benefit from the use of additively manufactured non-metallic materials such as silicon carbide are being evaluated by the DOE and industry for use in nuclear fuels and core components potentially replacing stainless or other steels and materials in certain high-heat applications. These ceramics lend themselves to AM application and the benefits of rapid design and production of complex geometries never before attempted.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Both DOE and the NRC have solicited research and inputs on the use of AM parts in nuclear applications. DOE Nuclear Energy (NE) has formed a program called the Advanced Materials and Manufacturing Technology (AMMT) to continue work begun under the Transformational Challenge Reactor (TCR) and other similar DOE laboratory programs that began the process of development and testing of non-steel materials for use in AM nuclear applications. The ORNL TCR program utilized previous DOE laboratory techniques and research originally developed in the 1960s to improve the use of silicon carbide and similar ceramics in AM applications (typically, binder jetting) to produce and test new forms of the high-heat tolerant fuels like the Tri-structural ISOtropic (TRISO) encapsulated fuel and potential reactor core components. The TRISO fuel is the favorite of potential new reactor designs due to its compact fuel density, high-heat tolerance, and improved radionuclide retention capabilities combined into a much safer fuel form.

Recommendation: Additional guidance and research is required to ensure the development, qualification, certification, implementation, disposition, and licensing of nuclear AM parts utilizing advanced non-steel materials for high-heat applications.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): NRC, DOE, NEI, EPRI, ASME, ASTM, AMMT

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☒Energy; ☐Medical; ☒Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☒Other (specify) Combines digital twin, computer controls, in-situ monitoring, and artificial intelligence.

Current Alternative: Traditional part manufacturing and qualification may require additional testing and qualification processes.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.3.3.6.2 Oil and Natural Gas Industry

Overview: As with other market segments, the big issue with additive manufacturing (AM) relates to whether the finished products are suitable for service. The features of AM products, in addition to geometry, that are critical for Oil & Gas products often include combinations of surface finish, residual stress, microstructure, toughness, fatigue resistance, wear resistance (adhesive, erosive and abrasive), mechanical and physical properties, corrosion resistance and environmental cracking resistance. The service environments are very different between the products that are used to produce petroleum and those used in the refining of petroleum. The exploration, drilling, completion of wells for production are in the business segment known as “upstream” Oil & Gas. This contrasts with the transportation and refining of products that are in the business segment known as “downstream” Oil & Gas. The interface between the two segments is generally considered the exiting of petroleum products out of the series of valves located at the wellhead.

The products used in the upstream segment have service temperatures that range from roughly -50°C to +200°C and often need to be resistant to corrosion and environmental cracking in naturally occurring acid gases (carbon dioxide and hydrogen sulfide) as well as salt (sodium chloride) and, occasionally, elemental sulfur. The downstream products usually do not need to contend with many of the corrosion related issues but may need to survive at temperatures up to 900°C and be resistant to both the feedstock (oil) and by-products along the refining path.

Additive manufacturing is currently used for components in both the upstream and downstream Oil & Gas Industry segments. The major end-users are all actively engaged in evaluating and using AM. The major original equipment and service providers are involved in using and qualifying AM components The widespread penetration into the Oil & Gas Industry was demonstrated by the size and width of the team that developed API Standard 20S Additively Manufactured Metallic Components for Use in the Petroleum and Natural Gas Industries. Some 215 members contributed from over 80 organizations including end-users, original equipment manufacturers, AM machine manufacturers, and AM feedstock manufacturers.

AM Processes and Materials being used: The laser PBF process is the most pervasive in terms of number of applications but there is use of electron beam (EB) powder bed fusion (PBF), wire and powder directed energy deposition (DED) and binder jetting (BJ) Though many different materials are used, the most common alloys are 17-4PH and 316 stainless steels, 718 and 625 nickel alloys and Ti6Al4V.

Published Standards and Codes

The published documents that are most referenced in Oil & Gas AM products include:

- API STD 20S, Additively Manufactured Metallic Components for Use in the Petroleum and Natural Gas Industries, First Edition (10/1/2021)
- API STD 20T, Additively Manufactured Polymer-Based Components for Use in the Petroleum and Natural Gas Industries First Edition (8/1/2022)
- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing
- ASME Boiler & Pressure Vessel Code Sections V, VIII and IX

In-Development Standards and Codes

In the Oil & Gas Industry, API 20S and 20T are standards but not product standards. For these standards to be required in Oil & Gas products, they need to be referenced in an API Product Standard. This was recognized as a barrier to implementation of AM and the API Sub-Committee SC06 took this on as a task to evaluate how API 6A, Specification for Wellhead Equipment, would need to change to address AM. API 6A was selected because of known AM candidates as well as the API 6A standard being the key to incorporating AM into multiple product standards. API 6A is the basis for material and quality requirements in several additional API product standards. A working committee was formed in late 2021 to review and identify sections of API 6A that need to change to address AM and reference API 20S. The working committee presented their findings to the 6A members in June 2022 and those recommendations will be considered during the development of API 6A 22nd edition that should start by 2024.

Recent activity related to but external to Oil & Gas includes ASME Code case 2020 and ISO/ASTM DIS 52904. The code case 3020 will be incorporated into AMSE B&PV Section IX, QW-600.

In July 2021, AMPP[29] formed the TR21522 Task Group that is creating a technical report (TR) detailing the current state of knowledge on corrosion testing for products that are manufactured using AM processes. The TR21522 report is expected to be published in 2023 (discussed in greater detail in the gap identified below). The membership of this TR is comprised of about 35 subject matter experts in AM and corrosion. Though there is some emphasis on the Oil & Gas Industry, the membership encompasses a broad spectrum from the various business segments. It was recognized from the onset that the effort was more general in nature, applying to all industries.

New Gap QC28: Susceptibility of AM Products to Corrosion and Environmental Cracking Mechanisms. There are no standards or reliable guidance for testing additively manufactured products for service where a corrosion related mechanism is a major consideration. The resistance to corrosion and environmental cracking mechanisms is often the limiting factor in applying AM to Oil and Gas products. From a search of several industry sectors, this lack of guidance or standard is not isolated to Oil and Gas products or to any particular industry.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: The scope of AMPP TR21522 is to present the current state of knowledge and gap analysis on corrosion testing of metallic materials for products that are manufactured using AM processes. The report will include testing recommendations and identify existing applicable testing standards that may need to be modified to address AM and where a suitable standard does not exist.

The scope of the report is not limited to any specific AM market sector and includes the state of the art with respect to general corrosion, localized corrosion, high temperature oxidation, corrosion fatigue, hydrogen or hydrogen sulfide associated cracking mechanisms, and stress corrosion cracking.

The TR21522 report is currently in the text drafting stage and the target date for ballot is June of 2023. The work to date has revealed technology and knowledge gaps related to the subject. The current assessment summary indicates that the existing AMPP and ASTM standards for corrosion and environmental cracking are acceptable but will require some modifications to address the specifics associated with additive manufacturing. The largest identified gap pertains to the selection and specifics of the test sample used to measure resistance/acceptability.

The next step will be to assess and edit the identified corrosion test standards from the TR21522 report to better address testing with respect to AM products. It is anticipated that a new standard will be required to provide guidance on the selection of test specimens from AM builds/products.

[29] AMPP, the Association for Materials Protection and Performance, was established in 2021 following a merger between NACE International and SSPC: The Society for Protective Coatings.

Recommendation: Complete work on AMPP TR21522 and use the results to inform future work.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): AMPP

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify) AM details, testing & prediction of product perform with respect to corrosion related phenomena

Current Alternative: Each user lacking guidance on how to select specimens and how to test for resistance to corrosion related degradation/failure mechanisms makes those decisions.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.3.3.7 Medical Industry[30]

2.3.3.7.1 Introduction

The medical industry adopted AM, to produce existing products as well as devices that may be patient-specific or integrated with lattice structures.[31] Patient-specific devices (devices matched to a single

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[30] Readers of this section are also encouraged to review other relevant parts of this roadmap that have application to the medical industry. These would include, for example Design (2.1.2; 2.1.4.3), Finished Material Properties (2.2.4.4), and Data (2.6.2; 2.6.9).

[31] While the discussion herein focuses on AM of medical devices, the FDA has approved at least one AM pharmaceutical.

patient's anatomy) are becoming more prevalent for surgical cutting guides and orthopaedic implants. Consensus standards, used internationally and recognized by the FDA in the U.S., are important tools to ensure the best information contributes to the evaluation of medical devices. Standards for traditional manufacturing methods may not encompass all of the capabilities, parameters, and considerations for AM. Additionally, international requirements and regulations may vary. This section will describe the currently available standards, work in progress by the SDOs, and the gaps that need to be addressed from a qualification and certification perspective.

In the U.S. market, the FDA has been proactive in terms of internal research, evaluation, and approval of AM devices. FDA Guidance documents provide recommendations for device production and testing as well as regulatory submission requirements. In addition, manufacturers can use recognized consensus standards, established methods, or justified scientific rationale with validated test methods, to show the safety, effectiveness, or substantial equivalence of their medical devices. The FDA classifies medical devices as Class I, II, or III depending on the risk associated with the device.[32] This roadmap does not directly reference FDA classification; rather, the roadmap categorizes devices as having short term or long-term contact with an internal body system, and whether or not they are load bearing.

Standards gaps identified by the medical sector follow.

2.3.3.7.2 Data Output from Imaging Sources

Patient-specific data can be acquired by a variety of medical imaging modalities, including CT scan, MRI, and ultrasound. The Digital Imaging and Communications in Medicine (DICOM) standard is overseen by the Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA). The DICOM standard applies to communication and management of medical imaging information and related data. The standard facilitates interoperability of medical imaging equipment by specifying protocols for network communication, syntax and semantics of commands, media storage, and file format structure. DICOM is the standard used by all manufacturers of X-ray, CT scan, and MRI imaging equipment. However, the ability to capture radiological output data varies depending on the manufacturer.

Published Standards, etc.

- 3D Manufacturing Format (3MF)
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data
- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

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[32] See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/

- [Radiological Society of North America (RSNA) 3D Printing Special Interest Group (SIG): Guidelines for medical 3D printing and appropriateness for clinical scenarios (November 2018)]

In-Development Standards

- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)
- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)

Gap QC6: Importing 3D Source Data to CAD Application for Creation of Design File. There is a need for a standard to enable 3D source data to be imported to the CAD application for creation of a design file. There is a concern that the data coming from the ultrasound equipment similar to the CT scan or MRI data may not be providing adequately detailed images but this cannot be assessed until the interoperability concerns are eliminated.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: TBD

Recommendation: Develop a standard for importing 3D source data to the CAD application for creation of a design file.

Priority: ☐High; ☒Medium; ☐Low

Organization: IEEE, ASTM F42/ISO TC 261 JG 70, ISO TC150/ASTM F04 JWG1, RSNA 3DP SIG

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text ISO/ASTM 52915 and 52916 have been published. ISO/IEC 3532-1, ISO/IEC DIS 3532-2, ISO/IEC CD 8803, and ISO/IEC CD 16466 address/will address importing 3D source Data to CAD application.

2.3.3.7.3 Data Acquisition for 3D Modeling: Imaging Protocols

The issue here is multifold:

- Diagnostic CT and MRI image data is routinely acquired for the CAD file or modelling application used to create the 3D file for use in the additive manufacturing process. However, the metadata that describes the accuracy, precision, and quality of the source files may not meet the needs of 3D printed patient-matched medical devices.
- Different imaging equipment has different installed protocols and many patient-matched medical device manufacturers require specialized protocols.
- There is a clinical balance between image quality and patient exposure.

Published Standards

- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data
- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)

Gap QC7: Imaging Protocols. Problems associated with data acquisition for 3D modeling either individually or in combination contribute to image inaccuracies that will result in inaccuracies of the 3D model and eventually the final device produced. Imaging protocols typically prioritize patient exposure for patient safety and then consider resolution. Therefore, alignment is needed between the imaging resolution requirements, the printer resolution, and the final part accuracy and quality requirements.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: TBD

Recommendation: Develop standard protocols for acquiring data for 3D modeling to ensure image accuracy, precision, and quality of source files for validation of the AM design file.

Priority: ☐High; ☒Medium; ☐Low

Organization: IEEE, ASME, ASTM F42/ISO TC 261, RSNA (Radiological Society of North America), American College of Radiology (ACR)

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ISO/ASTM TR 52916, Additive manufacturing for medical-- Data -- Optimized medical image data, was published. ASME V&V 40 Subcommittee on Verification and Validation in Computational Modeling of Medical Devices is working to form a working group on this item. ISO/IEC 3532-1 and ISO/IEC DIS 3532-2 address imaging protocols.

2.3.3.7.4 Patient Imaging Files and Segmentation

There are currently no standards for patient imaging files within a clinical environment, including the methods from standard-of-care medical images to print-ready files.

Process: Anatomical reconstruction is rarely done by the physicians themselves because it is: (a) time consuming; (b) requires different technical skills than segmentation for visualization/quantification purposes; and (c) uses a panoply of specialized software that is evolving frequently. Instead, a request to print anatomy from a particular study is sent to expert staff at a “3D Printing Lab” (often an outgrowth of a “3D Visualization Lab”). The physicians then review the 3D model and accept the print-ready file or suggest revisions. Currently, no professional society certifies a technologist for 3D reconstruction or 3D printing.

Consistency of data: Currently, most centers create print-ready files in common, and often open, file formats (STL, VRML, OBJ, X3D, etc.). These file formats were created without the intended purpose of medical integration. As such, these formats lack the structured schema and metadata needed for the clinical environment such as patient name, medical record number, institution of origin, etc. Centers currently rely on complex file naming conventions and deep folder hierarchies to tie the files to particular patient studies. These conventions are not appropriate for a clinical environment where information needs to be readily queried for medical needs (e.g., surgical planning).

Published Standards, etc.

ASME

- ASME V&V 40-2018, Assessing Credibility of Computational Modeling through Verification and Validation: Application to Medical Devices

FDA

Statements include:

- **On anatomical modeling:** Di Prima M., Coburn J., Hwang D., Kelly J., Khairuzzaman A., Ricles L. Additively manufactured medical products – the FDA perspective. 3D Printing in Medicine [Internet]. 2016 Jun 18 [cited 2016 May 22]; 2(1). Paraphrased: Anatomical models may sometimes be considered a hard copy of a medical image.
- **On other direct-contact 3D printing:** *Technical Considerations for Additive Manufactured Devices: Final Guidance for Industry and Food and Drug Administration Staff (AM Technical Guidance)*. Food and Drug Administration; 2017 December. Report No. UCM499809. See the discussion under Identified Guidance Documents earlier in the Q&C section of this roadmap.

HL7

- HL7 Standard for CDA Release 2: Imaging Integration; Basic Imaging Reports in CDA and DICOM, Release 1. This HL7 implementation guide describes how the HL7 Version 3 Clinical Document Architecture (CDA) Release 2 is used to record information for a Diagnostic Imaging Report. A Diagnostic Imaging Report contains a consulting specialist's interpretation of image data. It is intended to convey the interpretation to the referring (ordering) physician and become part of the patient's medical record. Note: This standard does not directly interact with 3D reconstructions currently, but will likely play a role following DICOM integration.

International Medical Device Regulators Forum (IMDRF)

- IMDRF/PMD WG/N74 FINAL: 2023 Personalized Medical Devices – Production Verification and Validation

ISO/ASTM

- ISO/ASTM 52915:20, Specification for additive manufacturing file format (AMF) Version 1.2**.** The standard for AMF file format includes the ability to incorporate meta data within the design file**.**

- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data. Per Section 12 of ISO/ASTM 52916, all appropriate metadata relating to the patient, institution of origin, etc. as well as source scans, segmentation modifications, accuracy and precision of output files, etc. can and should be added to the metadata list within the AMF file. This provides a reliable method to programmatically store and transmit key metadata through the entire work flow. This provides a reliable means of providing necessary information to validate and verify medical devices produced as compliant to FDA QMS requirements. All that is required to implement this is for an appropriate medical standards organization to provide the specific list of metadata schema and names to TC261 J64. This can be added as part of a planned technical report providing guidance on use of the AMF file format in medical AM applications, and to the next revision of ISO/ASTM 52915 as appropriate.

RSNA

- RSNA has a special interest group (SIG) that has published best practices on segmentation.

In-Development Standards

- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)

Gap QC14: **Segmentation.** There are currently no standards for patient imaging files including the methods from standard-of-care medical images to print-ready files.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Research on segmentation for patient imaging is needed because segmentation is a critical step for initiation of 3D printing for medical devices.

Recommendation: There is a need to create an augmented file specification for input into the DICOM file format. Incorporation of 3D files into the DICOM format will facilitate integration of 3D models into standard-of-care medical image databases present at all institutions. 3D models should include enough information to facilitate standardized methods for validation. DICOM itself addresses the process and also addresses consistency by enabling only a small subset of appropriate files.

Priority: ☐High; ☒Medium; ☐Low

Organization: RSNA SIG, ISO TC 261/ASTM F42, ISO/IEC JTC 1/WG12

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ISO/IEC DIS 3532-2 is in development.

2.3.3.7.5 Personnel Training for Image Data Set Processing

Image data sets are processed to create or replicate anatomy by "skilled personnel" to realize a 3D model and/or the final medical device. The process requires a good knowledge of anatomy (for identification of anatomical regions of interest [ROI]), graphic 3D design skills, and a fundamental understanding of AM procedures.

Gap QC9: Personnel Training for Image Data Set Processing. Currently, there are only limited qualification or certification programs (some are in process of formation) available for training personnel who are handling imaging data and preparing for AM printing.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop certification programs for describing the requisite skills, qualification, and certification of personnel responsible for handling imaging data and preparing for printing. The SME organization currently has a program in development.

Priority: ☒High; ☐Medium; ☐Low

Organization: SME, RSNA, ASTM F42/ISO TC 261

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

2.3.3.7.6 Phantoms

Phantoms refers to the creation of a physical object with known density and size properties for the purpose of verifying the accuracy of a medical scanning device to check the accuracy of imaging data or to be used for simulated in vitro imaging experiments.[33] These phantoms can be used to check accuracy as well as compare materials and processes. The process for creating accurate phantoms could also apply to the creation of teaching aid models for surgeons.

No published or in-development standards or specifications have been identified.

Gap QC8: Phantoms. Material and process guidelines are needed for phantoms to provide reliable models for imaging experiments and to check the accuracy of the process. These would include which materials and AM process to use, based on what is being imaged and the modality in use (e.g., X-ray vs. ultrasound).

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop guidelines for creating and using phantoms to include material and process used, based on use. Similar to gap QC7, they may make use of standard image formats that capture enough information to facilitate size, orientation and color normalization and/or validation in post-processing of data.

[33] The term phantom is defined in ASTM E1441-00 (Std Guide CT) as a “test object containing features of known size, spacing, and contrast, which can be scanned to determine spatial or density resolution.”

Priority: ☐High; ☒Medium; ☐Low

Organization: Biomedical Engineering Society, NEMA/MITA, ISO, ASTM, RSNA

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

2.3.3.7.7 Medical Materials and Materials Processing

All current AM materials for medical applications fall into the categories of potentially implantable or non-implantable materials, with some of the current AM materials shown in Figure 2. In the figure, short term (less than 30 days) and long term (greater than 30 days) refer to duration of patient-contacting materials.

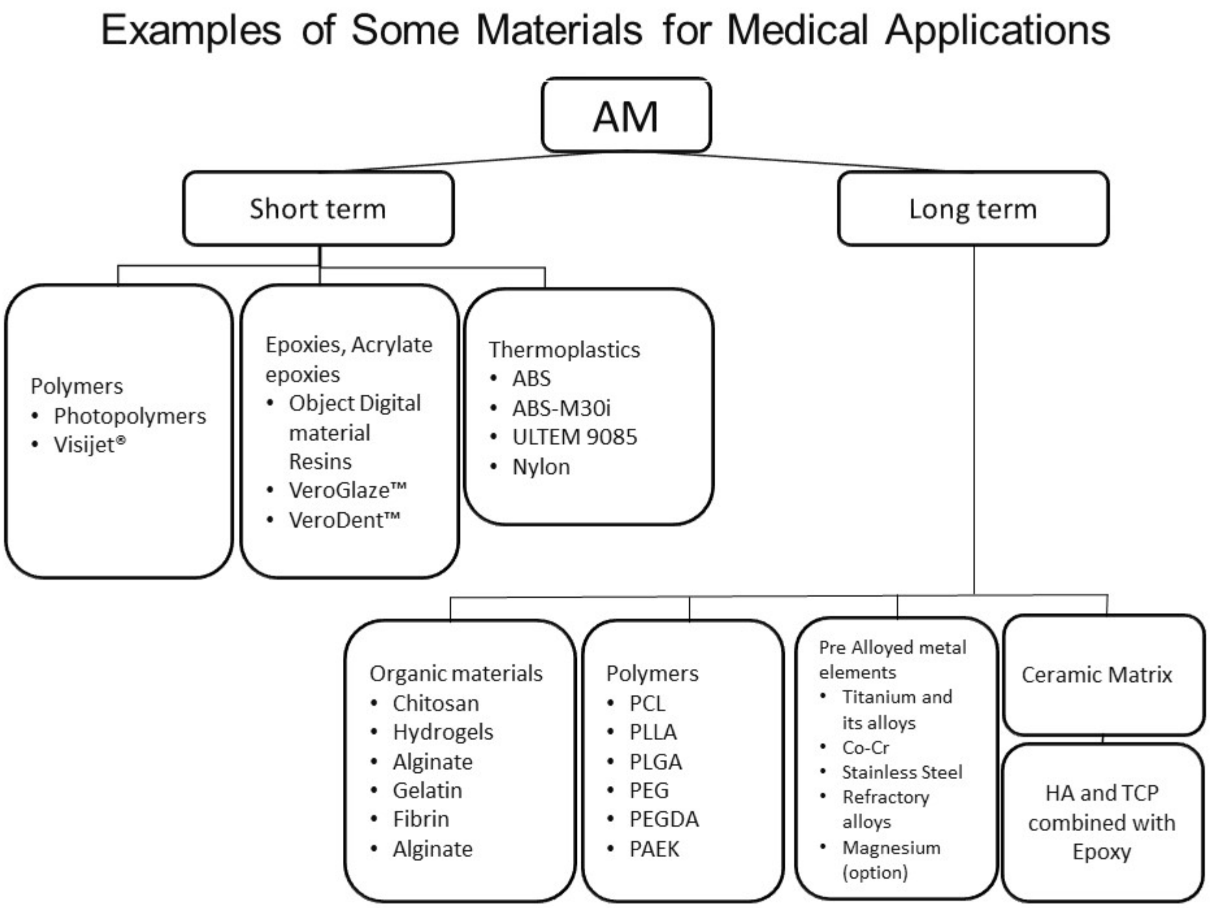

Figure 2: Examples of some AM materials for medical applications. Figure courtesy of Dr. Jayanthi Parthasarathy and Lauralyn McDaniel

2.3.3.7.8 Resorbable Materials

Some polymers, such as polycaprolactone, polyglycolic acid, and polylactic acid, may resorb when implanted in the body, allowing for replacement of the device by body tissues over time. Degradation kinetics of the device depends on the chemistry of the material, and structure and design of the scaffold.

Published Standards

- ASTM F1635-16, Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants
- ASTM F2902-16e1, Standard Guide for Assessment of Absorbable Polymeric Implants
- ASTM F3160-16, Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants
- ASTM F3268-18a, Standard Guide for In-Vitro Degradation Testing of Absorbable Metals
- ISO 10993-13:2010, Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices

- ANSI/AAMI/ISO 10993-15:2000 (R2011), Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
- ISO/TS 20721:2020, Implants for surgery – General Guidelines and requirements for assessment of absorbable metallic implants
- ISO/TR 37137:2014, Cardiovascular biological evaluation of medical devices -- Guidance for absorbable implants
- ISO/CD TR 37137-2, Biological evaluation of absorbable medical devices -- Guidance for absorbable implants -- Part 2: Standard guide for absorbable metals

In-Development Standards

- ASTM WK83979, New Guide for Corrosion Fatigue Evaluation of Absorbable Metals (formerly WK61103)

No specific AM standards gap has been identified with respect to resorbable materials.

2.3.3.7.9 Biocompatibility Testing Standards: Resorbable & Non-resorbable Materials

Existing standards include ANSI/AAMI/ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. This document supersedes Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*," dated May 1, 1995. The FDA also issued *Technical Considerations for Additive Manufactured Devices: Final Guidance for Industry and Food and Drug Administration Staff (AM Technical Guidance)* in December 2017. This includes FDA recommendations for medical device submissions.

2.3.3.7.10 Material Control Data and Procedures

While no published standards or standards in development specific to AM have been identified for medical applications, 21 CFR 820 provides the needed processes and data requirements. Specifically, § 820.65 – Traceability, § 820.140 - Handling , § 820.150 – Storage, and Subpart M--Records which includes § 820.181 - Device master record, and § 820.186 - Quality system record details needs for materials.

Published Standards

- ASTM F3456-22, Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials
- ISO/ASTM 52907:2019, Additive manufacturing — Feedstock materials — Methods to characterize metal powders
- SAE ARP7044 - Powder History Scoring Metric and Labeling Schema

In-Development Standards

- ASTM WK66030, New Guide for Quality Assessment of Metal Powder Feedstock Characterization Data for Additive Manufacturing
- ASTM WK75184, Guide for Additive Manufacturing of Metals – Powder Bed Fusion – Guidelines for Feedstock Re-use and Sampling Strategies
- SAE AS7040, Requirements for powder distributors (Initiated Jun 28, 2021)
- SAE AS7041, Distributor for AM build distributors Requirements (Initiated Jun 28, 2021)

Gap QC13: Material Control Data and Procedures. There is a need for well-established material control data and procedures. Materials are primarily manufactured through proprietary methods and, while recommended handling practices exist for each company and each product, standard procedures or standardized considerations are not available.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: A standard or specification describing a data set for material pedigree, recommended testing, and handling procedures would simplify evaluation of material suitability.

Priority: ☐High; ☐Medium; ☒Low

Organization: Material providers, ASTM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text.

2.3.3.7.11 Qualification and Control of Suppliers

A medical device company should have procedures in place to control their suppliers. Additionally, when they audit their suppliers, they should ensure that the supplier has the proper controls in place to control their sub-suppliers. Qualification and control of suppliers will align with other industry guidance and standards such as:

- FDA Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
- ANSI/AAMI/ISO 10993-1:2018, Biological evaluation of medical devices - Part 1:Evaluation and testing within a risk management process
- FDA Guidance Document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

2.3.3.7.12 Qualification & Certification of the Finished Device

As per FDA guidance, even if the raw material is certified by the supplier, the device manufacturer is responsible for qualification of the final device. Additionally, per the Code of Federal Regulations (21 CFR 820.70) and ISO 13485:2016, the device manufacturer is responsible for establishing and maintaining procedures for the use and removal of manufacturing materials to ensure that the device's quality is not adversely affected. This is applicable to AM for a number of reasons: some raw materials are toxic in their uncured state, and post-printing operations such as support structure removal, conventional machining, polishing operations, sterilization, etc. expose the device to chemicals and manufacturing materials that may be unsafe to the patient or that may adversely affect the device's performance.

Published standards and regulations (Non-resorbable materials) include:

- ASTM F2924-14(2021), Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
- ASTM F3001-14(2021), Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
- ASTM F3213-17, Standard for Additive Manufacturing – Finished Part Properties – Standard Specification for Cobalt-28 Chromium-6 Molybdenum via Powder Bed Fusion
- FDA 21 CFR 820.70, Production and process controls
- ISO/ASTM52903-1-20 Additive manufacturing — Material extrusion-based additive manufacturing of plastic materials — Part 1: Feedstock materials
- ISO 13485:2016, Medical devices - Quality management systems - Requirements for regulatory purposes

No gap exists. ISO 13485:2016 and 21 CFR 820 adequately describe the need to ensure that the final finished device – including raw materials, pigments, contact materials, etc. – meets the design requirements and does not cause harm to the patient. Emerging material standards will be developed as the need arises.

2.3.3.7.13 Quality, Verification, and Validation of Medical Product 3D Models

3D models are typically created for a region of interest (ROI). Image processing therefore entails functions such as data segmentation (determining ROI), deleting (eliminating artifacts, noise, and non-ROIs), smoothening, texturing (better visualization, surface finishing), and reducing post-processing time. Models are transferred back and forth between image processing and graphic software to create the best model.

Published Standards

- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)
- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1)

Gap QC10: Verification of 3D Model. There are currently no standards for the final verification of a 3D model after it is created from source imaging. The 3D model that goes into the AM fabrication system must also be verified.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: In terms of tolerances

Recommendation: Develop standards for verification of the 3D model.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM F42/ISO TC 261 J64, AAMI, ASME, NIST, ACR, RSNA 3DP SIG, ISO/IEC JTC 1/WG12

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ISO/IEC 3532-1, ISO/IEC DIS 3532-2, ISO/IEC CD 8803, and ISO/IEC CD 16466 address/will address quality, verification, and validation of medical product 3D models.

2.3.3.7.14 Validation of Sterilization Processes

The issues of concern are: validation of the ability to clean, disinfect, and sterilize products intended for subsequent processing and impact on final mechanical properties and geometric fidelity.

The U.S. FDA regulates medical products and requires data to support claims of sterility or claims that a device can be sufficiently sterilized for use. A list of standards recognized by the FDA in this respect (which includes standards and guidance related to equipment, facilities, and sterilization-related microbiological testing) is available online.[34] See also the FDA Guidance *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 21, 2016).

Validation of sterilization processes: A number of published standards govern the validation of sterilization processes used for medical devices, including ANSI/AAMI/ISO 11135:2014 (ethylene oxide sterilization), the ANSI/AAMI/ISO 11137 series (radiation sterilization), the ANSI/AAMI/ISO 17665-1:2006 (R2013) series (moist heat sterilization), and ANSI/AAMI/ISO 20857:2010 (R2015) (dry heat sterilization). For animal tissue-based products sterilized via glutaraldehyde, ANSI/AAMI/ISO 14160:2011 (R2016) applies and AAMI TIR37:2013 provides guidance for the sterilization of human tissue-based products using radiation. See also the FDA's *Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*. However, these standards were written for surface contact testing and did not incorporate considerations for complex geometric structures that additive manufacturing can produce.

[34] Go to https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm and select "Sterility" in the Specialty Task Group Area. The search results identify some 129 documents with further information available by clicking on the title.

For products requiring unique sterilization processes, ANSI/AAMI/ISO 14937:2009 (R2013) governs. For medical devices that cannot be sterilized to a Sterility Assurance Level (SAL) of 10^{-6}, ANSI/AAMI ST67:2019 provides a risk management framework for justifying alternative SALs. For medical devices produced via aseptic processing, the ANSI/AAMI/ISO 13408 series provides guidance.

Validation of the ability to clean, disinfect, and sterilize products intended for subsequent processing: ANSI/AAMI/ISO 17664:2017, *Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices (supersedes ST81)* specifies what information a medical device manufacturer must verify or validate for the cleaning, disinfection, and sterilization of products intended to be sterilized by the product users (e.g., patients of healthcare providers). AAMI TIR12:2020, Designing, testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers, provides guidance on designing, testing and labeling devices intended to be sterilized by healthcare facilities or other device users. An international technical specification, ISO/TS 19330:2017, Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6, provides a framework for evaluating alternatives for medical devices that cannot be adequately sterilized via standard protocols.

Reprocessing of reusable additively manufactured devices: Any device that is intended to be reused should be reprocessed with a validated cycle per appropriate labelling as described in FDA Guidance on "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (issued March 17, 2015). The considerations for additively manufactured devices are not expected to be different than devices made in other ways. Rather, it is of paramount importance to assess the material stability and limitations of the chosen AM production process. AAMI TIR12, AAMI TIR30:2011 (R2016), A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, and ANSI/AAMI/ISO 17664:2017 (supersedes ST81) are also applicable.

Impact of sterilization on mechanical properties and geometric fidelity of medical products: The standards for validation listed above require evaluation of the effect of the sterilization process on the final product. Other testing (e.g., biocompatibility testing) is also required on medical devices in their final sterilized state. AAMI TIR 17:2017(R2020), Compatibility of Materials Subject to Sterilization provides information on materials compatibility with sterilization processes.

Gap QC15: Sterilization of AM Medical Products. AM medical products, such as anatomic models, can be made in a healthcare setting. In some instances, these medical products may enter a sterile environment and would therefore require sterilization. The effects of sterilization on the geometric fidelity of the medical product should be assessed. While many standards and industry best practices exist, procedures and protocols for determining appropriate materials, sterilization cycles, and validation tests are available. There is a need for test methods to assess critical geometric features that can be implemented in non-traditional manufacturing environments (e.g., healthcare facilities).

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop test methods, guides, and best practices for AM medical products to help identify critical parameters (e.g., geometric features) and apply existing sterilization standards in a clinical setting.

Priority: ☐High; ☐Medium; ☒Low

Organization: AAMI, AOAC International, ASTM, ISO, Parenteral Drug Association (PDA), USP, RSNA 3DP SIG.

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒Polymer; ☒Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: N/A

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided

2.3.3.7.15 Sterilization of Tissue Engineered Products

Sterilization of tissue engineered products: There are some recognized standards and guidance in this area (see above and see the work of ISO/TC 194/SC 1, Tissue product safety). Other standards exist such as ANSI/AAMI/ISO 13022:2012, Medical products containing viable human cells - Application of risk management and requirements for processing practices and ISO 18362:2016, Manufacture of cell-based health care products - Control of microbial risks during processing. The development of additional standards in this area may require more research and testing and greater clarity and guidance from regulators.

Aseptic processing, or production under sterile conditions, of AM tissue-based products is another method to ensure sterility of the final product. It is especially important when a construct contains cells embedded in a printable, biocompatible substrate intended for implantation. FDA Guidance on *Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice* provides an overview of best practices. See also gap DE14. on Best Practices and Guidance for AM Data Collection.

Gap QC16: Sterilization of 3D Printed Tissue Engineered Products. 3D printed tissue engineered products present a particularly challenging circumstance for sterility assurance. While using a validated aseptic processing protocol for tissue engineered products can maintain sterility, it is not always sufficient or practical. Risk management standards applied during the 3D printing process can help decrease the risks of contamination but do not provide defined measures to ensure sterility or to assess contamination.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: A wide variety of aseptic processing and sterilization protocols exist for tissue engineered products; however, no standards have been published to address validation and testing of these protocols in 3D printed tissue engineered products.

Recommendation: Develop and validate standard methods of sterilizing and verifying the sterility of 3D printed tissue engineered products, especially those that can be applied in healthcare settings.

Priority: ☐High; ☒Medium; ☐Low

Organization: R&D: OEMs, FDA, BioFabUSA. Standards: AAMI, ISO, ASTM, AATB.

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: N/A

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided

2.3.4 Conclusions

Taken as a whole, this chapter substantiates what almost seem as two contradictory realities. First, across industries, there is a consistent view that the “big picture” concepts of qualification and certification for AM are not unique – the existing frameworks generally hold. Yet second, it is also clear that the “how” of AM qualification and certification, the all-important details, does not yet have broad consensus even within industries. This should be expected given the breadth of the technology across multiple process types and material classes. It will take time for AM to develop what may be referred to as a common engineering practice, where the expectations of what is needed to adequately qualify and control AM processes are mostly a subject of common understanding. This will come with the progression of standardization that eventually develops and defines the common engineering practice. In the meantime, qualification and certification in AM will have to rely upon open communication to bridge the standardization gaps, reduce reliance on assumptions, and provide the common understanding.

2.4 Nondestructive Evaluation (NDE)

2.4.1 Introduction (metals)[35]

Nondestructive evaluation (NDE), also commonly known as nondestructive testing (NDT) or nondestructive inspection (NDI), is one of the engineering disciplines used to verify the integrity of high value components. Task-specific NDE methods have been developed over many years. The most common methods recognized and controlled by industrial standards are: X-ray (including computed tomography and digital radiography), dye penetrant, eddy current, magnetic particle, and ultrasonic testing. Adaptations of all these methods should be under consideration for aerospace, medical, automotive, energy, and other sectors that use AM components. As additive manufactured part’s complexity and criticality grow, the reliance on computed tomography and other advanced NDE methods has grown. Understanding and control of these techniques need to be addressed.

NDE methods to detect discontinuities and anomalies (defects, discontinuities, flaws, indications, residual stresses and unmelted or partially fused powder etc.) are often cataloged by the character of the anomalies it can detect and the location within the part for which the inspection method is best suited. These anomaly locations are often referred to as: embedded (volumetric), subsurface (near and below the surface), or surface. Embedded flaw detection methods include: acoustic emission, thermal imaging, ultrasonic (i.e., pulse echo and through transmission ultrasound, process compensated resonance testing (PCRT)] and X-ray radiography. Surface anomaly detecting methods include: acoustic

[35] The scope of this NDE section is generally focused on additive manufacturing of metal components. Other materials are discussed in section 2.4.6.

emission, dye penetrant, eddy current, magnetic particle, photogrammetry, ultrasonic (UT), and visual testing (VT). Applicable NDE methods may be used during manufacturing (in-situ NDE), or after fabrication or post-processing (ex-situ NDE).

NDE methods have differing outputs to display or record the testing results. For example, an X-ray radiograph is viewed by an inspector who interprets what is recorded by the film or digital image. Film based X-ray imaging is qualitative and dependent on the imaging direction and inspector skill, while three-dimensional, digital X-ray imaging is quantitative and requires careful digital manipulation of the data that involve converting 3D data into 2D-slices, which are then used to determine the size, shape and distribution of the flaws. Ultrasonic pulse echo results are viewed in real time using an A-scan presentation for real time inspection or an amplitude response C-scan map created during the scanning of the part and subsequently interpreted by the inspector. The inspector sees a reflection as a measurement of a returned signal (echo) “amplitude” either on the A-scan or C-scan map (normally color-coded amplitude bar).

There are currently eight categories of processes used to manufacture AM metal parts. Each one has its own level of complexity and presents challenges for NDE and the future standards that will provide the direction or guidance of the inspection practices. The categories are:

- BJ, Binder Jet powder bed AM processing
- PBF-LB, Laser beam powder bed fusion
- PBF-EB, Electron beam powder bed fusion
- DED-LB, Laser beam directed energy deposition
- DED-EB, Electron beam directed energy deposition (EWAM)
- DED-GMA, DED-GTA, DED-PA, Gas metal arc, gas tungsten arc, and plasma arc directed energy deposition processes[36]

AM non-metal and metal parts manufacturing categories are:

- FDM / FFF / DIW – Fused deposition modeling, Fused filament fabrication, and Direct ink wiring (material extrusion),
- SLS – Selective laser sintering
- SLA – Stereolithography (vat photopolymerization)
- Material jetting
- Sheet lamination

[36] Including WAAM – Wire Arc AM (direct energy deposition)

A determination to separate or combine these different processes into one or more standards should provide a coordinated answer to both NDE and equipment users. Many of the various drafts currently in development appear either focused on the PBF processes or combine a mix of different processes.

The U.S. industrial and governmental NDE standardization needs or gaps have been evaluated and are summarized in the discussion that follows. Figure 3 shows NDE gaps identified in this and previous versions of this roadmap. The figure shows high, medium, and low priority gaps appear in **bold**, black, and grey. Approved and draft standards or standards content appears in black and grey, respectively. The status of Roadmap version 3 appears as green (completed), yellow (in progress), pink (not started), grey (moved), or blue (new).

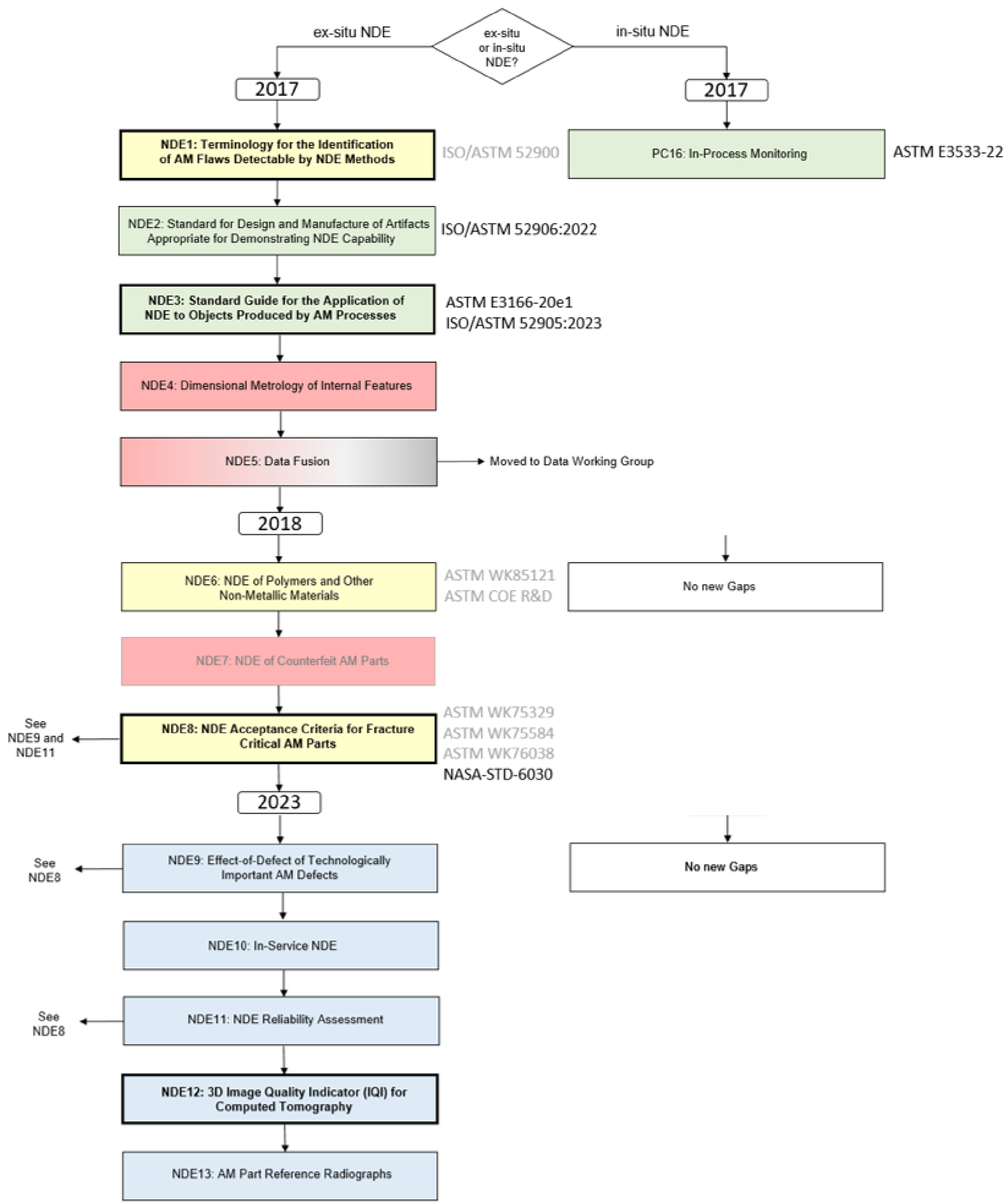

Figure 3: Additive Manufacturing NDE gap status as of 2023.

2.4.2 Common Defects Catalog Using a Common Language for AM Fabricated Parts

2.4.2.1 Terminology

Historically, anomaly types, names, or classifications have been associated with the generating process, e.g., castings may contain “shrinkage” and welds may contain “incomplete penetration.” There are also overlapping anomaly types, for example, porosity. Additive manufacturing is another form of part manufacturing with unique anomaly types and classifications associated with the process. The AM industry and standards development organizations have groups formed addressing the need to establish consensus anomaly descriptions.

As a new technology operating on principles many of which are foreign to conventional machining, additive manufacturing needs industry agreement on definitions of specific terms to communicate flaws and flaw types, ideas, and concepts, and to spur further innovation. In the absence of this common agreement as to the precise meaning of words in their relative context, individuals and organizations risk inevitable delays, misaligned objectives, and confusing outcomes. As an example, the words “accuracy” and “precision” in common parlance are synonymous but, in metrology, the science of measurement, they are not. Each describes a specific, unrelated attribute.

There are industry-based standards being developed both in the US and Europe. Published standards addressing terminology but not the individual flaw types or classifications needed to accept or reject AM parts by nondestructive testing include:

- ASTM E1316-22a Standard Terminology for Nondestructive Examinations, developed by ASTM E07.92 contains anomaly terminology useful for the NDE of AM parts.
- ASTM E3166-20, Standard Guide for Nondestructive Examination of Metal Additively Manufactured Aerospace Parts After Build
- ASTM E3353-22, Standard Guide for In-Process Monitoring Using Optical and Thermal Methods for Laser Powder Bed Fusion
- ISO/ASTM 52900:2021, Additive Manufacturing - General Principles - Fundamentals and Vocabulary developed by ISO/TC 261 and ASTM F42 under their PSDO cooperation agreement
- ISO/ASTM TR 52906:2022, Additive manufacturing — Non-destructive testing — Intentionally seeding flaws in parts has defect terminology.
- ISO/ASTM 52921:2013, Standard terminology for additive manufacturing - Coordinate systems and test methodologies
- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components using Additive Manufacturing.

In-Development Standards

- ASTM WK75329, Standard Practice for the Nondestructive Testing (NDT), Inspection Levels and Acceptance Criteria for Parts Manufactured with Laser Based Powder Fusion Aerospace *Components* (under F42.07) will provide flaw terminology in support of the acceptance criteria
- ISO/ASTM DTR 52905, Additive manufacturing of metals—Non-destructive testing and evaluation—Defect detection in parts
- ISO/ASTM AWI 52948 Additive manufacturing for metals — Non-destructive testing and evaluation — Imperfections classification in PBF parts (see also ASTM WK83468)
- ASME's Boiler & Pressure Vessel Code group will be looking at NDE of a pressure vessel. They are also looking at working with ASTM.

Gap NDE1: Terminology for the Identification of AM Anomalies Interrogated by NDE Methods. Industry driven standards related to defects have been developed. Many anomalies have been identified but more effort is needed to adopt and reference harmonized anomaly terminology, with appropriate names and descriptions, by the AM industry in standards. The logical repository for AM defect terminology is ISO/ASTM 52900. Therefore, effort needs to be made to adopt consensus anomaly terminology drawn from the existing published standards and from the in-development standards mentioned above so that there is consistency across all voluntary consensus organizations. See also gap FMP10.

R&D Needed: ☐Yes; ☒No; ☒Maybe

R&D Expectations: There may be open ended questions arise as the AM industry considers adoption of the NDE terminology because the effect of an anomaly (e.g., quasicrystalline microstructure) may need to be studied.

Recommendation: ASME BPVC Section V NDE, ASTM F42, SAE AMS K, ISO TC 261 adopt standardized defect terminology which identify and describe anomalies, and typical locations in a build.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM E07, ASTM F42/ISO TC 261, SAE AMS K, ASME BPVC, AWS D20, NIST

Lifecycle Area: ☒ Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒ Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: E3166 and ISO / ASTM DTR 52905 and 52906

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: Standards development has matured, as noted in the text, and contain preliminary definitions for AM anomalies, including pictures of technologically important anomalies, processing and post-processing factors related to their generation and removal, and applicable NDE methods. The ultimate goal is to ballot vetted definition for AM anomalies in ISO/ASTM 52900. Additionally, NDE methods for welded metals are well established and should be reviewed for AM needs. The techniques, minimum flaw sizes indicated and the naming conventions are used for welded metals to join metals together and for weld metal buildups.

2.4.2.2 Equipment Standardization and Demonstration of NDE Capability

Additively manufactured metal parts are made by sintering or melting powder, wire, or other feedstock primarily using two basic techniques referred to as powder bed fusion and directed energy deposition. These two techniques employ different processing approaches but there are enough similarities to create a list of flaws and defects, detectable by NDE examination methods, as tailored to the various equipment approaches.

Currently, flaw types have been recognized by individual activities but lack formal review and acceptance by the industry. Various U.S.-based committees have folded this subject into their purview with little alignment. Calibration and phantoms are needed to standardize both industrial and medical nondestructive equipment. Welding flaw types have been identified specifically in areas such as electron-beam welding for fatigue critical applications. A possible approach is to categorize and catalog allowable defects as shown in SAE AMS2680C-2019, Electron-Beam Welding for Fatigue Critical Applications.

The ASTM Standard Guide E3166 (under the ASTM E07 committee on NDT) contains a table with defects (Table 1) and their detectability using various NDE methods (Table 2). ISO/ASTM TR 52906:2022 Additive manufacturing — Non-destructive testing — Intentionally seeding flaws in metallic parts was jointly developed by ISO/ASTM to address "how to seed flaws" in AM processes for use in nondestructive testing. Another work item, ISO/ASTM CD 52905 JG59, has categorised defects which are unique to AM (after reviewing existing standards for casting and welding) and concentrates on creating artifacts with such defects.

Additionally, in ISO TC261/ASTM F42 JG59 'NDT for AM Parts' group we are working on the first of six standards which will cover both PBF and DED. Each process will have three standards following the welding standards format where the first one covers classification of imperfections; the second specifies quality levels (criticality) and the last one specifies how to relate quality levels to NDT requirements. The first one ISO TC 261 is working on is ISO/ASTM PWI 52948 Additive manufacturing of metals — Non-destructive testing and evaluation —Imperfections classification in PBF parts.

Nondestructive testing uses physical standards – typically physical reference standards and representative quality indicators (RQIs) – to ensure the equipment and measurement process are functioning at a specified level. These are well-established for the inspection of mature product forms. The complexities of emerging 3D printed parts require new approaches for fabrication of AM reference standards and quality indicators to set and demonstrate equipment functionality. These new approaches and standards must have industry acceptance as the basis for inspection techniques.

Published Standards

- ASTM E1817-08(2022), Standard Practice for Controlling Quality of Radiological Examination by Using Representative Quality Indicators (RQI)
- ASTM E3166-20e1, Standard Guide for Nondestructive Examination of Metal Additively Manufactured Aerospace Parts After Build
- ISO/ASTMTR52906-EB, Additive Manufacturing—Nondestructive Testing—Intentionally Seeding Flaws in Metallic Parts (see also ISO/ASTM TR 52906:2022)

In-Development Standards

- ASTM WK75584, Standard Test Method for Additive Manufacturing Non-destructive testing and evaluation of fatigue cracks using tensioned computed tomography (F42.01)
- ASTM WK76038, Standard Test Method for Additive Manufacturing of Metals -- Non-destructive testing and evaluation -- Porosity Measurement with X-ray CT (F42.01)
- ASTM WK83515, Standard Specification for Additive manufacturing - Non-destructive testing and evaluation - Defect classification in metallic PBF parts (F42.01)
- ASTM WK83468, Standard Classification for Additive manufacturing for metals -- Non-destructive testing and evaluation -- Imperfections classification in PBF parts (F42.01)
- ASTM WK84977, New Practice for controlling Computed Tomographic (CT) dimensional measurement performance by using Representative Quality Indicators (RQIs) (E07.01)
- ISO/ASTM DTR 52905, Additive manufacturing of metals—Non-destructive testing and evaluation—Defect detection in parts
- ISO/ASTM AWI 52948, Additive manufacturing for metals — Non-destructive testing and evaluation — Imperfections classification in PBF parts

Gap NDE2: Standard for the Design and Manufacture of Physical Reference Standards, Image Quality Indicators, and Representative Quality Indicators to Demonstrate NDE Capability. One published standard exists (ISO/ASTM 52906) for the design or manufacture of specimens that contain intentionally seeded flaws that can be used to calibrate NDE equipment or demonstrate detection of naturally occurring and intentionally introduced anomalies (lack of fusion, porosity, etc.), or intentionally added features (watermarks, embedded geometrical features, etc.). ISO/ASTM JG59 (previously JG60) has published 52906 which includes ways to design and manufacture artefacts or parts with such defects. ISO/ASTM CD 52905 JG59 is partially addressing this with seeded "imperfections" (or flaws) and demonstration of NDT detectability. This standard should identify the naturally occurring anomalies and intentional features. This standard should also include recommendations regarding the use of existing subtractive machined calibration standards or AM representative artifacts or phantoms. When Image Quality Indicators (IQI) do not work which are representative of the material and process, Representative Quality Indicators (RQI) may be used that are representative of the production part and expected anomaly state. The use of IQIs and RQIs is common in X-ray-based NDE methods such as RT [including digital radiography (DR) and computed radiography (CR)], and in CT. The use of RQIs should be considered for incorporation into the standard(s).

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: (1) Consistently and successfully printing phantoms and measuring them inside the RQI bodies. (2) R&D to define all anomalies that affect the performance of a product and calibration of NDE methods for quantitative analysis of durability of the AM products. (3) Methods to develop phantoms for X-ray CT probability of detection (POD) analysis using AM, traditional manufacturing, and advanced micro/nano-fabrication techniques. The approach of generating artificial flaws may be different for different NDT methods as well.

Recommendation: Complete work on applicable ASTM F42/ISO TC 261 standards (JG59) and ISO/ASTM DTR 52905.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM F42/ISO TC 261

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☒Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Internal practices

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text. See also sections 2.1.7 Design for Anti-counterfeiting (gap DE29); 2.2.2.13 (process control); and 2.4.2 gap NDE7.

2.4.3 Test Methods or Best Practice Guides for NDE of AM Parts

Additive manufacturing technologies for the development, prototyping, and production of 3D printed objects are maturing rapidly. There are several different process categories of AM technology being developed. Due to the rapid advancement of additive manufacturing, NDE practitioners new to the inspection of additively manufactured objects are not aware of the differences in the process categories and the flaws they can produce. NDE practitioners need to be made aware of the types of flaws each process method can produce and the appropriate NDE methods for detecting those flaws.

Although there are some commonalities in the types of defects in AM parts compared to the defects in parts made by conventional processes such as casting, forging, and welding, AM parts can have additional unique defects such as trapped powder and layer defects. In addition, AM typically provides an increased level of geometric complexity, which increases the risk deeply embedded volumetric defects may be missed during inspection. Some are being addressed in ISO/ASTM CD 52905 JG59.

Published NDE standards include those under the jurisdiction of ASTM committee E07 and SAE AMS committee K. These NDE process standards contain the details necessary to control the application of each NDE method in general or to a specific application (e.g., welding, castings, forgings). Each NDE method must have acceptance levels for accurate and repeatable results, which are typically referred to as classes. The standard classes can be used in engineering analysis and provide quality criteria for acceptability. By way of example, ultrasonic inspections for wrought products use flat bottom holes defined by ASTM E127-20 and implemented as acceptance classes in SAE AMSSTD2154E and ASTM E2375-22. Similarly, X-ray inspection of titanium castings uses reference radiographs to measure severity as defined in ASTM E1320-20. Acceptance standards may be imbedded in the process standard or in a stand-alone standard such as MIL-STD-1907 NOT 6 for the penetrant inspection of castings and weldments. Many of these existing standards will be directly applicable to objects produced by AM without modification. Some modification or new standards may be needed for the complex objects produced by AM that were not possible using conventional manufacturing techniques.

ASTM E3166-20e1 Standard Guide for Nondestructive Examination of Metal Additively Manufactured Aerospace Parts After Build and ISO/ASTM DTR 52905 Additive manufacturing of metals — Non-destructive testing and evaluation — Defect detection in parts provide the NDE industry starting points for designing inspection processes for additively manufactured objects. E3166 contains a thorough list of practices which can be applied and the knowledge generated with these documents establishes a baseline for determining when existing NDE standards can be used and where new ones specific to additive manufacturing must be developed. Current inspection results indicate that object which are similar to those manufactured by traditional methods can be inspected using existing standards. To enhance detection of relevant defects, post-processing of the additively manufactured objects may be required to allow the use of currently released non-process specific NDE standards.

Several applications have been identified where additive specific NDE standards are needed. One example is the CT of complex parts which ASTM work item WK71550 intends to address. Additional ones can be found in the In-development standards section below.

For characterizing the process quality during the build, acoustic emission, eddy current, laser UT, and infrared thermography techniques could provide data that could be used in closed loop controls to minimize the need to do NDE (see section 2.2.2.12 In-Process Monitoring). The type of probe applications and method for ultrasonics needs to be considered.

Published Standards

- ASTM E3166-20e1, Standard Guide for Nondestructive Examination of Metal Additively Manufactured Aerospace Parts After Build (revision underway, see ASTM WK78773)
- ISO/ASTMTR52906-EB, Additive Manufacturing—Nondestructive Testing—Intentionally Seeding Flaws in Metallic Parts

In-Development Standards

- ISO/ASTM DTR 52905, Additive manufacturing of metals—Non-destructive testing and evaluation—Defect detection in parts (anticipated approval in spring 2023)
- ASTM WK69731, Guide for Additive Manufacturing -- Non-Destructive Testing (NDT) for Use in Directed Energy Deposition (DED) Additive Manufacturing Processes (F42.01)
- ASTM WK71550, New Practice for Computed Tomographic Examination of Additive Manufactured Parts (E07.01)
- ASTM WK75584, New Test Method for Additive Manufacturing Non-destructive testing and evaluation of fatigue cracks using tensioned computed tomography (F42.01)
- ASTM WK76038, New Test Method for Additive Manufacturing of Metals -- Non-destructive testing and evaluation -- Porosity Measurement with X-ray CT (F42.01)
- ASTM WK78773, Revision of E3166-20e1 Standard Guide for Nondestructive Examination of Metal Additively Manufactured Aerospace Parts After Build (E07.10)
- ASTM WK78465, New Specification for Additive Manufacturing for Medical- Non-destructive Testing and Evaluation-Test Method for Evaluation of Porous Structures in Medical Implants via Computed Tomography Scanning (F42.07)
- ASTM WK78911, Standard Guide for Additive Manufacturing of Metal -- Finished Part Properties -- Methods for Density Measurement (F42.01)

- ASME is looking at NDE vis-a-vis its boiler and pressure vessel code (Section V BPVC).

Gap NDE3: Standard Guide for the Application of NDE to Objects Produced by AM Processes. There is a need for an industry-driven standard led by nondestructive testing experts and supported by the additive manufacturing community to assess current inspection practices and introduce nondestructive testing and inspection requirements.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Round robin testing is underway under ASTM WK78773 (revision of E3166-20e1) to bring in new resonant ultrasonic spectroscopy (RUS) method for whole body characterization of parts. that complements the existing process compensated resonance testing (PCRT) method. ASTM E3397 involves impulse excitation resonance frequency testing. Also, reference radiographs used for radiographic testing of castings and welds are needed for additive manufacturing (see gap NDE10). A future need will be to spin off test methods from E3166 and ISO/ASTM 52905 guides, which contain precision and bias statements that can be used in accept/reject and in procurement of AM parts.

Recommendation: Complete work on in-development standards listed above.

Priority: ☒High; ☐Medium; ☐Low

Organization: ASTM E07, ASTM F42/ISO TC 261, ASME, NIST

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☒ Other (specify) Test coupons and phantoms

Current Alternative: Current draft of ASTM E3166

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ASTM WK78773 and ISO/TC 261/JG 59 are in development. ASME is also looking at NDE vis-a-vis its boiler and pressure vessel code. The International Committee for Non-Destructive Testing

(ICNDT) has formed a specialist international group on NDT reliability to address the deficiencies. There are working groups on standardization of reliability evaluations, human and organizational factors, and reliability for NDE 4.0. Additive manufacturing is one of the interests in this group.

2.4.3.1 NDT Reliability Assessment

NDT reliability assessment is a critical aspect of NDT qualification. To demonstrate NDT reliability, the concept of probability of detection (POD) has been used to demonstrate NDT flaw detection capability and uncertainty associated with the process. The concept was adopted for many industries (e.g., aerospace, military, and energy/nuclear) using fracture critical components. POD relies on a monotonic relationship between the flaw size and the probability that the flaw will be detected. Based on the POD curve, the largest true flaw size that can be missed during the inspection (i.e., $a_{90/95}$, true flaw size with 90 % POD with 95 % confidence) can be estimated. This value allows one to estimate in-service inspection interval by assuming that a flaw with this size ($a_{90/95}$) exists in the part. The POD curves for pre-service and in-service inspections can be direct inputs for probabilistic fracture mechanics simulation, which estimates the risk of the component. For AM components used for critical applications, POD of NDT inspection is expected to be required by regulatory agencies.

POD curves are generally estimated based on empirical inspection trials of representative phantoms with flaws. The process can be both costly and time-consuming, and there exist challenges associated with developing phantoms for complex AM designs. Customized parts or design change may require quick modification of phantoms. Model-assisted POD (MAPOD) approach potentially reduces the NDT validation costs by fully or partially replacing practical NDT trials with simulation results made from NDT models. The NDT simulations require validation against physical measurements to ensure they are realistic. Realistic simulation reduces burdens of phantom fabrication and making measurements. More advanced statistical models can also reduce experimental needs or help merge similar experimental and simulation results. In addition to traditional flaw size parameter, multiple parameters of flaw characteristics or NDT acquisition settings need to be considered with POD estimation (e.g., multi-parametric POD). Simulation models can help optimize NDT inspection parameters to reduce uncertainty. Simulations for POD should also factor in the normal measurement-to-measurement variation caused by equipment.

The POD curves estimated from laboratory measurements and simulation only accounts for intrinsic measurement capability. In many inspection scenarios, human inspectors are still making the NDT inspections and decisions. The human inspector can be affected by various field conditions such as organizational pressures (e.g., deadlines, revenue goals, etc.) and the environment (e.g., temperatures, concern with radiation exposure, etc.). Various human and organizational factors need to be considered for more realistic POD curve estimation.

Many emerging NDT techniques and their advancements allow automated/assisted flaw detection using computer algorithms, which provides various characteristics of the anomalies in addition to simple detection of the existence of the anomalies. These algorithms may involve data-driven AI and/or machine learning (ML) algorithms. There is a growing need to assess accuracy, trustworthiness, and reliability of these algorithms used for NDT applications.

Published Standards

- API RP 581, Risk-Based Inspection Methodology (Addendum 2 published Oct 2020)
- ASTM E2862-18, Standard Practice for Probability of Detection Analysis for Hit/Miss Data
- ASTM E3023-21, Standard Practice for Probability of Detection Analysis for â versus a Data
- ASTM E3327/E3327M-21, Standard Guide for the Qualification and Control of the Assisted Defect Recognition of Digital Radiographic Test Data (E07.01)
- DIN EN 16991:2018, Risk-Based Inspection Framework
- NASA-STD-5009, Nondestructive Evaluation Requirements for Fracture Critical Metallic Components
- MIL-HDBK-1823A, Nondestructive Evaluation System Reliability Assessment (2009-04-07)

In-Development Standards

- International Committee for Non-Destructive Testing (ICNDT) SIG: NDT Reliability
- British Institute of Non-Destructive Testing (BINDT) technique validation working group

New Gap NDE11: Reliability of NDT. Current standards only cover binary and signal response ($\hat{a}\ vs\ a$) POD analysis methods based on logistic or linear regression. There are needs for standards and guidance documents dealing with more advanced statistical models, physics-based simulation models, and applications incorporating other factors affecting NDT inspection. Complex AM designs can pose challenges to developing physical reference standards, IQIs and RQIs with representative flaws, and the uses of NDT simulation tools and advanced statistical models are expected for model-assisted or model-based qualification. Guidance on incorporation or assessment of human factors and the evaluation of automated detection/measurement algorithms are also needed.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to improve POD analysis using advanced statistical model, using realistic simulation models, incorporating human factors, and incorporating automated/assisted flaw detection algorithms.

Recommendation: Develop standards or guidance documents on using advanced statistical model for POD analysis. Develop standards or best practice documents on implementing model-assisted or model-based approach POD analysis or NDT qualification. Topics such as physics-based model validation, calibration of the simulation model, statistical models to combine experimental and simulation results are expected to be discussed for various NDT techniques. Develop or improve physics-based simulation tools for emerging NDT techniques and develop workflows/tools to computationally seed desired type of flaws in realistic part geometry. Standards or guidance documents on carrying out POD analysis for different parameters of the flaws or NDT inspection process may be needed. Extension of NDT from binary flaw detection to flaw characteristic measurements (e.g., flaw sizing accuracy) may be discussed. Develop standards or guidance documents on estimating and incorporating human factors or organizational factors into POD analysis. Standards or guidance documents on assessing accuracy of automated/assisted detection algorithms and incorporation to POD analysis are needed.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): API, ASTM, DIN

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☒Aerospace; ☐Automotive; ☐Construction; ☒Defense; ☐Electronics; ☒Energy; ☐Medical; ☒Spaceflight; ☐Other (specify) ______________________

Material Type: ☐All/Material Agnostic; ☒Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☐Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐ Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Internal procedures, NASA-STD-5009 imposes POD requirements; or USAF is using MIL-HDBK-1823A

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.4.3.2 3D Image Quality Indicators (IQI)

In 2D radiography there exists a prescribed method to evaluate either the radiographic technique, the radiographic system, or both. These are referred to as Image Quality Indicators (IQIs) and wire line pairs. These tools are used as a visual aid for the technician, and other interested parties, to ensure that a pre-described minimum radiographic dataset quality has been achieved and to provide evidence that the radiographic system is functioning as desired. Wire line pairs are used to evaluate the minimum spatial resolution of the system and the IQI is used to ensure that a minimum optical density change is observable.

The above-described issue is not to be confused with, nor replace, part specific Representative Quality Indicators (RQIs) which are designed to provide evidence that the prescribed imperfection(s) (minimum flaw size, distribution, material conditions, etc.) are captured within the specific radiographic dataset for each individual part geometry.

To this point there does not exist a public standard to verify the image quality, the system performance, and objective quality of CT data acquisition systems. Currently, CT systems are qualified by RQIs with pre-identified flaws which are used to provide evidence that the data is comparable and repeatable. This lack of a global 3D Image Quality Indicator (IQI) creates a subjective approach to comparing CT system capability and equivalence. This need is independent of the need for a reference quality indicator (RQI) for specific part inspection.

Published Standards

- ASME B89.4.23: 2020, X-Ray Computed Tomography (CT) Performance Evaluation provides guidance for performance evaluation for users of the machine to assess.
- ASTM E1695–20e1 Standard Test Method for Measurement of Computed Tomography (CT) System Performance)
- ASTM E1441-19: Standard Guide for Computed Tomography (CT)

In-Development Standards

- ASTM WK84836 New Practice for Standard Practice for Visual Determination of Computed Tomographic (CT) Image Quality (in development in E07.01)
- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)

New Gap NDE12: 3D Image Quality Indicator for determining the sensitivity of a CT system. A 3D IQI will provide objective evidence for the sensitivity of a CT system independent of the final part geometry scanned.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: An 3D IQI that produces CT image data sets which accurately represent system sensitivity.

Recommendation: Complete work on ASTM WK84836 to publish a 3D Image Quality Indicator for CT systems standard

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASME; ASTM E07.01.02 Radiology (X and Gamma) Method, Non-Film Methods

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Proprietary methods for comparing CT system sensitivity.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.4.3.3 Reference Radiographic Images

Radiographic testing of castings and welds rely on reference radiographic images and associated acceptance standards. Work has not been done by SDOs to develop reference radiographic images for the types of anomalies produced in additive manufacturing and the 3D radiographic test (primarily CT) used to inspect for them.

Published Standards. No published standards were identified.

In-Development Standards

- WK84977 Standard Practice for Standard practice for controlling Computed Tomographic (CT) dimensional measurement performance by using Representative Quality Indicators (RQIs)

New Gap NDE13: Reference Radiographic Images and Standards for Additive Manufacturing Anomalies. To standardize the radiographic inspection of additive manufactured components, reference radiographic data (2D and 3D) of common anomalies in AM need to be developed.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Reference radiographic images (2D and 3D) for additive manufacturing anomalies.

Recommendation: Develop reference radiographic images (2D and 3D) and acceptance standards for additive manufacturing anomalies.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM E07.02 Reference Radiological Images

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☐All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☐Material Extrusion; ☒Material Jetting; ☒Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Proprietary test methods and acceptance criteria

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.4.4 Dimensional Metrology of Internal Features

The additive manufacturing process presents unique challenges in dimensional and surface roughness measurement. Additive manufacturing processes can produce internal features that are difficult to impossible to measure using traditional methods. Internal structures, tolerances and their limits, and surface roughness of complex 3D structures cannot be measured with traditional metrological methods. Destructive measurement methods can be used to measure these features but result in lower process yields from the cut-up process. Radiographic, ultrasonic, or electromagnetic techniques may produce results that differ from those generated by destructive evaluation creating the need to establish correlations. Therefore, accurate dimensional measurement is a challenge for internal features created by the AM process.

Among measurement technologies, X-ray computed tomography (CT) can measure internal features after fabrication and structured light can measure external features either during or after fabrication. CT technology provides important measurements such as wall thickness and radii of complex internal hollow structures that are otherwise impossible to measure.

Additive manufacturing processes may produce surfaces with high surface roughness, variable surface roughness or both. Surface roughness is difficult to assess on internal features or over large surfaces. Surface roughness may meet the print specifications but there can be abnormalities (uneven surface, etc.) from the build that may impact part performance. All these factors must be kept in mind when applying measurement techniques to AM parts.

Published Standards

Published CT or related standards include:

- ASTM E1441-19, Standard Guide for Computed Tomography (CT)
- ASTM E1570-19, Standard Practice for Fan Beam Computed Tomographic (CT) Examination
- ASTM E1695–20e1 Standard Test Method for Measurement of Computed Tomography (CT) System Performance).
- ASTM E3166-20e1, Standard Guide for Nondestructive Examination of Metal Additively Manufactured Aerospace Parts After Build
- ASTM E3375-23, Standard Practice for Cone Beam Computed Tomographic (CT) Examination
- ASME B89.4.23-202,0 X-Ray Computed Tomography (CT) Performance Evaluation
- ISO 15708-1:2017, Non-destructive testing – Radiation methods for computed tomography – Part 1: Terminology
- ISO 15708-2:2017, Non-destructive testing – Radiation methods for computed tomography – Part 2: Principles, Equipment and Samples
- ISO 15708-3:2017, Non-destructive testing – Radiation methods for computed tomography – Part 3: Operation and Interpretation
- ISO 15708-4:2017, Non-destructive testing – Radiation methods for computed tomography – Part 4: Qualification
- VDI/VDE 2630 Blatt 1.1, Computed tomography in dimensional measurement: Fundamentals and definitions
- VDI/VDE 2630 Blatt 1.2, Computed tomography in dimensional measurement: Influencing variables on measurement results and recommendations for computed tomography dimensional measurements
- VDI/VDE 2630 Blatt 1.3, Computed tomography in dimensional measurement: Guideline for the application of DIN EN ISO 10360 for coordinate measuring machines with CT sensors

Standards on techniques to evaluate measurement uncertainty using CT:

- ISO 15530-3:2011, Geometrical product specifications (GPS) - Coordinate measuring machines (CMM): Technique for determining the uncertainty of measurement - Part 3: Use of calibrated workpieces or measurement standards is often used as a technique to look at CT, but is not CT specific.
- VDI/VDE 2630 Blatt 2.1, Computed tomography in dimensional measurement: Determination of the uncertainty of measurement and the test process suitability of coordinate measurement systems with CT sensors (an adaptation of ISO 15530-3)

In-Development Standards

- ASTM WK61161, New Practice for Volumetric Computed Tomographic (CT) Examination (E07.01)
- ASTM WK71550, New Practice for Practice for Computed Tomographic Examination of Additive Manufactured Parts (E07.01)
- ASTM WK78465, Specification for Additive Manufacturing for Medical- Non-destructive Testing and Evaluation-Test Method for Evaluation of Porous Structures in Medical Implants via Computed Tomography Scanning (F42.07)
- ASTM WK84836, Standard Practice for Standard Practice for Visual Determination of Computed Tomographic (CT) Image Quality (E07.01)
- ASTM WK84977, New Practice for controlling Computed Tomographic (CT) dimensional measurement performance by using Representative Quality Indicators (RQIs) (E07.01)
- ISO 10360-11, Geometrical product specifications (GPS) - Acceptance and reverification tests for coordinate measuring systems (CMS) - Part 11: CMSs using the principle of X-Ray computed tomography (CT) (deleted)
- ISO TR 11335, Structural Resolution Tests for X-Ray Computed Tomography used in Dimensional Measurement Applications
- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)

It should be noted that, while the above CT standards address internal metrology indirectly (E1570 and E1695) providing a basis for dimensional metrology of internal features in AM parts, none are written specifically for AM parts.

Gap NDE4: Dimensional Metrology of Internal Features. The utility of existing and draft CT standards is needed for the dimensional measurement of AM internal features and surface roughness.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Characterization of machine performance and task specific measurement uncertainty on AM parts.

Recommendation: ASTM E07 should address the applicability of current and draft CT standards (E1570, E1695, and WK61161) for measurement of internal features and surface roughness in additively manufactured parts, especially parts with complex geometry, internal features, and/or embedded features. Current CT metrology state-of-the-art needs to be tailored to evolving AM part inspection requirements. See also gap DE26, Measurement of AM Features/Verifying the designs of features such as lattices, etc. Standard methods need to be developed for assessing surface roughness from CT and structured light data from AM surfaces. See also Post Processing section 2.2.3.4 gap P4.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM, ISO/IEC JTC 1/WG12

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Ultrasonic and hall effect wall thickness measurements can be used for walls with one external surface. Company specific internal procedures, as well as other existing standards and CT software to determine dimensional accuracy of topology optimized complex geometry AM parts are used.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: As noted in the text. Also, E1570 and E1695 are more general in their approaches and are not specific to AM. There is guidance for testing; however, it does not provide a definitive method for internal features.

2.4.5 Data Fusion

Data fusion in the NDT metrology world is defined as applying more than one NDT technique to provide additional, complementary, or redundant information that can conform with the result. Data fusion provides the ability to measure the same location from different viewpoints. This is needed because of the complex geometry that might exist in AM parts. Setting this process up is not easy as it might require a robotic-based or automated positioning system. One example of this methodology can be applying the eddy current method to check surface detection, but then using ultrasonic methods to get volumetric information. Combining the data sets from both will provide a simple, unified interpretation of results.

Data fusion also is used in a scenario where model-based inspection techniques for AM rely on the combination of a number of different models and data sets to derive meaningful interpretation and utility of the inspection results. NDE data plays an important role in product acceptance/rejection, validation of simulation/predictive models, process improvement, and potentially process control. Models include: the original part or feature model (either a surface or solid model); the build model to include support structure, fixture, or base features (hybrid parts); and models or data sets associated with NDE or metrology scans such as CT reconstructions and 3D and 2D feature maps. The orientation of these data sets in a common frame of reference is critical to interpreting the differences and relationship of the features. In one example, an as-built model calculated from a CT reconstruction may be compared to an original part model to determine geometric fidelity, or how to orient the as-built part to find the finished product within the near net shaped deposit. In another example, the finished part model may be compared with the as-deposited model and the location of near surface defects, to ensure adequate machining allowance is provided to remove the defects identified within an NDE-generated data set. Thermomechanical simulation may be compared with as-built data sets, to derive the character or location of distortion or feature resolution from form metrology methods.

See gap DA9 and gap DA10 (formerly NDE5) in section 2.6.3.1 Data Registration and Fusion.

Published Standards. No published standards were identified.

In-Development Standards

- ASTM WK73978 New Specification for Additive Manufacturing-General Principles-Registration of Process-Monitoring and Quality-Control Data
- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)

2.4.6 NDE of Polymers, Ceramics and Composite Materials

For polymers, ceramics and composite materials, the most common NDE methods recognized and controlled by industrial standards are acoustic emission, computed tomography, infrared thermography, leak testing, radiographic testing, shearography, spectroscopy (FTIR, Raman), strain measurement, ultrasonic testing, and visual testing. ASTM E2533-21, Standard Guide for Nondestructive Testing of Polymer Matrix Composites Used in Aerospace Applications, is valid for NDE of polymer matrix composites (PMCs), and therefore has peripheral relevance to NDE of plastics used in AM [acrylonitrile butadiene styrene (ABS), polycarbonate (PC), polylactic acid (PLA), nylon, polyaryl ether ketones (PEAK), and polyetherimide (PEI)]. That said, AM plastic parts are expected to have similar characteristics to PMCs; therefore, the same or similar NDE techniques might be applicable. Standards development for ceramic materials is currently underway, with an emphasis being placed on common structural ceramics like alumina, zirconia, and silicon nitride. NDE of these common ceramics will be prioritized.

NASA-STD-6030 is applicable to mature AM polymeric materials (thermoplastic powder and filament and SLA thermosetting resins), and processing technologies (powder bed fusion (PBF-LB), vat photopolymerization (SLA), and material extrusion (FDM and FFF)). These materials and processes are used in AM spacecraft parts with either nonnegligible (Class B) or negligible (Class C) consequence of failure. Furthermore, while NDE is waived for Class C polymeric parts, Class B polymeric parts shall receive NDE for process control with full coverage of the surface and volume of the part, with any coverage limitations due to NDE technique(s) and/or part geometry documented. Lastly, it should be noted that NDE of Class B parts for process control requires the use of physical reference standards for calibration and acceptance criteria based on the capability of the NDE technique but does not require quantitative validation of flaw detection, as would be the case for metallic Class A high consequence of failure parts.

There are currently five categories used to create AM polymer parts. The categories are:

- Powder bed fusion and sintering (PBF-LB, SLS)
- Material extrusion (FDM, FFF, DWI)
- Vat polymerization (SLA)
- Material jetting
- Sheet lamination

Current initiatives in the development of ceramic AM standards need to be applicable to the following technologies:

- Vat photopolymerization
- Material extrusion
- Binder jetting

Some initiatives to be noted are:

- NASA 6030 Additive Manufacturing Requirements for Spaceflight Systems covers non-metallic parts and address NDE and physical-mechanical property testing.
- CMH-17 Composite Materials Handbook, has an effort related to non-metallic NDE (composites)
- NDE in Additive Manufacturing of Ceramic Components
- ASTM Interlaboratory Study 1814, Mechanical Property Evaluation of Ceramics Fabricated with Vat Photopolymerization

In-Development Standards

- ASTM WK85121, Nondestructive examination of polymeric and nonmetallic additively manufactured parts after build

Gap NDE6: NDE of Polymers, Ceramics and Composite Materials. No published or in-development standards or specifications have been identified for NDE of polymers, ceramics and composite materials.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Research who uses filaments, powder, or pellets with and without continuous fiber, chopped fiber, and particle reinforcement. Of interest are low density, high specific strength plastics used in secondary structural applications, and polymers with a high degree of fiber or particle loading in applications requiring strength, toughness and low weight. Users and manufacturers of such materials need to be surveyed to determine what requirements they are anticipating for NDE inspection of parts made from polyetherimides (PEI), polyaryl ether ketones (PAEK), composite non-metallic AM parts (for example, carbon-filled nylon), unfilled thermoplastics (ABS, PC, PLA, nylon, etc.), and SLA UV-curable resins. Polymers such as Ultem® 9580 PEI, which is used in FFF/FDM parts (air ducts, wall panels, seat frameworks) and is flame, smoke and toxicity (FST) compliant and has excellent specific strength are noteworthy. Ceramic materials of interest are those with high flexural strength and hardness, such as alumina, zirconia and silicon nitride, fabricated using photocurable resin or other aqueous and non-aqueous-based, sheer thinning feedstocks.

Recommendation: There is a need for an industry-driven standard led by NDE experts and supported by the additive manufacturing community to assess current inspection practices and introduce NDE inspection requirements for structural or load bearing polymers, ceramics, and composite materials. Use ASTM E2533 as a starting point and guideline when applicable.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM F42/ISO TC 261, ASTM E07, ASTM D20, ASME, SAE AMS AM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☐All/Material Agnostic; ☐Metal; ☒ Polymer; ☒Ceramic; ☒Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Company specific internal methods

V3 Status of Progress: ☒ Green; ☒Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; New

V3 Update: As noted in the standards list above, ASTM WK85121 will address polymers and ASTM Interlaboratory Study 1814 will recommend standards needs for ceramics.

2.4.7 NDE of Counterfeit AM Parts

To protect against counterfeit 3D parts, anti-counterfeiting methods are being developed for components produced via AM. Nondestructive evaluation methods may be used in conjunction with some anti-counterfeiting methods to verify product authenticity. AM-specific considerations for aligning NDE with anti-counterfeiting include:

- Using as-manufactured NDE data, especially for polymers, to establish a standard for later field validation
- Incorporate and keep current cybersecurity practices to manage the creation and storage of NDE data used for anti-counterfeiting verification
- Simple NDE methods that are compatible with decentralized inventory management enabled by the AM manufacturing model.
- Methods to detect covert markings

Best practices in other industries recognize the interplay between security and quality, address the advantages of providing authentication options at multiple points in the supply chain and encourage scalable approaches that make it difficult to counterfeit the anti-counterfeiting measures.[37] An Aerospace Industries Association (AIA) report covering counterfeiting recommended that standards in the area of mechanical parts and materials be established.[38]

Anti-counterfeiting can be viewed as essentially an arms race with an economically-motivated foe that aims to exploit a brand's good name and a trusted maker's quality procedures. Covert markings are therefore preferable, since they delay notifying the counterfeiter that updates are needed. NDE is particularly suited to AM protection, because:

- NDE methods can detect subsurface, chemical, and other covert taggants, optimally quickly, portably, and with minimal training
- Affordable, scalable protections are more likely to be adopted, and anti-counterfeiting can, optimally, align with existing NDE that is useful for quality monitoring. This alignment recognizes that counterfeit detection is part of quality: a counterfeit part is a quality failure.
- AM's smaller batch sizes and focus on customization limits the applicability of sampling; NDE makes it possible to test the end product without sacrificing any units to destructive testing.
- Distributed manufacturing empowers additional players as production sites. Inspecting and certifying each site (and its suppliers) would introduce potentially crippling costs compared to

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[37] See for example *Best Practices in the Fight Against Global Counterfeiting*, published by ANSI in 2011.
[38] See *A Special Report Counterfeit Parts; Increasing Awareness and Developing Countermeasures*, published by AIA in March 2011.

simply checking their output, both for quality and for the correct anti-counterfeiting marks, using NDE.

- NDE makes it possible to compare field-collected verification data (for a print) with a stored file (for a correct, authorized version), so that trust can be established. This model can apply to authorized repair parts printed as needed, or to point-of-care medical and pharmaceutical printing, for example. In the latter case, the stored model and match requirements can be complex, permitting only certain kinds of variation (size and shape; limited changes in dose or ingredients such as adding flavor or removing allergens).

Potentially relevant published standards for general industry include:

- ISO 22380:2018, Security and resilience — Authenticity, integrity and trust for products and documents — General principles for product fraud risk and countermeasures
- SAE AS5553D-2022, Counterfeit Electrical, Electronic, and Electromechanical (EEE) Parts; Avoidance, Detection, Mitigation, and Disposition. SAE G-19 Counterfeit Electronics Parts committees have a suite of standards which may be useful.
- SAE AS6174A-2014, Counterfeit Materiel; Assuring Acquisition of Authentic and Conforming Materiel

Much of the standards work on counterfeit electronic parts focuses on trust of upstream suppliers. AM's distributed nature, with many more players, further complicates supplier verification. Electronic parts are a particularly difficult counterfeiting challenge because a part may function, but fail early. Uncovering those uplabeled components is best accomplished via functional (electronic) testing, not NDE. Including authentication marks or taggants on certified parts, and then using NDE to check for their presence, is a possible workaround. For other AM products (metal, polymer, pharmaceutical), shape, strength, and materials (including particle size and distribution) are the quality targets, all well suited to NDE; in those instances, NDE can seamlessly test both for the presence of an authenticator and for other quality elements.

Gap NDE7: NDE of Counterfeit AM Parts. There are no published or in-development NDE standards for methods used to verify anti-counterfeiting methods.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: Future R&D may be needed if an anti-counterfeiting method is developed which cannot be verified by existing NDE methods or standards.

Recommendation: Develop NDE methods and standards for anti-counterfeiting that are not addressed by existing methods or standards. See also sections 2.1.7 Design for Anti-counterfeiting (gap DE29); 2.2.2.13 Anti-counterfeiting (process control); and 2.4.2 gap NDE2.

Priority: ☐High; ☐Medium; ☒Low

Organization: ASTM F42/ISO TC 261, ASTM E07, SAE AMS-AM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☒Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: ISO 22380 has been published and SAE AS5553B has been revised, the current edition, D, was approved in 2022.

2.4.8 NDE Acceptance Criteria for Fracture Critical AM Parts

In general, fracture critical AM hardware (such as flight hardware) requires comprehensive volumetric and surface NDE to ensure the hardware is acceptable for use. Since the first release of the roadmap in 2017, NDE community has been learning what works and what does not when inspecting high value and limited production run flight hardware. For example, penetrant inspection of the part's surface requires surface preparation that may depart from normal post-processing. For volumetric inspections, radiation or ultrasound are transmitted through AM structures using the same inspection procedures developed for conventional welded and wrought products, which may yield results not tailored to AM. Consequently, most of the acceptance criteria for AM parts are derived from inspection of product forms produced using materials and processing developed outside of the AM community. The question then becomes whether AM parts are being inspected and accepted with the appropriate level of rigor and conservatism so that risks associated with the use of newer AM processes are mitigated.

New industry-based acceptance criteria are needed for AM parts. These acceptance criteria may be based on criticality, loads and environments, safety, consequence of failure, or NDE inspectability. In addition to practical and meaningful acceptance criteria, a deeper understanding is needed involving determination of the role specific types of AM defects play in part failure (see gap NDE9). A lot of frameworks must be developed so that appropriate industry-based acceptance criteria can be implemented. Towards this goal, harmonized defect terminology must first be adopted (see gap NDE1). Second, because of the need to have high quality parts in fracture critical applications that are relatively defect-free and have a low probability of failure, the industry must lay the groundwork to allow the production of parts using qualified material processes in which the defect state is known, reproducible, and controlled. Third, given the need to mitigate the higher risk associated with the use of newer AM parts due to the presence of unique flaw types at sizes and distributions for which little engineering experience exists, there is a need to develop sensitive NDE methods such as micro-CT, or whole-body resonance methods such as PCRT, so that fracture critical AM parts can be adequately screened before acceptance. For example, the high usage and reliance on micro-CT to detect and characterize small defect sizes (< 100 μm) in fracture critical metal AM parts is prevalent in NASA, the DOD, and elsewhere in the aerospace industry. These factors entail the adoption of acceptance criteria with the appropriate level of conservatism so that all relevant flaws are detected.

Towards this goal, an ASTM WK75329 Standard Practice for the Nondestructive Testing (NDT), Inspection Levels and Acceptance Criteria for Parts Manufactured with Laser Based Powder Fusion has been in work and expected to be balloted in 2023. This practice provides two NDE inspection levels (Level I and II) for metal PBF-LB parts and lists acceptance criteria and applicable NDE methods. Three defect types considered that are unique to PBF-LB:

1) lack of fusion porosity
2) keyhole porosity
3) trapped powder

Level I NDE, which is more comprehensive consists of CT, PCRT, PT, RT, UT, and VT, while Level II NDE consists of PCRT, PT, and VT. The practice is not based on part-driven engineering criteria but on the practical inspection capability of the applied NDE methods.

In the application of NDE, the types of defects that are applicable to the AM process must be matched to the appropriate NDE method. Such matching guidance appears in ASTM E3166-20e1 (Table 2) and in ISO/ASTM DTR 52905 (Table 3). There are longstanding NDE standard defect classes for welds and castings with matching NDE methods. The defects characteristic to these processes may not be applicable to the AM process. Welding flaw types have been identified specifically for use such as electron-beam welding for fatigue critical applications. A possible approach is to define allowable defects as shown in SAE AMS2680C-2019, Electron-Beam Welding for Fatigue Critical Applications. Discontinuity limits could be approached (developed) for each AM process where flaws may be slightly different, e.g., PBF-LB, DED-LB. This implies that until an accepted defects catalog and associated NDE detection limits for defects are established, the NDE techniques and acceptance criteria may remain part-specific point designs.

Published Standards

- AWS D20.1/D20.1M:2019 Specification for Fabrication of Metal Components Using Additive Manufacturing

- NASA-STD-6030 Additive Manufacturing Requirements for Spaceflight Systems Section 4.8 provides guidance for NDE with full coverage of surface and volume of the part including verifiable detection of critical initial flaw size and fracture critical damage tolerant parts performed on Class A and B parts including the concept of AM risk is introduced, which governs the quantitative NDE performed for a given part. See also NASA-STD-5009, Nondestructive Evaluation Requirements for Fracture Critical Metallic Components

In-Development Standards

- ASTM WK75329, Practice for Nondestructive Testing (NDT), Part Quality, and Acceptability Levels of Additively Manufactured Laser Based Powder Bed Fusion Aerospace Components (in development under F42.07)
- ASTM WK75584 Standard Test Method for Additive Manufacturing Non-destructive testing and evaluation of fatigue cracks using tensioned computed tomography (in development under F42.01)
- ASTM WK76038 Standard Test Method for Additive Manufacturing of Metals -- Non-destructive testing and evaluation -- Porosity Measurement with X-ray CT (in development under F42.07)

Gap NDE8: **NDE Acceptance Criteria for Fracture Critical AM Parts.** There is a need for an industry standard that establishes NDE acceptance criteria and classes for fracture critical AM production parts. The classes could be based on:

1) fracture criticality (NASA-STD-5009)
2) consequence and likelihood of failure (NASA-STD-6030)
3) design loads (JAXA and LMCO)
4) NDE inspection capability (ASTM WK75329)
5) other factors such as mission or safety criticality

Potential stakeholders are NASA, its international space partners, the aerospace industry, the commercial aviation industry, the FAA, the DoD, the DOE (for example, the NRC), the nuclear industry, or any entity that produces or uses fracture critical AM hardware.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: This gap interfaces with gap NDE9 described in Section 2.4.9 and focuses on the acceptance of AM production parts destined for service. Acceptance consists of NDE of production parts or components. It is anticipated that parts will be made using optimized processes (for example, NASA-STD-6060 qualified material processes), which contain minimal or otherwise controlled loadings of technologically important AM defects. These in-family parts will then be compared to out-of-family parts, which either contain excessive loadings of technologically important AM defects, or have been made with questionable feedstock, or have been subjected to a known process anomaly, thus compromising their acceptance and subsequent use in service. Research can then focus on identifying what feedstock or process (or post-process) conditions led to nonconformance and out-of-family behavior. The role of NDE will be to distinguish between in-family (nominal) versus out-of-family (non-nominal) production parts possessing different characteristic damage states. For example, one of the key questions to answer would be to determine which process variable(s) are relevant and have the greatest effect on the performance of the part. Also, the type of scanning (i.e., X-ray radiography, CT, micro-CT, PCRT) relative to the material type/thickness and design complexity of the part should be considered.

Recommendation: Develop an industry standard that establishes different acceptance classes and NDE acceptance metrics for high fidelity of finished production parts and components depending on feedstock, and process (or post-process) conditions. The acceptance metrics (criticality, consequence and likelihood of failure, loads, etc.) are expected to be industry specific (aerospace, medical, energy sectors). Part and component level NDE inspections may be corroborated with effect-of-defect coupon (or witness specimen) level testing described in gap NDE9 using specimens that have the appropriate level of fidelity, i.e., sufficient similarity between the defect state and mechanical response in sacrificial samples (for example, ASTM E8 compliant dog bones, and witness coupons showing the same level of defects) with natural flaws in actual production parts.

Priority: ☒High; Medium; ☐Low

Organization: ASTM F42 / ISO TC 261 JG 59, ASTM E07, ASTM E08 on Fracture and Fatigue

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify)

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: AWS D20.1 contains acceptance criteria but is also planning to address internal flaws matched with surface finish for fatigue applications. ASTM WK75329 will be a standard practice for NDE of PBF-LB aerospace components, establishing NDE acceptance classes and acceptance criteria. The criteria are based on the practical limits of NDE technology, not effect-of-defect.

2.4.9 Effect-of-Defect of Technologically Important AM Defects

As noted in Section 2.4.8 on Acceptance Criteria, fracture critical metal AM hardware (such as a high consequence of failure flight hardware) requires comprehensive volumetric and surface NDE to ensure the hardware is acceptable for use. To quantify the risks associated with the part and to demonstrate acceptable damage tolerance, it is incumbent upon the structural assessment and fracture and fatigue communities to define critical initial flaw sizes (CIFS) for the part to define the objectives of the NDE. Knowledge of the CIFS will allow the NDE and fracture control community to evaluate risks and communicate meaningful recommendations regarding the acceptability of the risk.

In NASA-STD-6030, high-risk, high consequence of failure parts are categorized as Class A parts. Implicit in NASA's Class A-B-C formalism is the ability to:

1) detect flaws that bracket the critical initial flaw size at a requisite reliability (e.g., 90/95 POD)
2) detect flaws that are relevant (i.e., effect on finished part performance has been demonstrated)
3) detect flaws that are unique to AM for which engineering experience is lacks.

Similar considerations might be for non-fracture critical AM parts that have a nonnegligible consequence of failure. For example, such parts might be used in applications are that are safety and mission critical, and may include both polymeric and metallic AM hardware. In NASA-STD-6030, such parts are categorized as Class B parts. Like Class A parts, Class B parts also require comprehensive volumetric and surface NDE to ensure the hardware is acceptable for use. However, the requirement to detect flaws at a requisite reliability is waived, for example, 90/95 POD as levied by NASA-STD-5009 is not imposed. Instead, in the case of ASTM WK75329, acceptance criteria are based on the practical limits of NDE technology, not knowledge of the CIFS, fracture mechanics, reliability of the NDE, or effect-of-defect. However, an important caveat exists for non-fracture critical Class B parts that cannot be ignored. Namely, the effect-of-defect is currently unknown for technologically important flaws unique to AM such as:

1) lack of fusion porosity
2) keyhole porosity
3) trapped powder

In this case, it is premature, therefore, to conclude flaws of a given type and size are irrelevant and thus do not need to be detected.

To rectify this situation, this gap implements guidance to prepare subscale test specimens that allow the effect of technologically important defects on relevant end-use properties to be determined. Contrary to gap NDE8, which is applied to production parts, gap NDE9 investigates the effect-of-defect using representative, subscale coupons (or witness specimens). This allows a direct cause-and-effect relationship to be established between processing (and/or post-processing), the resulting defect state, and end-use properties, thus establishing succinct process-structure-property relations for specific defects. Important questions such as whether defects can be healed through hot isotactic pressing (HIP) or heat treatment can also be examined if needed.

To obtain meaningful results, control coupons (or witness specimens) are made using the same materials and processes as used for high fidelity or finished production parts and components. The defect state is then intentionally altered using guidance in ISO/ASTM TR 52906-EB. The coupons and subscale test specimens so obtained can possess a range of defect states. To facilitate ensuing NDE inspections and destructive tests (T&I), the specimens called out in this standard are fabricated in the form of standard test specimens for tensile testing (ASTM E8, D638, D5766, D6742), compressive testing (ASTM D395), fatigue life (ASTM E466, E606), fracture toughness (ASTM E399, E1820), etc., as outlined in Tables 13 through 16 in NASA-STD-6030. For a given defect or characteristic defect state great care must be taken to ensure the effect-of-defect exhibited by coupons and subscale test specimens is representative of the effect-of-defect exhibited by the production part of interest. To accomplish this, coupon or subscale test specimen data should be verified or augmented by production part data when doubts of equivalency exist.

Published Standards

- NASA-STD-6030, Additive Manufacturing Requirements for Spaceflight Systems Section 4.8 provides guidance for NDE with full coverage of surface and volume of the part including verifiable detection of critical initial flaw size and fracture critical damage tolerant parts performed on Class A and B parts including the concept of AM risk is introduced, which governs the quantitative NDE performed for a given part. While the NDE approach used for fracture critical (Class A) parts covered by gap NDE8 must follow the intent of NASA-STD-5009 towards meeting a 90/95 POD requirement, this standard instead focuses on effect-of-defect.
- ISO/ASTM TR 52906-EB, Additive Manufacturing—Nondestructive Testing—Intentionally Seeding Flaws in Metallic Parts

Published standards for fracture control of metals (currently agnostic to AM):

- NASA-STD-5009, Nondestructive Evaluation Requirements for Fracture Critical Metallic Components

In-Development Standards

- ASTM WK75329, Practice for Nondestructive Testing (NDT), Part Quality, and Acceptability Levels of Additively Manufactured Laser Based Powder Bed Fusion Aerospace Components (in development under F42.07)

New Gap NDE9: Effect-of-Defect of AM Defects Detectable by NDE. There is a need for an industry standard to determine the effect of technologically important flaws unique to AM, which are considered to relevant and have a significant effect on end-use properties. Contrary to gap NDE8, which uses acceptance criteria based on NDE capability developed for production parts or components, gap NDE9 investigates the effect-of-defect at the coupon level (or witness specimen level). Direct cause-and-effect relationships between process (and/or post-processing), the resulting defect state, and final properties is established (process-structure-property relationship). Important questions such as whether defects can be healed through hot isotactic pressing (HIP) or heat treatment can also be examined if necessary. Questions about equivalency between subscale and production parts can be accomplished by verifying or augmenting subscale part with production part data.

To obtain meaningful results, control coupons (or witness specimens) are made using the same materials and processes as used for the production part. The defect state is then intentionally altered using guidance in ISO/ASTM TR 52906-EB. The specimens so obtained will possess a range of defect states, which will be characterized by NDE. The specimens called out in this standard can be fabricated in the form of standard test specimen geometries for tensile testing (ASTM E8, D638, D5766, D6742), compressive testing (ASTM D395), fatigue life (ASTM E466, E606), fracture toughness (ASTM E399, E1820), etc., as outlined in Tables 13 through 16 in NASA-STD-6030.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: A multidisciplinary effort is needed encompassing feedstock selection, AM processing and post-processing, NDE, and physical and mechanical property testing. Coupons (or witness specimens) are made at one or several manufacturers are analyzed by NDE and finally by destructive testing (mechanical and physical property testing). Round robin testing following the outline of than ASTM interlaboratory study (ILS) would be ideal subscale test coupons are interrogated by NDE at several labs to assess NDE reproducibility and repeatability and leading to NDE Precision and Bias statements. This gap interfaces and with proper coordination can be combined with gap NDE8 by fabricating witness coupons at the same time as production parts. The coupon-level test specimens fabricated by this standard will contain controlled loadings of technologically important AM defects, which are then used to determine the effect-of-defect in order to assess relevance or nonrelevance. The relevance of flaw type, size and distribution as characterized by NDE is compared to part performance as indicated by mechanical and physical property test results. The goal thus is to develop acceptance criteria based on knowledge of the characteristic defect state rather than on NDE reliability and fracture mechanics and has application to both metallic and polymeric (including composite) AM parts.

Recommendation: Develop an industry standard that allows fabrication of subscale test specimens (standard test coupons) that directly link the characteristic defect state with end-use performance properties such as strength, modulus, fracture toughness, and part density.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM F42 / ISO TC 261 JG 59, ASTM E07 on NDT, ASTM E08 on Fracture and Fatigue, NASA

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ☒Test coupons and artefacts

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

It was noted that digital image correlation (DIC) is one way to find and measure the surface strain in finished AM components or samples which may not visible to the eye. NASA also includes DIC equipment in its NDE equipment inventories. In addition to strain mapping, DIC is used to measure warpage (out-of-plane and in-place displacement or departure of dimensions from engineering drawing), which can be a common AM manufacturing flaw. DIC could also aid in qualification and certification determinations.

No standards gaps were identified with regards to DIC.

2.4.10 In-Service NDE

2.4.10.1 In-service Inspection

A key step in using AM-fabricated components will be the assurance that safety-critical components meet the quality and performance requirements of the industry and regulatory authorities throughout the components' lifetime. In-service inspection refers to the periodic inspection of components that have already been placed into service, which could not be practically removed once in use, to monitor flaw initiation and growth. AM materials provide unique in-service inspection challenges. For example, porosity, grain microstructure, and surface roughness are common issues with AM components, and there is a lack of data on the effects of these issues on emerging or unconventional nondestructive test methods such as ultrasonic (signal-to-noise, scatter, and attenuation come into play), eddy current testing, and radiographic testing. The nuclear sector primarily uses ultrasonics for volumetric inspections and eddy current for surface inspection of the heat exchange tubing. As industries progress toward the use of AM-built components, the inspection capabilities to monitor the safety and integrity of these components need to be effective and reliable.

Issues such as critical flaw types, critical flaw sizes, flaw locations, and degradation mechanisms need to be understood so that appropriate NDE methods can be implemented, adapted, or developed. Research is needed to demonstrate that NDE can identify the critical flaws early enough so that mitigating action can be taken. Also, AM components may have complex geometries that will challenge existing NDE approaches, so new inspection approaches may be needed such as whole-body resonance approaches. Design of AM components where NDE inspectability is factored into early design phases to facilitate detection of critical flaws throughout the service life at the critical location, size, and distribution is also expected to play a role.

Published Standards

- ASME BPVC-XI-1 – 2021, Rules for Inservice Inspection of Nuclear Power Plant Components
- ASTM E3213-19, Standard Practice for Part-to-Itself Examination Using Process Compensated Resonance Testing Via Swept Sine Input for Metallic and Non-Metallic Parts (E07.06)

No in-development standards have been identified.

New Gap NDE10: In-service Inspection. There is a need for standards for in-service inspection of safety-critical AM components. Some installed AM parts (e.g., nuclear industry applications) cannot be removed for inspection. The effects of chemical, heat, and radiation degradation on AM materials and components, and the service life and inspection intervals thereof, are presently unknown.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D is needed to demonstrate which in-service NDE methods or techniques can identify critical flaws in safety-relevant AM components. Prior to implementing in-service NDE, critical flaw types and locations should be identified in addition to degradation mechanisms. The effects of material microstructure and geometry should be explored. New or emerging NDE techniques, such as ultrasonic full matrix capture, targeted micro-CT, and PCRT, may need to be tested. An increased understanding about how surface finish issues common with additive parts would affect eddy current measurement states is needed.

Recommendation: Develop standards for in-service inspection of AM components. Standards may describe issues including, but not limited to, what types of flaws to look for, where critical flaws might occur (i.e., the relevant inspection volume), how critical flaws might propagate (i.e., rates of propagation, degree of branching), the level of component surface finish that is needed, methods for inspecting complex geometries, and guidelines for reference mockups and standards. It is recommended that exemplar AM components used in critical applications (nuclear, aerospace, and/or medical) that present unique NDE inspection challenges will be fabricated with known relevant flaws (e.g., porosity) and distributed to stakeholders in a round robin study conducted over the course of a component's life cycle. For example, components with accumulated service as measured by time and number of cycles would be inspected at intervals characteristic of 1) post—fabrication/pre-installation (new or early life), 2) periodic-remove and inspect (mid-life), 3) decommissioning/component replacement (near end-of-life), and 4) ultimate failure (end-of-life).

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASME, ASTM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☐Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☒Energy; ☐Medical; ☐Spaceflight; ☒Other (specify) Nuclear

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion;☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: Use existing in-service inspection standards developed for non-AM parts and materials.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.5 Maintenance and Repair

2.5.1 Introduction

Maintenance

For purposes of this discussion, "maintenance" is defined as encompassing maintenance of AM machines; condition-based maintenance (CBM)[39] as it relates to the use of metal and polymer AM processes and equipment; level of repair analysis (LORA)[40] and reliability centered maintenance (RCM)[41] analysis of AM parts, tools, and equipment; training of maintenance personnel; and maintenance inspection of AM machines.

Additive Repair

Additive repair processes apply exclusively to metal components and refer to processes used to add or build up material onto a substrate. The repaired surface(s) and component are then returned to the as-designed condition by subtractive manufacturing methods. Additive repair processes in current use include blown metal powder systems and hybrid (additive + subtractive) systems. For some applications, metal cold spray processes (high pressure cold spray systems) can be used to add metal to an existing surface for structural purposes. Other aspects of additive repair include: requirements for metal powder used for additive repair, surface preparation requirements, qualification and certification of the repair process, and inspection of repairs performed with AM technology. There are currently no materials, processes or equipment that are used to additively repair polymer AM parts.

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[39] Conditioned Based Maintenance: Performing Maintenance based on Need (i.e., based on the Condition or Health of a component or system rather than on a periodic or scheduled basis). Source: ARP6461, *Guidelines for Implementation of Structural Health Monitoring on Fixed Wing Aircraft.* The purpose of Condition Based Maintenance (CBM) is to reduce the maintenance and life-cycle costs by using a proactive strategy of performing maintenance based on evidence of need. That is contrasted with Interval Based Maintenance, where the action is performed at a set interval (measured by time, mileage or some other metric). Source: SAE TAHB0009, *Reliability Program Handbook*

[40] Level of Repair Analysis (LORA): An analytical methodology used to assist in developing maintenance concepts, influencing design, and establishing the maintenance level at which components will be replaced, repaired, or discarded based on economic/noneconomic constraints and operational readiness requirements. Source: AS1390, *Level of Repair Analysis (LORA)*

[41] Reliability Centered Maintenance (RCM) is a logical, structured framework that leverages reliability assessment activities to determine the optimum mix of applicable and effective maintenance activities needed to sustain the desired level of operational reliability of products/systems while ensuring their safe and economical operation and support. Source: SAE TAHB0009, *Reliability Program Handbook*

Tools and Tooling

As more fully described below, tools and tooling refer to creation or repair of those artifacts needed to execute a parts repair and/or remanufacture for the purposes of scheduled maintenance or general upgrade/overhaul. Tools and tooling as applied here may also include molds and dies that are manufactured using AM processes. Tools refer to those parts and assemblies designed and manufactured by AM processes and used to support the manufacture and/or repair of aerospace, energy, industrial, medical, and other sectors' equipment and systems. Tooling refers to those parts that are designed and manufactured by AM processes and used to make the end use parts that become part of the aircraft itself (or the industrial or aerospace equipment and systems).

2.5.2 Maintenance and Sustainment of Machines

Manufacturers have prescribed methods for maintenance of their particular additive machines. The intent of focusing on this area is not to circumvent manufacturer-recommended machine maintenance practices, but to establish boundaries for standardization of the various maintenance activities that may be unique to AM machines whether the machines are used to produce metal AM or polymer AM parts. These may include for example:

- Facility requirements that will provide for future maintenance of the AM machines including but not limited to: electrical power supply requirements; power conditioning requirements; standby power requirements or recommendations; water availability and quality or filtration requirements; structural requirements for supporting the AM machine; lighting; limits on temperature and humidity where the AM machine is installed; and distance from machine to wall of room (required to support maintenance, air flow, people, etc.)
- Safety overviews
- Skill set required to perform maintenance on AM machines
- Training of maintenance personnel
- Documentation of AM maintenance programs
- Hazardous materials related to AM machines
- Software maintenance and cybersecurity related to AM machines

SAE committee G-41 Reliability standards portfolio has several resources but they are more broadly applicable and not specific to AM.

Published Standards

- IEC 60300-3-11:2009 Dependability management - Part 3-11: Application guide - Reliability centred maintenance (IEC TC 59) but is not specific to AM.
- ISO 17359:2018 Condition monitoring and diagnostics of machines — General guidelines (TC 108 / SC 5)
- ISO / ASTM 52941: 2020 Additive manufacturing — System performance and reliability — Acceptance tests for laser metal powder-bed fusion machines for metallic materials for aerospace application (Aerospace PBF) defines relevant testing.

- SAE JA1012: 2011, A Guide to the Reliability-Centered Maintenance (RCM) Standard (2011-08-22)
- SAE JA1011: 2009, Evaluation Criteria for Reliability-Centered Maintenance (RCM) Processes (2009-08-26)
- SAE AMS7032 Machine Qualification for Fusion-Based Metal Additive Manufacturing (2022-08-17)

Gap M1: AM Analyses in RCM and CBM. With respect to maintenance and sustainment of AM machines, standards for AM analyses in Reliability Centered Maintenance (RCM) and Conditioned Based Maintenance (CBM^+) are needed. CBM^+ is built upon RCM.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Update SAE JA 1012-2011, a guide to provide analytics for AM trade-offs in RCM and CBM^+.

Priority: ☐High; ☒Medium; ☐Low

Organization: SAE, ISO, ASTM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: OEM preventative maintenance requirements outlined in maintenance manuals.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: SAE G-11M, Maintainability, Supportability and Logistics Committee, will consider inclusion of analytics for AM trade-offs in the next update of JA1012.

See also gap PC2 on machine calibration and preventative maintenance, and gap PC14 on environmental health and safety issues and protection of AM machine operators.

2.5.3 Standard Repair Procedures

AM technology for sustainment-related repairs can provide faster solutions to obsolescence and diminishing sources of supply due to the large quantity of systems, subsystems, parts and tooling that are no longer available or manufactured, or where no data exists. It has the potential to provide relief to weapon systems support required in the field by providing on-site repair capability. Materials are a factor since there are several types of powder metal materials that can be used. Different powders can be engineered for each application, operational load spectrum, and standards should be established for the AM repair industry (see gap PM7). Other factors to be addressed in the use of AM processes to repair end use parts or tooling include:

- Qualification and certification of the repair, including inspection of repairs (See also Q&C section of this roadmap.)
- Standard cleaning, and handling to prepare surfaces for adding material
- The urgency of the maintenance required, e.g., requiring creation of a missing tool using additive technology
- Trade space related to different levels of repair and methods for accomplishing similar repairs using traditional technologies and AM, e.g., relating to Life Cycle Cost (LCC)[42] Analysis, LORA, and RCM[43]
- Reverse engineering of legacy parts (2D drawing conversion to 3D model) for AM tool path generation; dimensional measurement during AM repair development and post inspection; and load/stress analysis substantiation.
- Development of test plans and specifications to qualify an organization's use of an additive repair process, including acceptance criteria.
- Adaptation of existing standards requirements into the development of qualification test plans and specifications.

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[42] Life Cycle Cost (LCC): Life Cycle Cost consists of research and development (R&D) costs, investment costs, operating and support (O&S) costs, and disposal costs over the entire life cycle of a product. Source: AS1390, *Level of Repair Analysis (LORA)*

[43] "Trade space" refers to an aspect of analysis where variables are introduced to allow for alternate solutions to be developed and compared. Amending doctrine on LCC Analysis, LORA, and RCM will allow for new variables to be analyzed.

In addition to the different levels of repair methods for accomplishing similar repairs, Modular Open Systems Approach[44] (MOSA) integrates the schema of repair into design and can offer guidelines for a repair strategy. MOSA can be leveraged like a standard to improve transferability, reduce costs, and enhance sustainability efforts.

Published Standards

- ASME B107 series of standards (B107.100; B107.14M; B107.17; B107.300; B107.4; B107.400; B107.410; B107.500; B107.56; B107.600)
- AWS B2.1/B2.1M:2014-AMD1, Specification for Welding Procedure and Performance Qualification, which also has published errata (see document page).
- AWS D17.1/D17.1M:2017-AMD2, Specification for Fusion Welding for Aerospace Applications
- AWS D20.1/D20.1M:2019, Standard for Fabrication of Metal Components using Additive Manufacturing
- ISO 15609-1:2019, Specification and qualification of welding procedures for metallic materials - Welding procedure specification - Part 1: Arc welding (TC 44 / SC 10)
- Metallic Materials Properties Development and Standardization Handbook (MMPDS), (2017-07)
- MIL-STD-3021 CHG-2, Department of Defense Manufacturing Process Standard: Materials Deposition, Cold Spray (2015-03-04)
- MIL-STD-3049-CHG-1, Department of Defense Manufacturing Process Standard: Materials Deposition, DDM: Direct Deposition of Metal for Remanufacture, Restoration And Recoating (2014-01-10) on DED metal remanufacture/restoration
- SAE AMS2680C-2019, Electron-Beam Welding for Fatigue Critical Applications (2019-01-14)

In-Development Standards

- SAE AS1390A, Level of Repair Analysis (2014-04-15) provides a framework for evaluating cost/benefit analysis of repairing a part versus replacing it.
- SAE AMS2680C, Electron-Beam Welding for Fatigue Critical Applications (2019-01-14)
- SAE TA-STD-0017A, Product Support Analysis, which is a partnering document to AS1390A. (2022-03-01)
- SAE AMS-AM, Additive Manufacturing Repair for Aerospace Applications

Gap M9: Laser Based Additive Repair. Current standards do not specifically address the use of laser-based systems (metal powder or wire feedstock) to additively repair parts or tools.

[44] "Modular Open Systems Approach (MOSA), Defense Standardization Program, U.S. Department of Defense, last accessed on June 13, 2023, https://www.dsp.dla.mil/Programs/MOSA/.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Ensure that laser based additive repair processes are included in AWS D20.1 and SAE AMS-AM Additive Repair for Aerospace Applications.

Priority: ☒High; ☐Medium; ☐Low

Organization: AWS, SAE AMS-AM, DoD

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: Qualifying repair documents provided to customers.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: AWS D20.1 contains requirements for qualifying wire-fed and powder-fed laser DED procedures. In paragraph 5.2.3.2, AWS D20.1 requires that tension test specimens that include the material interface in the gage region be removed from procedure qualification builds used to qualify repairs.

SAE's AMS-AM Additive Manufacturing Committee established the Additive for Repair Working Group in September 2018. Currently developing a scenario to establish the specification framework utilizing a damaged airframe component requiring a directed energy deposition repair. Once finalized, the working group plans to develop material and process specifications for aerospace repair applications.

2.5.4 Standard Technical Inspection Processes

Physical inspection of parts and tools/tooling requires a standardized assessment of defects, including corrosion, abrasion/wear, cracks/fractures, and the suitability of additive manufacturing technologies as a corrective repair action for such defects. Standard inspection procedures provide guidance to maintainers to schedule preventative maintenance tasks, prioritize part or tooling defect cases, assess risks, determine corrective action measures, and determine repair vs. remanufacture from a technical feasibility and cost standpoint. Standard inspection procedures do not adequately consider the viability of additive manufacturing technologies for preventative and corrective maintenance actions. Inspection tools and procedures include:

- Visual inspection
- Magnetic particle inspection
- Fluorescent and liquid penetrant inspection
- Computed tomography (CT) scan
- Radiography/X-ray inspection
- Acoustic emission
- Model-based inspection (e.g., 3D scanning) covered more in the next section
- Ultrasonic inspection
- Preventative maintenance scheduling
- Risk assessment
- Part condition categorization

Published Standards

- ASTM E1742/E1742M-18, Standard Practice for Radiographic Examination (2018-03-21)
- ASTM E1444/E1444M-22a, Standard Practice for Magnetic Particle Testing (2022-07-11)
- SAE JA1011, Evaluation Criteria for Reliability-Centered Maintenance (RCM) Processes (2019-08-26)
- SAE JA1012, A Guide to the Reliability-Centered Maintenance (RCM) Standard (2011-08-22)
- SAE AS1390A, Level of Repair Analysis (2014-04-15)

No standards in development have been identified.

Gap M4: Physical Inspection of Parts Repaired Using AM. A standard inspection process for component or tooling defects is needed to consider additive manufacturing technologies as potential solutions for preventative and corrective maintenance actions.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Update SAE JA1011/1012 to include an inspection process for additive manufacturing repairs.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM, ISO, SAE

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Existing inspection methods being used to determine if it still meets the original requirements of the original part.

V3 Status of Progress: ☐Green; ☒Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: SAE G-11M, Maintainability, Supportability and Logistics Committee, will consider inclusion of an inspection process for AM repairs in the next update of JA1011 and JA1012.

2.5.5 Model-Based Inspection

Model-based inspection methods and tools, including 3D scanning, can be used to assess the level of damage or nonconformance of material and provide insight into repairs necessary to restore parts to ready-for-issue condition. The model used to assess the level of repair could be used to support the business case for repair via AM, remanufacture via AM, or scrapping the part. Currently, model-based inspection tools including 3D scanners and coordinate measuring machines (CMM) are used by maintainers to measure tolerances of parts and level of damage for used components. Model-based software tools can enable automated inspection routines for repeatability.

Model-based inspection, including 3D scanning, offers NDI for both end-use parts and AM machines. Models can be utilized to assess level of damage for used components and assess the "health" of the AM machine itself. Digital models can provide a cost-effective approach to assess level of damage and provide predictive analytical models to monitor AM machine performance for maintenance scheduling.

Published Standards

- ASME Y14.41-2019, Digital Product Definition Data Practices
- ISO 16792:2021, Technical product documentation — Digital product definition data practices

- ISO/IEC 23510:2021, Information technology — 3D printing and scanning — Framework for an Additive Manufacturing Service Platform (AMSP) focuses on operational aspects.
- QIF 3.0:2018, Quality Information Framework (QIF) (free download)

In-Development Standards

- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1)

Gap M5: Model-Based Inspection. Standard practices for model-based inspection methods using AM are needed for repair assessments and scheduling.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop standard practices for assessing level of damage for end-use parts.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASME, ISO/ASTM, Dimensional Metrology Standards Consortium

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Existing inspection methods being used to determine if it still meets the original requirements of the original part.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

2.5.6 Standards for Tracking Maintenance Operations

Maintenance tracking for AM machines is used to facilitate the management and organization of a maintenance operation. Maintenance actions that are tracked include: routine maintenance, preventative maintenance, work order maintenance, and breakdown maintenance. Maintenance tracking can require a computerized maintenance management software (CMMS) tool. Tracking maintenance operations is important to:

- Ensure readiness of the system by tracking part maintenance
- Evaluate and implement new technologies
- Collect data for metrics
- Develop information from collected data for prognostics and spares estimations
- Verify spare parts inventories control and management
- Verify skills requirements
- Track time to repair
- Ensure optimized use of budget for parts and manpower

Maintenance operations for AM include:

- Monitoring machine usage to ensure capacity and identify demand for specific machines
- Scheduling of machine maintenance (including cleaning, preventative parts replacements, etc.)
- Maintenance on parts that have been made using AM to ensure durability and reliability
- Documenting maintenance trends
- Verifying skills levels for machine maintenance
- Verifying environmental requirements and safety for AM machines

Published Standards

- DoD Directive 8320.03, Unique Identification (UID) Standards for Supporting the DoD Information Enterprise, Incorporating Change 1, November 15, 2017, is a policy for development, management, and use of unique identifiers and their associated data sources to preclude redundancy. A "unique identifier" is a character string assigned to a discrete entity or its associated attribute that serves to uniquely distinguish it from other entities.
- SAE AMS7002A, Process Requirements for Production of Metal Powder Feedstock for Use in Additive Manufacturing of Aerospace Parts (2022-05-16)
- SAE AMS7003A, Laser Powder Bed Fusion Process (2022-08-05)
- SAE AMS7005, Wire Fed Plasma Arc Directed Energy Deposition Additive Manufacturing Process (2019-01-31)
- SAE AMS7007, Electron Beam Powder Bed Fusion Process (2020-07-01)
- SAE AMS7010A, Laser Directed Energy Deposition Additive Manufacturing Process (L-DED) (2021-10-28)

- SAE AMS7022, Binder Jetting Additive Manufacturing (BJAM) Process (2020-11-19)
- SAE AMS7027, Electron Beam Directed Energy Deposition-Wire Additive Manufacturing Process (2020-11-18)
- SAE AMS7031, Batch Processing Requirements for the Reuse of Used Powder in Additive Manufacturing of Aerospace Parts (2022-03-29)

In-Development Standards

- ASTM WK71395, New Practice for Additive manufacturing -- accelerated quality inspection of build health for laser beam powder bed fusion process (Jan 2020)

- SAE AMS7012A, Precipitation Hardenable Steel Alloy, Corrosion and Heat-Resistant Powder for Additive Manufacturing 16.0Cr - 4.0Ni - 4.0Cu - 0.30Nb (2020-03-24)
- SAE AMS7029, Cold Metal Transfer Directed Energy Deposition (CMT-DED) Process (2020-02-03)
- SAE AMS7034, Hybrid Laser Arc Directed Energy Deposition (HLA-DED) (2020-08-31)

Gap M6: Tracking Maintenance. A standard is needed for how preventative maintenance operations of AM machines are tracked (e.g., monitoring printer health, need for servicing, etc.).

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop a standard for tracking maintenance operations to ensure a printer is ready when needed. See also gap PC2 on machine calibration and preventative maintenance and PC3 on machine health monitoring. Develop a standard to address emergency repair/limited life parts for urgent cases in the field.

Priority: ☐High; ☐Medium; ☒Low

Organization: AWS, ASTM, ISO, TAPPI

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Machine operations and maintenance manuals

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: No general machine maintenance standard is in development. Individual standards may have sections within them that recommend maintenance. Additionally, each machine will have its own maintenance manual which should be followed. Lastly, ASTM AM CoE *Strategic Roadmap for Research & Development* (April 2020) notes that AM CoE Project 1901 (WK71395) under F42.01 addresses AMSC gap M6.

2.5.7 Additive Repair

Additive manufacturing can be used to rapidly repair end-use components to a ready-for-issue (RFI) condition. However, many end-use structural components contain some protective coating or plating to protect the component in its operational environment and extend its usable life. Component defects are influenced by a multitude of conditions, including corrosion, abrasive wear, thermal stress, and cracking. In order to sufficiently repair the component, coatings, and electro-plating finishes may need to be stripped from the component surface and properly treated for additive manufacturing repair. The preparation for an additive repair process can include removal of protective coatings and treatment of the material surface. Surface preparation can include abrasive removal of coatings, such as sand blasting, chemical removal, or reverse electro-plating. Additionally, the surface to be repaired via an additive process needs to address surface preparation, including removal of dust, grease, oil, and particulate matter. Standard processes and materials need to be identified that are compatible for use with additively manufactured components, without compromising the functionality and performance characteristics of the part.

Standards development committees active in this space include ASTM Committee B08, AWS D1.1, ISO/TC 107, and SAE AMS G-8. However, no specific standards have been identified at this time.

Gap M8: Surface Preparation for Additive Repair. Standards are needed for chemical compatibility with additively manufactured materials for surface cleaning in preparation for an additive repair process. Additionally, standards are needed for removal of coatings, including paints and powder coating, and plating (chrome, zinc, etc.) for additively manufactured parts.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Develop standards for approved chemical substances and mechanical processes used for the removal of coatings and plating on additively manufactured components, to include metals, polymers, ceramics, and other materials.

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM, SAE, ISO, AMPP, AWS D20.1

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Agreement between customer and organization performing repair.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☒Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

There is a lack of industry best practices on the maintenance and repair using additive manufacturing. General guidance to support various sectors would be beneficial. Specific sectors will have different requirements and more specific guidance. Guidance to help users understand qualification considerations, especially as it relates to critical parts, and how it impacts safety, liability, and obtaining performance criteria (tensile properties, hardness, wear, etc.). Additionally, moving repairs from machine to machine is not always straightforward, especially in DED. Significant changes to the configuration of the machine would require requalification of the repair. Considerations such as data needs, powder feeding, laser spot size, speed, material flow rate (among others) should be taken in to account.

Published Standards

- ISO/ASTM 52931: 2023 - Additive manufacturing of metals — Environment, health and safety — General principles for use of metallic materials (2023-01)

- NEMA Policy on Reconditioned Electrical Equipment (2020-09)
- NEMA/MITA RMD P1-2019, Considerations for Remanufacturing of Medical Imaging Devices (2019-09)
- SAE AMS7015, Titanium 6-Aluminum 4-Vanadium Powder for Additive Manufacturing (2022-04-22)
- SAE AMS7006, Nickel Alloy, Corrosion- and Heat-Resistant, Powder for Additive Manufacturing 52.5Ni – 19Cr – 3.0Mo – 5.1Cb (Nb) – 0.90Ti – 0.50Al – 18Fe (2022-03-21)
- SAE AMS7020, Aluminum Alloy Powder 7.0Si – 0.55Mg – 0.12Ti (2022-11-09)
- SAE AMS7037, Steel, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 17Cr – 13Ni – 2.5Mo (316L) (2021-11-23)
- SAE AMS7018, Aluminum Alloy Powder 10.0Si – 0.35Mg (2020-05-11)

In-Development Standards

- ISO/ASTM DIS 52938-1 Additive manufacturing of metals — Environment, health and safety — Part 1: Safety requirements for PBF-LB machines
- ISO/ASTM DIS 52933 Additive manufacturing — Environment, health and safety — Test method for the hazardous substances emitted from material extrusion type 3D printers in the non-industrial places
- SAE AMS-AM Repair Committee guidance and specifications for AM repair of aerospace parts.

New Gap M10: Best Practices on Repair using Additive Manufacturing. Currently, there is no standardized guidance on the maintenance and repair using additive manufacturing. This could be a horizontal guidance applicable to all sectors detailing the best practices for manufacturers or servicers performing maintenance and repair using AM.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop best practices on maintenance and repair using additive manufacturing covering topics such as safety and reliability parameters, certification of product, and qualifications of AM parts. Considerations for moving repairs from machine to machine (e.g., for DED) should be included.

Priority: ☐High; ☐Medium; ☒Low

Organization: ASTM, NEMA, ISO, SAE

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☐Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Agreement between customer and organization performing repair.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6 Data

2.6.1 Introduction

As a digital production process, the formatting, extraction, transfer, integration, security and interoperability of data is critical along the entire additive manufacturing value chain. Data will impact the design, testing, validation, qualification, and quality assurance of parts and systems in nearly all industry sectors. Standards which support data management will help inform decision making in AM production. The following links provide more background regarding how data and data management support AM:

- Data Driven Decision Support for Additive Manufacturing
- A Collaborative Data Management System for Additive Manufacturing[45]

Standards related to data management (and other topics mentioned in the prior paragraph) are currently being developed. Typically, these standards are industry agnostic but can serve as a foundation from which specific sector related standards can be built on. Several of the standards referenced in this chapter acknowledge the existing standardization activities either as helpful resources to support AM specific standards or for adoption more broadly. The roadmap does not recommend which path but leaves that to the SDOs to determine. The AM sector has begun development of AM specific data

[45] Lu, Y., Witherell, P. and Donmez, M. (2017), A Collaborative Data Management System for Additive Manufacturing, 37th Computers and Information in Engineering Conference (CIE), Cleveland, OH, [online], https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=923075 (Accessed April 21, 2023)

standards, for example under ASTM F42.08 and in cooperation with ISO have published ISO/ASTM 52950:2021, Additive manufacturing -- General principles -- Overview of data processing. This section may also include domain specific data needs, such as:

- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements (ISO/IEC JTC 1) deals with image data processing throughout the full lifecycle of 3D printing.
- ISO/IEC 27000:2018, Information technology — Security techniques — Information security management systems — Overview and vocabulary

General and domain specific data standards issues may overlap.

As an increased focus continues to be placed on AM data specific considerations are being made for laying strong foundations moving forward. For instance, a deliberate effort is being made to adopt FAIR Data Principles, which stands for Findable, Accessible, Interoperable and Reusable, as they are seen as important for widespread adoption of AM data sets. These principles have been adopted globally by research institutions because they help increase transparency, collaboration and accelerate R&D. In innovative and data reliant sectors, like AM, they can improve data management because of the volume and speed of data leveraged. The FAIR concept was first defined by Scientific Data[46] in March 2016. FAIR principles impact on AM is discussed further in the Unleashing the Potential of Additive Manufacturing: Fair Am Data Management Principles[47] paper.

Section 2.6 Data was not developed until this version of the AMSC roadmap. All of the issues, gaps and recommendations are recently identified (with the exception of DA10 and DA21 which have been relocated and revised from other chapters). The structure of this section breaks down topics by data related issues agnostic of sectors, AM processes or qualification and certification. Existing standards development to support broader data concerns have been acknowledged (such as ISO/IEC JTC1 SC32) and influenced the breakdown this section. On the other hand, the gaps within this chapters' subsections (2.6.2 through 2.6.9) attempt to focus not only specifically to additive manufacturing but also were considered applicable to issues that would impact various AM processes. There are data related gaps in other chapters of the roadmap which focus on the specific needs of, for example, design or qualification and certification.

Section 2.6.10 contains several topic areas identified by the working group members as gaps in standardization. However, discussions for these areas did not mature enough to result in content

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[46] Wilkinson, M., Dumontier, M., Aalbersberg, I. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 3, 160018 (2016). https://doi.org/10.1038/sdata.2016.18

[47] Frazier, W., Lu, Y. and Witherell, P. (2021), Unleashing the Potential of Additive Manufacturing: FAIR AM Data Management Principles, Advanced Materials & Processes magazine, [online], https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=932826 (Accessed April 21, 2023)

development. It is recommended that the AM industry discuss these further and be considered for a future iteration of the AMSC roadmap.

Data Related Gaps in the AMSC Roadmap

The following gaps which appear in other chapters of the roadmap are related to data. These gaps were either found in prior versions of the AMSC Roadmap or developed with a specific focus to the respective chapter. The intent of this chapter is to address standardization issues that may impact several aspects of the additive manufacturing sectors processes and needs. This table is provided to aid in the identification of other data related standardization needs.

GAP NUMBER & TITLE
GAP DE8: Machine Input and Capability Report.
GAP DE12: Imaging Consistency.
GAP DE13: Image Processing and 2D to 3D Conversion.
GAP DE17: Contents of a Data Package.
GAP DE19: Organization Schema Requirement and Design Configuration Control.
GAP DE20: Neutral Build File Format.
GAP PC15: Configuration Management.
GAP PC16: In-Process Monitoring.
GAP PC1: Digital Format and Digital System Control.
GAP QC6: Importing 3D Source Data to CAD Application for Creation of Design File.
GAP QC7: Imaging Protocols.
GAP QC10: Verification Of 3D Model.
GAP QC14: Segmentation.

2.6.2 Data Formats and Representation

2.6.2.1 Standard Data Format for Material Characterization

To produce AM parts with consistent, predictable, and repeatable characteristics, materials in various forms and thermal conditions need to be characterized by specific properties that support the quality required by the end product. As such, material characterization data play a critical role in AM. Although various standards are published by SDOs to define methods for material characterization, inspection, there is no uniform way to represent material characterization results, neither any standard format to represent their metadata. However, engineers, business analysts, data scientists, both OT and IT teams, rely on standard formats of material characterization data and metadata to communicate, collaborate, and make decisions for AM development.

Published Standards

- ASTM F3490-21, Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree
- ASTM F3560-22, Standard Specification for Additive Manufacturing – Data – Common Exchange Format for Particle Size Analysis by Light Scattering
- ASTM F3049-14(2021), Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes
- ASTM E8/E8M-22, Standard Test Methods for Tension Testing of Metallic Materials
- ASTM E21-20, Standard Test Methods for Elevated Temperature Tension Tests of Metallic Materials
- ASTM E139-11(2018), Standard Test Methods for Conducting Creep, Creep-Rupture, and Stress-Rupture Tests of Metallic Materials
- ASTM E466-21, Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
- ASTM E468-18, Standard Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials
- ASTM E606/E606M-21, Standard Test Method for Strain-Controlled Fatigue Testing
- ASTM E112-13(2021), Standard Test Methods for Determining Average Grain Size

No in-development standards have been identified.

New Gap DA1: Standard Data Format for Material Characterization. There are no standard material characterization data models and formats supporting the curation and exchange of AM material test, inspection and characterization results and metadata.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: R&D activities are needed to collect various material characterization reporting requirements and to develop a unified data model as well as type specific models to represent AM material characterization data and metadata.

Recommendation: Various SDOs, professional organizations, their technical committees' members should get together to harmonize the existing data reporting requirements and turn them into standards data formats. Multiple standards should be developed to capture 1) (standard practice) General data structure for AM material characterization; 2) Type specific standards format for AM material characterization data representation.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM, ISO, SAE, ASM

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☐Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.2.2 Process Specific Common Data Dictionary

A common data dictionary allows AM data pedigree to be discovered, mapped, federated, and analyzed to improve both the understanding and qualification of AM processes and parts. In 2021, ASTM published a common data dictionary which captures general data elements applicable to most AM process categories. They are broadly applicable to all the process categories defined in ASTM 52900 (2015). It is intended to be a starting point, not all-encompassing.

To capture, integrate or federate comprehensive data elements through AM development lifecycles using various technologies, the data dictionary has to be expanded to cover process specific data elements, for example, process parameters, process control, process monitoring, process validation and process specific AM system descriptions.

Published Standards

- ASTM F3490-21 Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree [also known as the Common Data Dictionary (CDD)]

No in-development standards have been identified.

New Gap DA2: Process Specific Common Data Dictionary. There are no standard process specific common data dictionary supporting the curation and exchange of data associated with a specific process type, for example, data terms used specifically for PBF, DED, BJ, FDM etc.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: R&D activities are needed to explore type-specific process data and equipment data elements, which also depend on the vendors of the equipment.

Recommendation: Develop process specific common data dictionary standards. ASTM COE, SAE ITC AMDC and America Makes etc. are creating standard data collection templates to curate data contributed by their members. The standard efforts should leverage on those efforts.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM F42, ISO TC 261, SAE AMS

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Proprietary data dictionaries.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.2.3 Digital Format for In Process Monitoring Data

Due to various sensing technologies, vendors, and AM OEMs, there is no consistent digital format for AM process monitoring to assure the interoperability of process monitoring data. There are no guidelines/standards for users to leverage process data collected from different sensing capacities/machine OEMs.

In-Development Standards

- WK74390 New Practice for Additive Manufacturing of Metals -- Data -- File structure for in-process monitoring of powder bed fusion

There are no known published standards.

New Gap DA3: Digital Format for In Process Monitoring Data. No published or in-development standards have been identified for "digital format for in process monitoring" for additive manufacturing technology. See also section 2.6.4.1 / gap DA14 for AM Data Collection.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Possible development of a protocol /procedure to standardize processing monitoring data format to facilitate data/knowledge sharing for process monitoring.

Recommendation: Develop standard protocol for "digital format for in process monitoring" and address process-specific needs and/or variations in how process technologies could be monitored. The process data collected from diversified sensing systems and different machines can be transformed into a unified format with standardized data importing/exporting and sharing routines to facilitate broader collaboration.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): unknown

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.2.4 Data Capturing for Machine Logs

A machine log is in effect an output of the machine operations (PLCs, humidity sensors, or other parts of the machine). It is important to capture this data for process control, among other applications. Due to various methods additive manufacturing machine vendors use to produce machine logs, there is no consistent standard for what data should be captured in them or how to deliver the information. There is no concrete specification of what should be reported during the process. For some critical parts, monitoring in-process variables is required - which should be put on the data format. Getting this data is difficult due to the various methods machine vendors settle on. Different machine vendors use different ways for capturing machine logs. Machine owners must use additional software like OSIsoft Pi Connector, Montana Digital Academy (MTDA), or other machine sensor data translators. For a simple log file, even a small script is needed to parse through and produce information in a useable way for given investigatory needs. Logging of build interruptions is inconsistent. Lastly, there should be a method to specify what events should be reported.

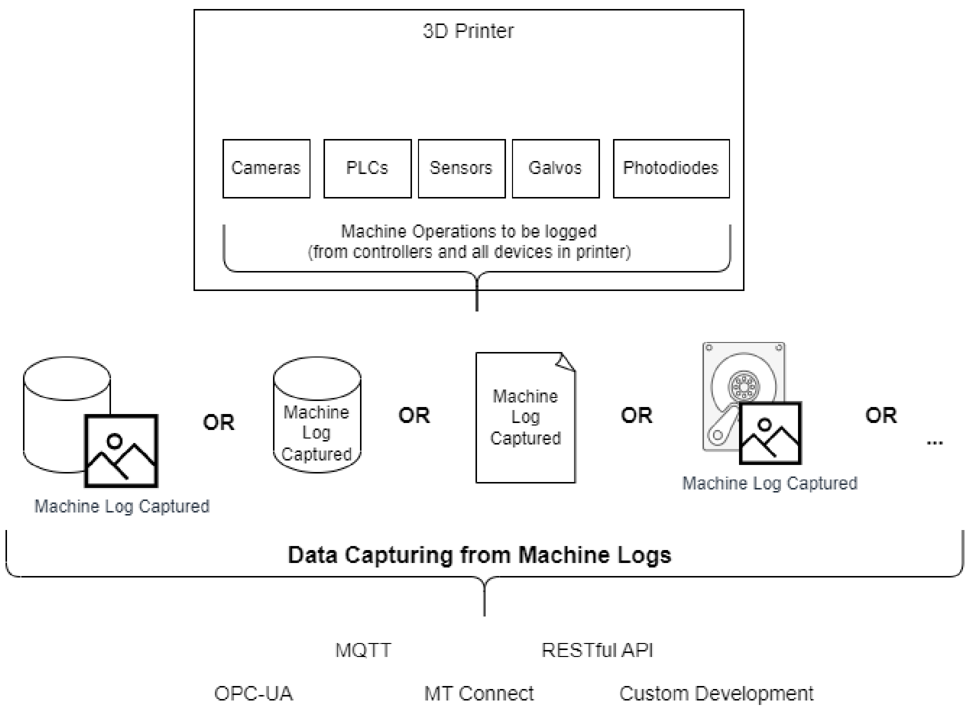

Figure 4: Example of Data Capturing for Machine Logs

There are no known published or in-development standards.

New Gap DA4: Data Capturing for Machine Logs During a Build. No published or in-development standards have been identified for "Data Capturing of Machine Logs During A Build" for additive manufacturing technology.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Possible development of a service to standardize machine log data outputs.

Recommendation: Develop standards for "Data Capturing for Machine Logs During a Build." The machine's status can be communicated through OPC-UA, MT Connect, MQTT, RESTful API calls to local databases (or equivalent) where data is being logged, reports generated from vendor software, or clear text log files on the machine itself. This new standard should pick one that provides the most well-rounded machine data results and provide a standard format for the output and a method to declare what outputs should be generated.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM, ISO

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify) Additional machine sensors

Current Alternative: Adoption of OPC-UA, MQTT, or log file parsing on a company-by-company basis.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.2.5 Extended Design Meta-Data Definition, Format and Management

The ISO/ASTM 52915:20 AMF specification includes support for 14 types of defined meta data, including material, color, unit of measure, author, etc., and provides meta data fields for designer specified meta data in XML v1 format. Additional design specification information can easily be added in the current meta data fields. Examples include: Intellectual property attributes, cyber security attributes, source ID number, author, organization, version, creation date, dimension attributes, tolerances attributes, color attributes, and material attributes. Standardization of how these meta data fields are filled in will aid in addressing a wide range of technical, quality, legal and security issues for AM.

Published Standards

- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- ASTM F3490-21 Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree (also known as the Common Data Dictionary (CDD))

There were no standards in development identified.

New Gap DA5: Extended Design Specifications for Meta-Data Format Standardization. There is a need to standardize the type, naming conventions, and schema meta data used in design and work flow and is essential to additive manufactured part and assembly quality, cyber-security and intellectual property protection. This includes for example, meta data specifying unique file ID number, file source, material attributes, color attributes, dimension attributes, tolerance attributes, surface characteristics, assembly characteristics, intellectual property attributes, cyber-security attributes and any additional meta data needed to meet quality specifications, such as layer height, print orientation, support structure attributes, and embedded labeling requirements.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Standardize definitions and meta data schema for essential design, print, cybersecurity and intellectual property specification information for inclusion in the ISO/ASTM 52915:20 standard. Utilize and expand this standard's current list of meta data definitions and schema. The standard specifies meta data fields in XML v1 format for "material, color, tolerance, ID numbers, source "and other attributes, but lacks schema specifications for these meta data types. The standard includes a general purpose "meta data" attribute that allows for inclusion of additional types of meta data. Create definitions and schema for additional meta data identified necessary to ensure quality, cyber-security and intellectual property protection through the AM work flow to be listed in this "meta data" attribute.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM F42.08, ISO/ASTM TC261, J64, NIST

Lifecycle Area: ☒Design; ☐Precursor Materials; ☒Process Control; ☒Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photo polymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify): Design specifications and design file, meta-data

Current Alternative: Ad-hoc proprietary methods

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.2.6 Representation of Large Data Sets

Additive manufacturing is gaining an increasingly large digital presence, led by efforts such real time monitoring, real time control, and NDE. Reliance on this digital presence is growing as new efforts such as "born" qualified and digital twins emerge. To best leverage these data sets and maximize their utility in new roles, their proverbially ad hoc existence must become more structured and formalized.

Published Standards

- The HDF Group, HDF5[48], High-performance data management and storage suite (addresses big data representation but is not AM specific)
- ISO/IEC 11179-33:2023, Information technology — Metadata registries (MDR) — Part 33: Metamodel for data set registration (part 33 replaced part 7)

[48] Hierarchical Data Format (HDF) is a set of file formats (HDF4, HDF5) designed to store and organize large amounts of data.

No in-development standards have been identified.

New Gap DA6: Specifications and Representations for AM Big Data. There currently exists no best practices or standard specifications for capturing and curating the "Big Data" in AM. Emerging uses of this data, including part qualification and digital twins, will require standardized structure and best practices for consistent interpretability and analysis.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Identifying if a single specification, set of specifications, or a guide that best meets this gap. Identifying ways to meet the gap in a neutral format that can be accessed by different parties.

Recommendation: Develop standards which leverage the FAIR principles and ad hoc approaches, engage with software vendors, practitioners, and acceptance authorities to determine best way forward.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM/ISO, NIST

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Ad hoc

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.2.7 Additively Manufactured Electronics (AME) Data Transfer Format

Additively Manufactured Electronics (AME) is a new fully additive process with unique materials and structures to create printed circuit boards (PCB's). These products merge the mechanical and electrical design environments by incorporating additively formed passive and semiconducting electronic and mechanical components within the circuit board structure. Signal routing in a traditional PCB occurs orthogonally on layers that are connected by vertical drilled and copper plated vias. AME allows the interconnect to be routed in the X, Y and Z axes simultaneously using a variety of interconnect form factors. Currently no SDO has a unified data format standard for AME substrates. There is an ASTM mechanical data format (AMF) and an IPC Printed Circuit Board (PCB) electrical connectivity standard, IPC-2581. AME substrates create traditional 3D components and interconnect structures, e.g., antennas and coaxial cables, within and/or the surface of the substrate. To create a true design to manufacturing high reliability automated data transfer process requires the 3D CAD information to be incorporated into the 2.5D electrical CAD data.

Published Standards

- ISO/ASTM 52915:2020 Specification for additive manufacturing file format (AMF) Version 1.2
- IPC-2581C, Generic Requirements for Printed Board Assembly Product Manufacturing Description Data and Transfer Methodology (DPMX Committee)

No in-development standards have been identified.

New Gap DA7: Additively Manufactured Electronics (AME) Data Transfer Format. AME substrates create traditional 3D components and interconnect structures, e.g., antennas and coaxial cables, within and/or the surface of the substrate. To create a true design to manufacturing high reliability automated data transfer process requires the 3D CAD information to be incorporated into the 2.5D electrical CAD data.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Both ECAD and MCAD software will require development to define test and then implement the new data standard. Existing PCB layout software only allows trace routing on X-Y layers with vias connecting the layers. AME technology allows signal routing in the X, Y, &Z axis simultaneously without the use of vias. Also, 3D structures, such as coils, can be created within the structure and connected to signal nets at any z-axis coordinate, such as surface mounted components.

Recommendation: The industry needs to start the data format definition based on IPC-2581. It will take 1-2 years to define the standards, another 1-2 years to fully implement and another 4+ years for industry adoption using traditional new data format development cycle times. See also Section 2.3.3.5 and Gap QC22.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM, IPC

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Using multiple industry and proprietary data formats, email, and ePaper for data transfer with human intervention to interpret and transcribe the data.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐ Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.2.8 Customizable Standard AM Data Collection Templates

Prior to any AM data collection processes for various AM process and material (during product development) activities, plans should be developed for each step of data collection, data entry, and data storage. Data templates allows the data collection processes to be controlled, reducing potential for human error. However, currently, AM data templates are often proprietary and ad-hoc, with the use of numerous spreadsheets or forms to record data. Hence, the data curated are often not consistent, and they are difficult for sharing and reuse. Templates with customizable data fields would be beneficial so data can be uploaded digitally instead of manually.

Published Standards

- ASTM F3490-21, Standard Practice for Additive Manufacturing — General Principles — Overview of Data Pedigree (F42.08)
- IEC 61360-4, Common Data Dictionary (CDD)

There are no in-development standards.

New Gap DA8: Customizable Standard AM Data Collection Templates. There is no standard or customizable data collection template that simplify the data acquisition process and support AM process (e.g., DED would be different than PBF) and material (during product development) activities. This gap focuses on simplifying the acquisition of data, where gap DA19 Context and Scenario-specific Data Selection focuses on the selection of relevant AM requirements.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Data templates should be created for AM material, system, process and part qualification and requalification. Standardized and customizable AM data collection templates, with the use of AM common data dictionary like ASTM F3490-21, then can be established for various process categories, material types and part type.

Recommendation: Develop multiple standard data collection templates for material, process and parts respectively. Standard templates can then be customized for various material types, process categories and different part types.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): America Makes, ASTM CoE, NIST, ASTM F42

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Proprietary data collection templates, or consortium developed data collection templates, for example, AMNOW data templates, ASTM CMDS data entry excel sheets.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.3 Data Registration, Fusion and Visualization

2.6.3.1 Data Registration and Fusion

Massive complex data are generated from AM development and deployment, with a multitude of modalities and high dimensions, and at various scales and sampling rates. That is, information acquired from an individual data source exhibits limitations in AM decision makings. Instead, different data modes offer varying amounts of discriminative information that fused not only plays a key role in advancing the understanding of AM processes but also drive the engineering decision makings in the lifecycle and value chain. For example, multi-modal in-process monitoring data can be co-processed for better process anomaly detection and part detection prediction. For the purposes of this section, the following definitions are considered:

- *Data Registration: process of transforming different sets of data into one coordinate system (ISO/IEC 20005:2013)*
- *Data Fusion: a multilevel, multifaceted process dealing with the automatic detection, association, correlation, estimation, and combination of data and information from multiple sources [US Department of Defense, 1991].* While this definition best represents the intent, there are other definitions of data fusion that could be applied.

In the NDT metrology world, data fusion based on multiple techniques provides the ability to measure the same location from different viewpoints. One example of this methodology can be applying the eddy current method to check surface detection, but then using ultrasonic methods to get volumetric information. Combining the data sets from both will provide a simple, unified interpretation of results.

Data fusion also is used in a scenario where model-based inspection techniques for AM rely on the combination of a number of different models and data sets to derive meaningful interpretation and utility of the inspection results. Models include: the original part or feature model (either a surface or solid model); the build model to include support structure, fixture, or base features (hybrid parts); and models or data sets associated with NDE or metrology scans such as CT reconstructions and 3D and 2D feature maps.

Data registration that aligns the orientation of these data sets in a common frame of reference is critical to interpreting the differences and relationship of the features. In one example, an as-built model calculated from a CT reconstruction may be compared to an original part model to determine geometric fidelity, or how to orient the as-built part to find the finished product within the near net shaped deposit. In another example, the comparison of the finished part model may be compared with the as-deposited model and the location of near surface defects, to ensure adequate machining allowance is provided to remove the defects identified within an NDE-generated data set. Thermomechanical simulation may be compared with as-built data sets, to derive the character or location of distortion or feature resolution from form metrology methods.

Relevant Publications

- Data Registration for In-Situ Monitoring of Laser Powder Bed Fusion Processes[49]
- In-Process Data Fusion for Process Monitoring and Control of Metal Additive Manufacturing[50]
- Feature-Level Data Fusion for Energy Consumption Analytics in Additive Manufacturing[51]

Published Standards

- ISO/IEC TR 24722:2015, Information technology — Biometrics — Multimodal and other multibiometric fusion (2015-12)
- ISO/IEC 29159-1:2010, Information technology — Biometric calibration, augmentation and fusion data — Part 1: Fusion information format (2010-09)
- ISO 23150:2021, Road vehicles — Data communication between sensors and data fusion unit for automated driving functions — Logical interface (2021-05)
- ISO/IEC 20547, Big Data Reference Architecture
  - ISO/IEC TR 20547-1:2020, Information technology — Big data reference architecture — Part 1: Framework and application process (2020-08)
  - ISO/IEC TR 20547-2:2018, Information technology — Big data reference architecture — Part 2: Use cases and derived requirements (2018-01)
  - ISO/IEC 20547-3:2020, Information technology — Big data reference architecture — Part 3: Reference architecture (2020-03)
  - ISO/IEC 20547-4:2020, Information technology — Big data reference architecture — Part 4: Security and privacy (2020-09)
  - ISO/IEC TR 20547-5:2018, Information technology — Big data reference architecture — Part 5: Standards roadmap (2018-02)
- ISO/ASTM DIS 52953, Additive manufacturing for metals — General principles — Registration of geometric data acquired from process-monitoring and for quality control
- ASTM E2339-21, Standard Practice for Digital Imaging and Communication in Nondestructive Evaluation (DICONDE)

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[49] Feng, S., Lu, Y. and Jones, A. (2019), Data Registration for In-Situ Monitoring of Laser Powder Bed Fusion Processes, Proceedings of the ASME 2019 International Mechanical Engineering Congress and Exposition, Salt Lake City, UT, [online], https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=927979 (Accessed April 21, 2023)
[50] Yang, Z. , Lu, Y. , Li, S. , Li, J. , Ndiaye, Y. , Yang, H. and Krishnamurty, S. (2021), In-Process Data Fusion for Process Monitoring And Control of Metal Additive Manufacturing, Proc. of 41st Computers and Information in Engineering Conference (CIE), Virtual, MD, US, [online], https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=932382 (Accessed April 21, 2023)
[51] Witherell, P. (2020), Feature-level Data Fusion for Energy Consumption Analytics in Additive Manufacturing, Proc. of IEEE Conference on Automation Science and Engineering 2020, Hong Kong, HK (Accessed April 21, 2023)

In-Development Standards

- ASTM WK73978 New Specification for Additive Manufacturing-General Principles-Registration of Process-Monitoring and Quality-Control Data (F42.08)
- ISO/ASTM DIS 52953, Additive manufacturing for metals — General principles — Registration of geometric data acquired from process-monitoring and for quality control.

New Gap DA9: Best Practices and/or Specifications for Registering and Fusing Data Sets During the AM Manufacturing and Inspection Process. There are no data registration and fusion standard supporting AM data registration and data fusion for process monitoring and control, part inspection and testing, and AM qualification and certification.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D activities are needed to explore the equality of multi-modality data fusion for part qualification compared to the traditional test intensive qualification methods.

Recommendation: Multiple methods are needed to address the gap:

- AM data registration standards
- Specific industry data fusion standards for integrative AM data analysis for process monitoring, qualification and part certification
- Expert education, training, and certification for AM data fusion for process control, NDT and qualification.

Collaborative efforts should be made by government agencies, academia and industry to develop new data registration and fusion methods to support process control, NDE data fusion for post process part inspection and qualification, and material and process development based on both simulation and measurement data from various material and processes.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): IEC, ISO, ASTM

Lifecycle Area: ☒Design; ☐Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☒Binder Jetting; ☒Directed Energy Deposition; ☒Material Extrusion; ☒Material Jetting; ☒Powder Bed Fusion; ☒Sheet Lamination; ☒Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Proprietary solutions.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

Gap DA10 (formerly NDE5 in V2): Standard Guideline for NDE Data Fusion. NDE data plays an important role in product acceptance/rejection, validation of simulation/predictive models, process improvement, and potentially process control. Since multiple sources and results are combined in data fusion, there is a possible issue of a non-linear data combination that can produce results that can be influenced by the user. Additionally, data fusion may employ statistical techniques that can also introduce some ambiguity in the results. While likely more accurate than non-data fusion techniques, introduction of multiple variables can be problematic. Data fusion techniques also require a certain level of expertise by the user and therefore there might be a need for user certification. The demand is not NDE specific, but instead more for fusing NDE data with in-process data to correlate to determine effectiveness of methods or to create more of a digital record of the part. Some considerations are:

- What data is recommended to be exported out of these standards?
- What data processing and visualization come into play?
- What are the expected/necessary data outputs, CT, and/or other methods?
- What are the needs for real time vs not real time data fusion. These demands would be very different (alignment and processing of data) than going offline. Process data with fusion does relate to other real time needs. What are the cross correlations?

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A, information theory sciences are well established.

Recommendation: The following are needed to address the gap:

- Specific industry standards for data fusion in AM NDT techniques
- Expert education, training, and certification for AM data fusion in NDT

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; Finished Material Properties; ☐Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☒Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: None provided.

2.6.3.2 Anomaly Detection, Localization and Prediction

AM processes are inherently highly unstable. Therefore, even using the same process parameters and part design, the AM fabricated parts may demonstrate different quality. Given the high process uncertainty in AM processes, it is of utmost importance to perform timely anomaly detection, localization, and part defect prediction. By leveraging the real-time sensing systems, the process data can be collected and machine learning models (e.g., artificial neural networks and convolutional neural networks) can be trained for real-time anomaly detection, localization, and prediction. For supervised learning, labels are obtained from post-manufacturing characterization. However, the response labeling causes a critical issue, since there is no standard to set up the threshold to distinguish between healthy and anomaly in the post-manufacturing characterization. Furthermore, even though there are a lot of research efforts focused on anomaly detection for different AM processes, each research study focuses on one AM process using a specific sensing system/technology, there is no standard available for best practices for the evaluation of data set used for part defect prediction purpose.

Published Standards

- ASTM E3353-22, Standard Guide for In-Process Monitoring Using Optical and Thermal Methods for Laser Powder Bed Fusion
- ISO/ASTM52904-2019, Additive Manufacturing – Process Characteristics and Performance - Practice for Metal Powder Bed Fusion Process to Meet Critical Applications

No in-development standards were identified.

New Gap DA11: Best Practices for Anomaly Characterization and Localization for Part Defect Prediction Purpose. There are no standard AM process anomaly detection methods for part defect prediction for different AM processes.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Various technical committees should get together to consolidate a list of existing anomaly detection and location methods, categorized by different sensing capacity and different AM processes. Since different AM processes may present completely different anomaly, defect, and corresponding failure modes, multiple standards should be developed to summarize: 1) standard practice for sensing capability requirement determination for AM process anomaly detection; 2) standard operation procedure for anomaly detection method assessment in different AM processes; 3) labeling strategy for both qualitative (e.g., microstructure characterization) and quantitative (e.g., X-ray CT inspection for porosity size, morphology, and distribution) post-manufacturing characterizations.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM, ISO, SAE

Lifecycle Area: ☐Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Data analytics is handled on a case-by-case basis.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.3.3 Digital Twin Development and Application

While AM data continues to provide insight into AM processes, it is being increasingly used to provide insight into AM parts. From design to inspection, the fabrication of an AM part is leaving an increasingly large digital footprint. However, this large amount of data is not often deliberately packaged in a way that in can be interpreted and analyzed to support part evaluation and acceptance. Subsequently large data sets associated with AM parts are not easily interpreted and are subject to various unknown assumptions, idealizations, and simplifications that ultimately restrict the utility of the data in facilitating part acceptance.

For example, as AM is a complicated process, there is a need for high-fidelity, physics-based modeling and real-time interactive synchronization to replicate a physical asset or process accurately in the digital world. Digital twins could be used to enable in-situ monitoring, process optimization, and the prediction of the physical phenomena. While some tools are available, they are not well integrated to the functions in that AM lifecycle.

See also, NIST report on Digital Twin-Based Cyber-Attack Detection Framework for Cyber-Physical Manufacturing Systems

Published Standards

- ISO 23704-3:2023, General requirements for cyber-physically controlled smart machine tool systems (CPSMT) — Part 3: Reference architecture of CPSMT for additive manufacturing

In-Development Standards

- ISO/ASTM PWI 52951, Data Packages for AM

New Gap DA12: Need for Consistent Part Traceability and Provenance (Digital Twin). New methods are needed to define and guide how AM data can be associated with different phases of an AM part fabrication so that this data can be readily and consistently interpreted to establish traceability (including in-service) and part, process, facility, and supply chain provenance. An established approach to the development of an AM digital twin will help address this need.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: R&D to establish the guidance/meta model for development of an AM digital twin that explicitly establishes traceability and provenance of an AM part. Also, need to consider in-service life tracking and prediction using digital twin.

Recommendation: New efforts needed to focus on standard development that relates qualification gaps to data representations, including addressing formats, data structure, and digital thread. Standards which augment the connection between engineering intent and manufacturing systems (i.e., neutral file format, STEP, XML, HDF5, AMF, or others) and enable digital twin are needed.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM, ISO, NIST

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Ad hoc.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.3.4 Data Visualization

Visualizing part data collected during in-situ monitoring, ex-situ inspection (e.g., XCT), microstructure (e.g., EBSD SEM), and mechanical property (e.g., tensile, fatigue, and Charpy) with simulation data and AI-generated data on AM processes will support interpretation and implementation for control, qualification, and verification. Currently, multiple types of sensors are used to monitor the continuous AM process and the evolution of parts being fabricated layer by layer. There is visualization of spattering, melt pool formation, metal liquid flow, and solidification for both single track and multiple tracks. More discussion is needed on the visualization of terminology, models, input data, meta data, and interaction protocols to enable small- and medium-sized companies to use immersive interactive visualization methods and tools, such as Virtual Reality (VR), Augmented Reality (AR), Extended Reality (XR), and Mixed Reality (MR).

Other gaps in this chapter tie to this issue. For example, data format standardization helps interoperability where visualization (display method) aids in human interpretation.

New Gap DA13: Data Visualization. Data visualization technologies are used in other manufacturing processes and have shown benefits in controlling and visual verification. Standards can help address advanced visualization technologies of immersive, interactive virtual reality software systems from laboratory research to commercial applications, especially to make related visualization systems more readily and cost-effective to small- and medium-sized enterprises.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: General 3D immersive visualization theory sciences are well established. Specific AM data is lacking for visualization for AM processes.

Recommendation: Further discussions on specific standards to support data visualizations is needed. The following could be considered to help address the gap are:

- Defining data visualization system (i.e., heads up display, 2D screen), types, or methods to help with human interpretation
- Metrics (quantitative and/or qualitative)
- Data visualization across the AM lifecycle (more than in-process monitoring is needed)
- Available or needed software tools and considerations
- Control limits, data types and sources.
- Expert education, training, and certification for AM data visualization

Priority: ☐High; ☒Medium; ☐Low

Organization: ASTM, ISO, IEC

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: Proprietary implementations for visualization of select data sets. Paraview (software tool) for open data sets.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.4 Data Management

2.6.4.1 AM Data Collection

Currently AM machine OEMs create data with varying file naming standards, data content types, and timestamp formats. This leads to the need to support multiple data standards increasing the cost of leveraging data sets.

Published Standards

- F3560-22 Common Data Exchange Format for Particle Size provides a standardized JSON structure for reporting powder stock testing data.

No in-development standards were identified.

New Gap DA14: Best Practices and Guidance for AM Data Collection. Data from AM machines varies in its format, level of detail, and interoperability. A standard set of data formatting and available data types needs to be developed.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Collect A wider array of machine data examples should be gathered to provide further examples of the disparity and data available across various implementations.

Recommendation: Create a data standard that addresses at a minimum the expected minimum data availability from a machine, a variable and file naming structure for the data, and ensures interoperability on timestamp formats, data encoding, and packaging pertinent meta-data about the machine and the build. The goal should be to have a methodology that ensures that if, for example, two LPBF machines are being used and you receive similar data, that you can leverage that data in a common way. Ensure that the developed guidance works to use existing data standards where applicable, the format of the data is supported by common industry tools (similar to F3560-22's use of JSON), and that there is guidance on how to test methods and equipment that provide the data.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ASTM, All applicable SDOs

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.4.2 Data Aggregation

Both time-series and file object data related to additively manufactured parts, coming from various equipment, lack a standard method of aggregation (or grouping it together for one view of the data). Some companies aggregate by the machine's Build Job ID. However, some data (e.g., powder testing data) is created before the print process; so, another ID must be used to track and aggregate this data as well. The pre-print, print, and post-print data generators need a standard method to properly aggregate. The same method devised for aggregation is required for fusion, or the combining of data from multiple sources to achieve inferences that cannot be obtained from a single source, a similar method is needed to bring this data together.

No published or in-development standards have been identified.

New Gap DA15: Data Aggregation of Time Series and Object Data. No published or in-development standards have been identified for "Aggregation / Data Fusion of time series and object data" for additive manufacturing technology.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop guidance on the aggregation of time series and object data. Identifiers can be obtained from most 3D Printer devices as a result of a job instantiation. Identifiers can also be obtained from a chosen manufacturing execution system (MES) in relation the jobs to be performed. However, choosing which, both, or another separate identifier is a matter of the solution identified to properly close this gap.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM, ISO

Lifecycle Area: ☐Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☒Other (specify) Additional machine sensors

Current Alternative: Individual application development or manual data aggregation/fusion

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.4.3 Data Retention

Striking a balance amongst retaining data for immediate analysis, quality control, product qualification, and long-term regulatory requirements is difficult amidst the rising quantity of data and costs of data storage. Companies struggle to declare a one-size-fits-all approach to data retention due to these varying factors. Often, in aerospace for example, there are at least three factors for retention based on business unit, data owner, and regulatory bodies. Without a standard approach to rendering data down to just what is absolutely needed and providing a technological way to re-inflate the data for deeper analysis if needed later than the retention period, the persistent issue of data bloating is inevitable. Additionally, cloud technology providers continue to compete, providing various new technologies and cost differentiations with multiple tiers of storage. These complexities make it difficult for businesses to make quick and effective decisions for their data and costs.

No published or in-development standards have been identified.

New Gap DA16: Data Retention Guidelines. No published or in-development standards have been identified for “Data Retention Guidelines” for additive manufacturing and related technologies.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: Possible development of algorithms for data size reduction with minimal data loss (e.g., akin to the .jpeg format being a lossy format but still high quality enough for the naked eye).

Recommendation: Develop standards for "Data Retention Guidelines." New algorithms or recommendations for proper use of existing algorithms that target AM data (e.g., melt pool h5 data, optical tomography .raw or .tiff imagery). A standard cloud provider agrees to data reduction and lowest cost storage tiers. Also, recommendations to industries for duration data should be retained based on analysis and regulatory needs.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM, ISO, applicable regulatory and certifying bodies

Lifecycle Area: ☐Design; ☒Precursor Materials; ☐Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☐Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify) Additional machine sensors & imagery

Current Alternative: Complex architectures and agreements both with internal organizations and external cloud providers. Data simply retained for as long as possible because a standard is not declared.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.5 Data Quality

Data quality has been defined in ISO/IEC 8000 - Data Quality as "degree to which a set of inherent characteristics of data fulfils requirements" which is not specific to AM. Examples of data characteristics include accuracy, completeness, confidence, consistency, timeliness and usability. Data quality is vital for additive manufacturing because data are increasingly used to drive AM development and operations and directly impacts the reliability of the manufacturing processes and effectiveness of the decision-makings.

While there are several standards and guidelines that address aspects of data quality and management in the context of manufacturing and related industries, measurement and specifications on AM data quality are needed for process control, process optimization, preventive maintenance, supply chain management, part qualification and certification, and regulatory compliance.

The electronics sector looks at data quality from two perspectives; one from data structure and accuracy and the second if it matches the manufacturing capability and design intent. In the circuit board industry, less than 5% of the manufacturing requires editing.

Published Standards

- ISO 9001:2015, Quality Management Systems – Requirements (reconfirmed in 2021)
- ISO 19157:2013, Geographic information — Data quality
- ISO 22400-1:2014, Automation systems and integration — Key performance indicators (KPIs) for manufacturing operations management — Part 1: Overview, concepts and terminology (reconfirmed in 2022)
- ISO 22400-2:2014, Automation systems and integration — Key performance indicators (KPIs) for manufacturing operations management — Part 2: Definitions and descriptions (2014-01)
- ISO/IEC 8000, Data Quality: This series of standards focuses on data quality management and provides a general framework for managing data quality across different industries and applications, including manufacturing.
- ISO/IEC 27001:2022, Information security, cybersecurity and privacy protection — Information security management systems — Requirements (2022-10), which establishes requirements for information security management systems (ISMS) to protect the confidentiality, integrity, and availability of information, which can be critical for maintaining data quality in manufacturing systems.
- SAE AS9100D, Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations (2016-09-20)

No in-development standards were identified.

New Gap DA17: Assessment and Specifications of AM Data Quality. There are no standard metrics to measure AM data quality and the impact on AM decision making; There is no standard specification on AM data quality for data driven AM qualification and certification.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: Efforts should be made to review the existing data quality standards and identify the needs of AM data quality management and develop guidelines for AM data quality control.

Recommendation: Develop standards which define aspects of data quality specific to AM. NIST to assist with a review on existing data quality standards and their applicability to AM, as well as the gaps to enable data driven AM decision makings.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM, ISA, ISO, NIST, SAE

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) _______________________

Current Alternative: None specific for AM but sector agnostic standards listed above may be used.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.6 AM Value Chain Data Usage and Management

2.6.6.1 Digital Thread

AM process chains and value chains are inherently disparate, with organizations, processes, machines, and software all contributing to variations in the AM "digital thread." With the maturation of AM processes technologies, AM part fabrication is increasingly being integrated into supply chains. Additionally, AM data is being increasingly relied upon to establish AM part quality. Instances such as these require a consistent understanding of the AM fabrication process, especially when that process is organizationally and geographically distributed.

Published Standards

- [ISO 23704-3:2023, General requirements for cyber-physically controlled smart machine tool systems (CPSMT) — Part 3: Reference architecture of CPSMT for additive manufacturing]() (defines digital thread but is not commonly adopted by the AM sector)

In-Development Standards

- [ISO/ASTM PWI 52951, Data Packages for AM]()

New Gap DA18: Reference Workflow (Digital thread) for AM Part Fabrication. With AM workflows becoming increasingly important, for instance in establishing part provenance or integrating supply chains, new standardized references are needed. A standardized AM workflow, or digital thread, is needed to provide a consistent refence for the various processes and activities associated with AM part fabrication. A major concern relative to an AM manufactured repair part versus an OEM (or DLA) supplied part is the confidence the end user has in the part quality. Configuration management and acceptance thresholds of processes, machines and materials could be considered under this gap (as well as gap DA12 on digital twin) to help build confidence in the supply chain. These are all areas where standards can contribute.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: R&D to establish what level of detail for a reference makes sense, and the role of data representation/formats when referencing the workflow.

Recommendation: Continue to develop ISO/ASTM PWI 52951 and then create additional guidance as needed.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM, ISO, NIST

Lifecycle Area: ☒Design; ☒Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ________________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ________________________

Current Alternative: Ad hoc

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.6.2 Scenario-Specific Data Selection

Additive manufacturing technologies have had a pervasive impact across industries, from traditional manufacturing to medical to aerospace. The diversity of AM technologies includes differences in applications, user experience, and qualification requirements, among others. This diversity makes the universal standardization of AM part, process, and qualification requirements exceedingly challenging.

In-Development Standards

- ISO/ASTM PWI 52951, Additive manufacturing — Data packages for AM parts supports the selection of relevant AM requirements based on skillset and acquisition scenario.

There are no published standards on with respect to this issue.

New Gap DA19: Context and Scenario-specific Data Selection. Approaches to develop and communicate scenario-specific data requirements, scoped by areas such as technology, application, or even product family, are needed to support the common interpretation of AM data within the necessary context. This gap focuses on the selection of relevant AM requirements, where gap DA8 Customizable Standard AM Data Collection Templates focuses on simplifying the acquisition of data.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Develop standards to help develop and communicate scenario-specific data requirements which address technology, application, and/or product family.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASME (e.g., code cases), ASTM, ISO

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☒Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Ad hoc implementations which are under or over specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.7 AM Data Security & IP Protection

2.6.7.1 AM Security Guidelines

Manufacturers need AM security guidance. Factors contribute to this need:

1. Increasing industry adoption of AM technology
2. A large body of research demonstrating the ability of attackers to manipulate AM 3D geometry and process data and achieve adverse impacts to manufacturers and their customers
3. Layer-based technology introduces more attack vectors than non-layered manufacturing technologies, but also may provide more opportunities to detect or respond to an attack
4. Diversity of material types and processing technologies implies need for process technology-specific guidance, although there is some general guidance that applies across AM technologies

Published Standards

- ISO/IEC 27000:2018, Information technology — Security techniques — Information security management systems — Overview and vocabulary (2018-02)
- ISO/IEC 27001:2022, Information security, cybersecurity and privacy protection — Information security management systems — Requirements (2022-10)
- NIST Cybersecurity Framework 1.1
- NIST Cybersecurity Framework Version 1.1 Manufacturing Profile, NISTIR 8183 Rev. 1

In-Development Standards

- ASTM WK78322, New Guide for Additive Manufacturing -- General Principles -- Guidelines for AM Security (F42.08)

- NIST Cybersecurity Framework 2.0
- NIST Special Publication 800-82 Rev. 3, Guide to Operational Technology (OT) Security (Initial Public Draft)

New Gap DA20: AM-Specific Security Guidance. Although numerous groups have standardized IT cybersecurity and privacy guidance, and a growing number of standards address OT security, no standardized guidance specifically addresses AM security.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: More research needed on security for non-extrusion AM processes. More research needed on applying content management technologies to security guidance publications to better manage dependencies of process-specific guidance on general AM security guidance, AM security guidance on OT security guidance, etc.

Recommendation: Complete work on ASTM F42.08 WG WK78322, whose guidance should not be AM process-specific. Subsequent guidance standards should address specific process technologies.

Priority: ☐High; ☒Medium; ☐Low

Organization(s): ASTM, America Makes, NIST

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☐Processes/Procedures; ☐Machines/Equipment; ☐Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.7.2 Cybersecurity

Issues related to cybersecurity (digital thread) for AM technology and maintenance relate to both AM parts and AM machines. Examples of related concerns include: intentional corruption of drawing files; intentional corruption of tool files; hacking and theft of designs; industrial espionage; counterfeiting and anti-counterfeiting; theft of intellectual property rights including patents, trade, service, and certification marks; copyright; and unqualified (low quality) parts being fielded on viable systems risking degradation of performance, reliability, and potential safety issues.

Cybersecurity for AM maintenance relates to the users themselves, networks, devices, software, processes, information in storage or transit, applications, services, and systems that can be connected directly or indirectly to networks.

Published Standards

- ISO/IEC 27000:2018, Information technology — Security techniques — Information security management systems — Overview and vocabulary (2018-02)
- ISO/IEC 27001:2022, Information security, cybersecurity and privacy protection — Information security management systems — Requirements (2022-10)
- NIST Special Publication 800-37, Revision 2, Risk Management Framework for Information Systems and Organizations - A System Life Cycle Approach for Security and Privacy.
- NIST Special Publication 800-53, Revision 5, Security and Privacy Controls for Information Systems and Organizations.
- NIST Special Publication 800-82, Revision 3:(Draft), Guide to Operational Technology (OT) Security.
- NISTIR 8023, Risk Management for Replication Devices.
- NISTIR 8041, Proceedings of the Cybersecurity for Direct Digital Manufacturing (DDM) Symposium (April 2015)
- NISTIR 8183, Cybersecurity Framework Manufacturing Profile[52]
- National Defense Industrial Association (NDIA) Cybersecurity for Advanced Manufacturing White Paper (May 2014), which includes a short note that "While additive manufacturing is inherently no more vulnerable than other manufacturing methods, the opportunity exists to build more security into these emerging systems now"
- NEMA White Paper, Supply Chain Best Practices
- NEMA/MITA White Paper, Cybersecurity for Medical Imaging

[52] The landing page for NIST's research and standards activity for cybersecurity for general IT can be found at: https://www.nist.gov/topics/cybersecurity.

- PWG 5199.10-2019: IPP Authentication Methods v1.0

In-Development Standards

- ASTM WK76970**:** Guidelines for Technical and Intellectual Property Authentication and Protection
- ASTM WK78322, New Guide for Additive Manufacturing -- General Principles -- Guidelines for AM Security.

Other notable activities include:

- Defense Federal Acquisition Regulation Supplement (DFARS) Publication Notice 20160802, Detection and Avoidance of Counterfeit Electronic Parts – Further Implementation (DFARS Case 2014-D005).
- The National Defense Industrial Association (NDIA) Cybersecurity for Advanced Manufacturing (CFAM) Joint Working Group (JWG). CFAM was launched in November 2015 as a government and industry collaboration to identify cybersecurity threats, vulnerabilities, and consequences in defense contractors' manufacturing networks and to define actions to mitigate those risks. The group held its first public forum on August 18, 2016, to raise awareness to the manufacturing networks' cyber threats facing the defense industrial base and to introduce the CFAM JWG to a broader community. A second public forum was held on November 15, 2016 where JWG team leaders presented their findings and recommendations to improve cybersecurity in the defense industrial base's manufacturing networks.
- National Electrical Manufacturers Association (NEMA) anti-counterfeiting initiative
- International AntiCounterfeiting Coalition (IACC), which encompasses 250+ member companies in 40+ countries from various industries.

Gap DA21 (formerly M7 in V2): Additive Manufacturing Supply Chain Security: Guidance is needed that addresses cyber and non-cyber threat (i.e., side channel attacks) security considerations for ordering, maintenance, repair and replacement parts that have 3D models ready to print to ensure that a build has not been sabotaged and that IP has not been stolen. Secure storage should ensure that only authorized personnel can access files and print parts. Maintenance security guidance for AM machines should be similar to that of other industrial machines. However, AM machines could be used in environments where maintenance may not be executed with the same degree of rigor or with the same quality control checks as in conventional settings. For example, a military organization could use a 3D printer at a battle location to print replacement parts. AM security guidance could perhaps suggest compensating controls in such scenarios where the usual controls are infeasible.

R&D Needed: ☒Yes; ☐No; ☐Maybe

R&D Expectations: TBD

Recommendation: Guidance is needed to ensure the confidentiality, integrity, and availability of AM data as procurement, maintenance and repair operations may take place in an uncontrolled environment. See also gap PC15 Configuration management.

Priority: ☐High; ☒Medium; ☐Low

Organization: NIST, NEMA/MITA, NDIA JWG, ASTM, IEEE-ISTO PWG

Lifecycle Area: ☐Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☐Qualification & Certification; ☐Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☒Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: None specified.

V3 Status of Progress: ☒Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☐New

V3 Update: See full list of documents above. Since Roadmap v2.0, PWG 5199.10 was published. New ASTM WK78322 will establish AM Security practices necessary to protect additive manufacturing parts structural integrity, provenance throughout production chain, and protection of technical data. The standard will identify and categorize security threats in AM, highlight characteristic aspects of AM security that require special considerations, and describe the mitigations the manufacturing life cycle. This gap in AMSC Roadmap v2 was originally "cybersecurity for maintenance" however the issue was broader than maintenance, and instead across the supply chain and AM process. Updates have been made for v3 to better reflect the intent and need for standards.

2.6.7.3 Technical and IP Authentication and Protection

The primary issue is the lack of standards on how to record, display, transmit and retain the intellectual property rights for AM design files and derivative works created during the design to print to post process work flow. For example, copyrights, patents, and authorized use notices; access privileges, etc. The secondary issue has to do with how to protect the IP records, displays and archives of such files. A tertiary issue relates to other methods of authentication, including methods designed into the file, mechanical or chemical operations to the printed part, or post processing methods of authenticating the printed part.

In-Development Standards

- ASTM WK76970, New Guide for Additive Manufacturing -- General Principles -- Guidelines for Technical and Intellectual Property Authentication and Protection (F42.08)

No published standards have been identified.

New Gap DA22: Technical and IP authentication and protection. This gap is distinct from cybersecurity issues. There is currently no standardized method of labeling, securing and authenticating the intellectual property ownership and related rights to AM designs, files and metadata. This creates an opportunity for unauthorized use and/or counterfeiting of AM printed objects. There is no standardized method of authenticating printed parts for counterfeiting. R**&D Needed:** ☐Yes; ☐No; ☒Maybe **R&D Expectations:** TBD **Recommendation:** Complete and publish WK76970. Revise ISO/ASTM 52915 to include support for technical guidance and meta data specifications in WK76970. **Priority:** ☒High; ☐Medium; ☐Low **Organization(s):** ASTM F42.08, ISO/ASTM TC261, J64, NIST **Lifecycle Area:** ☒Design; ☐Precursor Materials; ☐Process Control; ☒Post-processing; ☐ Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data **Sectors:** ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; Medical; ☐Spaceflight; ☐Other (specify) ________________________ **Material Type:** ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite **Process Category:** ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photo polymerization **Q&C Category:** ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify): Source file data, meta-data **Current Alternative:** Ad hoc proprietary methods **V3 Status of Progress:** ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒ New

2.6.8 Data Architecture Integration and Interoperability

2.6.8.1 AM System Integration and Data Integration Architecture

AM technology is transitioning from prototyping to industrialization, however, with a limited scale. One of the more pressing problems is the lack of system and data integration. The AM systems are commonly siloed, and existing manufacturing executive systems are seldom set up for AM-based production. Hence real-time production monitoring and manufacturing intelligence cannot be established. The big data generated from AM in-process monitoring and nondestructive evaluation are commonly acquired manually and scattered around the shop floor. The AM engineering data are still seldom reused across departments. Challenges in AM data integration stem from the complexity of the tasks, including: the wide scope of integration across product, machine, and material domains, where communication methods and protocols diverge, the high variety of data types, the unstructured high volume and high velocity nature of the data.

For the purposes of this section, data integration is defined as the *process of combining data residing in different sources and providing users with a unified view of them, ISO/IEC 30145-3:2020(en), 3.1.7*

Published Standards

- ISA 95, Enterprise-Control System Integration (addresses traditional manufacturing system and data integration but leaves gaps for AM)
- ISA 88, Batch Control (for batch manufacturing)
- OPC 40540, The Future OPC UA Interface for Additive Manufacturing (UA4AM) is intended to facilitate the exchange of information between an AM machine and software systems such as MES, SCADA, ERP or data analysis systems
- IEC PAS 63088:2017 Smart manufacturing - Reference architecture model industry 4.0 (RAMI4.0)
- ISO/IEC 20547, Big Data Reference Architecture
    - ISO/IEC TR 20547-1:2020, Information technology — Big data reference architecture — Part 1: Framework and application process (2020-08)
    - ISO/IEC TR 20547-2:2018, Information technology — Big data reference architecture — Part 2: Use cases and derived requirements (2018-01)
    - ISO/IEC 20547-3:2020, Information technology — Big data reference architecture — Part 3: Reference architecture (2020-03)
    - ISO/IEC 20547-4:2020, Information technology — Big data reference architecture — Part 4: Security and privacy (2020-09)
    - ISO/IEC TR 20547-5:2018, Information technology — Big data reference architecture — Part 5: Standards roadmap (2018-02)

In-Development Standards

- IEC/CD TR 63319, A meta-modelling analysis approach to smart manufacturing reference models

New Gap DA23: AM Machine Data Framework and Guideline for Automated AM Data Integration and Management. Even though both AM machine builders and industrial automation software providers are creating partnerships to push the development of AM integration and data management solutions, the applications are not reported, and standard practices have not been established and shared on how AM machines can be easily integrated with existing manufacturing systems for industrialization, including supervisory control and data acquisition (SCADA), MES, product lifecycle management (PLM) and enterprise resource planning (ERP) systems. In addition, there are no communication specifications defined to integrate and stream high-speed and high volume in-process data.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: The following are needed to address the gap:

- Standardized AM machine data framework to support AM in-process data integration for real-time manufacturing operations
- Specifications for communication protocols for high-speed AM in-process big data streaming and analysis
- Extended existing system and data integration architecture, for example, ISA 95, for AM data and system integration for industrialization
- Guidelines, best practices and tools for AM data integration and management, including research data, engineering data, production data, inspection data and testing data.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): IEC, ISO, ASTM, OPC, UMATI

Lifecycle Area: ☒Design; ☐Precursor Materials; ☒Process Control; ☒Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☒Nondestructive Evaluation; ☒Maintenance and Repair; ☒Data

Sectors: ☒All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☐Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☒Materials; ☒Processes/Procedures; ☒Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☐Other (specify) ______________________

Current Alternative: Proprietary solutions.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.9 Sector Related Needs

2.6.9.1 Medical AM Design File Retention

There is no standard for retention of all medical radiologic image files and related metadata used to create AM design files that are input to AM systems to produce AM medical devices. Retention of all such files and versions of such files, and quality related meta data are required to meet U.S. federal and EU regulatory requirements and the latest International Medical Device Regulators Forum (IMDRF) published guidance on harmonization of international standards for manufacturing medical devices (includes AM medical devices).

Published Standards and Guidance

- DICOM, Digital Imaging and Communication in Medicine, The encapsulated DICOM format file containing an STL, OBJ or other 3D file is only a portion of what is required to be retained and made available for validation and verification of the medical device design quality per federal regulation. Proprietary design files can be stored in DICOM as a Private SOP Class.
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- IMDRF/PMD N74 FINAL:2023, Personalized Medical Devices – Production Verification and Validation (February 2023)
- IMDRF/SaMD WG/N23 FINAL: 2015, Software as a Medical Device(SaMD); Application of Quality Management System (2 October 2015)
- FDA Software as a Medical Device (SaMD), Clinical Evaluation Guidance for Industry and FDA Staff (8 December 2017)[53]

No in-development standards have been identified.

[53] https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd

New Gap DA24: Medical AM design file retention. Standards are needed on how to store, label and provide access to medical AM design files derived from radiologic scans.

R&D Needed: ☐Yes; ☒No; ☐Maybe

R&D Expectations: N/A

Recommendation: Draft standard guidance for storing, labeling and publishing medical AM design files to meet HIPAA and FDA regulatory requirements.

Priority: High; ☒Medium; ☐Low

Organization(s): ISO/ASTM TC261, DICOM

Lifecycle Area: ☒Design; ☐Precursor Materials; ☐Process Control; ☐Post-processing; ☐Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒Medical; ☐Spaceflight; ☐Other (specify) ______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify) Design File Data

Current Alternative: The information is discarded except the design file (STL, OBJ or other format) information addressed by DICOM. The DICOM specification for storing an encapsulated .STL file does not address all HIPAA and FDA quality management requirements for creating a regulated medical device.

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; ☐ Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.9.2 Medical AM Quality Management Systems

The FDA is proposing to expand regulation of hospitals and other "point of care" medical facilities conducting additive manufacturing of medical devices to include individual, patient specific medical devices. This will require point of care facilities to comply with FDA guidance governing manufactured medical devices. A critical requirement within this regulatory "framework" is the creation and use of a quality management system (QMS) that will facilitate validation of each medical device's quality by the producer of the device. The FDA has the authority to contract with accredited third-party organizations to audit and verify quality of medical devices produced by a POC facility.

A large percentage of medical devices produced using AM are derived from radiologic scans. Selected scan sets are edited and altered by segmentation software and saved in formats that can be input to CAD or other modeling software to design the medical device. The segmenting, editing, conversion and repairing of these files results in some degradation of the design files, thereby impacting accuracy, precision and overall quality of the medical device produced.

At the present time there is no standard for how to record, transmit and maintain the digital source files quality attributes and their modifications created by segmentation, file repair and 3D modeling applications (that affect resolution, accuracy, and dimensional tolerances) through this work flow. This creates a barrier to validation and verification of a medical device produced using AM technology.

Relevant Publications

- U.S. FDA published "Discussion Paper: 3D Printing Medical Devices at Point of Care"(December 2021)
- Radiological society of North America (RSNA) 3D Printing Special Interest Group (SIG): Guidelines for medical 3D printing and appropriateness for clinical scenarios (November 2018)
- 21 CFR Chapter 1, Subpart H, Medical Devices

Published Standards

- ISO/ASTM TR 52916:2022, Additive manufacturing for medical — Data — Optimized medical image data
- ISO/ASTM 52915:2020, Specification for additive manufacturing file format (AMF) Version 1.2
- ISO/IEC 3532-1, Information technology – Medical image-based modelling for 3D Printing – Part 1: General requirements

In-Development Standards

- IEEE P3333.2.3™, Standard for Three-Dimensional (3D) Medical Data Management
- ISO/IEC CD 8803, Information Technology — 3D Printing and Scanning — Accuracy and precision evaluation process for modeling from 3D scanned data (ISO/IEC JTC 1/WG12)
- ISO/IEC AWI 16466, Information Technology — 3D Printing and Scanning — Assessment methods of 3D scanned data for 3D printing model (ISO/IEC JTC 1/WG12)
- ISO/IEC DIS 3532-2, Information technology – Medical image-based modelling for 3D Printing – Part 2: Segmentation (ISO/IEC JTC 1/WG12)

New Gap DA25: Quality Management of Medical AM Files. There is no comprehensive standard method for recording, transmitting and maintaining AM quality related meta data from radiologic scan to final part. This information is needed to comply with FDA quality validation and verification requirements for AM medical device manufacturing.

R&D Needed: ☐Yes; ☐No; ☒Maybe

R&D Expectations: TBD

Recommendation: Revise ISO/ASTM 52915 and ISO/ASTM 52916 to address this gap. Draft revisions to augment specified standards to provide guidance on how to implement a method to record, transmit and maintain design file quality related meta data from radiologic scan to final part; including but not limited to: file resolution, accuracy, dimensional tolerances, surface characteristics, and any additional FDA specified meta data, such as device labeling, as well as work-in-process file retention to retain any revisions to such meta data. Standardization of meta data terminology will facilitate programmatic transmission of meta data through the entire work flow.

Priority: ☒High; ☐Medium; ☐Low

Organization(s): ISO/ASTM TC261, RSNA, NIH, American College of Radiology (funding)

Lifecycle Area: ☒Design; ☐Precursor Materials; ☒Process Control; ☐Post-processing; ☒Finished Material Properties; ☒Qualification & Certification; ☐Nondestructive Evaluation; ☐Maintenance and Repair; ☒Data

Sectors: ☐All/Sector Agnostic; ☐Aerospace; ☐Automotive; ☐Construction; ☐Defense; ☐Electronics; ☐Energy; ☒ Medical; ☐Spaceflight; ☐Other (specify) _______________________

Material Type: ☒All/Material Agnostic; ☐Metal; ☐Polymer; ☐Ceramic; ☐Composite

Process Category: ☒All/Process Agnostic; ☐Binder Jetting; ☐Directed Energy Deposition; ☐Material Extrusion; ☐Material Jetting; ☐Powder Bed Fusion; ☐Sheet Lamination; ☐Vat Photopolymerization

Q&C Category: ☐Materials; ☒Processes/Procedures; ☐Machines/Equipment; ☒Parts/Devices; ☐Personnel/Suppliers; ☒Other (specify) Source file data quality

Current Alternative: Ad hoc proprietary methods

V3 Status of Progress: ☐Green; ☐Yellow; ☐Red; Not Started; ☐Unknown; ☐Withdrawn; ☐Closed; ☒New

2.6.10 Data Gaps for Future Consideration

This contains several topic areas identified by the working group members as gaps in standardization. However, discussions for these areas did not mature enough to result in content development. It is recommended that the AM industry discuss these further and be considered for a future iteration of the AMSC roadmap. The additional standardization areas are listed under the originally proposed Section 2.6 subsection they were identified against.

2.6.2 Data Formats and Representation

Evaluating data maturity for usage and adoption

2.6.3 Data Registration, Fusion and Visualization

Digital twin (virtual machine) framework for testing models in simulation

2.6.4 Data Management

Exchange and reuse of AM data

Feedback of data

2.6.6 AM Value Chain Data Usage and Management

Capability of machine data sheets

2.6.7 AM Data Security & IP Protection

Cybersecurity framework profile / meta data provisions specifications

2.6.8 Data Architecture Integration and Interoperability

Guidance to integrate varying data sources

Guidance on high-volume and high-speed data integration

AM Data for Models and Machine Learning

Guidance for establishing correlation models

Data Through Part Development Lifecycle

Evaluation of data quality

Using in-process data

Product and coupon handling and management

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3. Next Steps

This roadmap should be widely promoted among interested stakeholders so that its recommendations see broad adoption.

To the extent R&D needs have been identified, the roadmap can be used as a tool to direct funding to areas of research needed in additive manufacturing.

In terms of standards activities, an ongoing dialogue among affected stakeholders would be beneficial to continue discussions around coordination, forward planning, and implementation of the roadmap's recommendations. Such a dialogue can also identify emerging issues that require further elaboration.

It is recognized that standardization activity will need to adapt as the ecosystem for additive manufacturing evolves due to technological innovations and as additional industry sectors enter the additive manufacturing market.

Depending upon the realities of the standards environment, the needs of stakeholders, and available resources, it is envisioned that a mechanism will be established to monitor progress to implement the roadmap's recommendations.

Ultimately, the aim of such efforts would be to continue to guide, coordinate, and enhance standardization activity and enable the market for additive manufacturing to thrive.

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Appendix A. Glossary of Acronyms and Abbreviations

TC	Type certification (see Q&C section)
2D	Two-dimensional
3D	Three-dimensional
3MF	3D Manufacturing Format
3MF	3MF Consortium
AA	The Aluminum Association
AAMI	Association for the Advancement of Medical Instrumentation
AATB	American Association of Tissue Banks
ABS	ABS Group
ACR	American College of Radiology
AFRL	U.S Air Force Research Laboratory
AI	Artificial intelligence
AIA	Aerospace Industries Association
AM	Additive manufacturing
AMC	Acceptable means of compliance
AMCOM	U.S. Army Aviation and Missile Command
AMDC	Additive Manufacturing Data Consortium (SAE-ITC)
AME	Additively Manufactured Electronics
AMF	Additive manufacturing file format
AMMT	Advanced Materials and Manufacturing Technologies
AMMTO	Advanced Materials and Manufacturing Technology Office
AMO	Advanced Manufacturing Office
AMO	Advanced Manufacturing Office
AMPP	Association for Materials Protection and Performance
AMSP	Additive manufacturing service platform
ANSI	American National Standards Institute
ANT	Advanced Nuclear Technology
API	Application programming interface
API	American Petroleum Institute
AR	Augmented reality
ARL	Applied Research Laboratory (Penn State)
ARP	Aerospace Recommended Practice (SAE)
ASM	ASM International
ASME	American Society of Mechanical Engineers
ASSP	American Society of Safety Professionals
ASTM	ASTM International
AWS	American Welding Society
BINDT	British Institute of Non-Destructive Testing
BJAM	Binder Jetting Additive Manufacturing

BNCS	Board on Nuclear Codes and Standards
BPTCS	Board on Pressure Technology Codes and Standards
BPVC	Boiler and Pressure Vessel Code
CAD	Computer aided design
CAE	Computer-aided engineering
CAM	Computer-aided manufacturing
CBM	Condition-Based Maintenance
CD	Committee draft (ISO)
CDA	Clinical Document Architecture
CDD	Common data dictionary
CFR	Code of Federal Regulations
CM4QC	Computational Materials for Qualification and Certification
CM4QC	Computational Materials for Qualification and Certification Steering Group
CMDS	Consortium for Materials Data Standardization
CMDS	Consortium for Materials Data Standardization (ASTM)
CMH	Composite material handbook (i.e., CMH-17)
CMM	Coordinate measuring machines
CMMS	Computerized maintenance management software
CMS	Coordinate measuring systems
CoE	Center of Excellence
CR	Computed radiography
CRADA	Cooperative research & development agreements
CSG	Constructive Solid Geometry
CT	Computed tomography
DA	Data (ANSI AMSC)
DARPA	Defense Advanced Research Projects Agency
DE	Design (ANSI AMSC)
DED	Directed Energy Deposition
DED-EB	Electron beam directed energy deposition
DED-GMA	Gas metal arc (DED process)
DED-GTA	Gas tungsten arc (DED process)
DED-LB	Laser beam directed energy deposition
DED-PA	Plasma arc (DED process)
DEVCOM	U.S. Army Combat Capabilities Development Command
DFAM	Design for additive manufacturing
DFARS	Defense Federal Acquisition Regulation Supplement
DFMA	Design for Manufacture and Assembly
DHS	U.S. Department of Homeland Security
DIN	Deutsches Institut für Normung
DIS	Draft international standard (ISO)
DIW	Direct ink wiring

DLP	Digital Light Processing
DMA	Dynamic mechanical analysis
DMSC	Dimensional Metrology Standards Consortium (QiF)
DO	Design organization
DoD	U.S. Department of Defense
DOE	U.S. Department of Energy
DR	Digital radiography
DSC	Differential scanning calorimetry
DTS	Draft technical specification (ISO)
EASA	European Union Aviation Safety Agency
EBSD SEM	Electron backscatter diffraction scanning electron microscope
ECAD	Electrical computer-aided design
ECSS	European Cooperation for Space Standardization
EEE	Electrical, Electronic, and Electromechanical
EFCP	Equipment and Facility Control Plan
EHS	Environmental health and safety
ELI	Extra low interstitial
EMB	Engineering in Medicine and Biology (IEEE)
EN	European Norm
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
ER	Extended reality
ETL	Extract, Transform, Load
ETWG	Emerging Technology Work Group
FAA	U.S. Federal Aviation Administration
FAIR	Findable, Accessible, Interoperable and Reusable
FDA	U.S. Food and Drug Administration
FDM	Fused deposition modeling
FFF	Fused filament fabrication
FGM	Functionally graded materials
FMEA	Failure Mode and Effects Analysis
FMP	Finished material properties
FR	Flame retardant
FST	Flame, smoke, toxicity
FTIR	Fourier transform infrared
GAO	U.S. General Accounting Office
GCC	General Coordination Committee
GD&T	Geometric dimensioning and tolerancing
GM	Guidance material
GPS	Geometrical Product Specifications
GSG	Government steering group

HDF	The HDF Group
HFIR	High-flux Isotope Reactor
HIP	Hot Isostatic Pressing
HIPPA	Health Insurance Portability and Accountability
HL7	HL7 International
HT	Heat treatment
ICNDT	International Committee for Non-Destructive Testing SIG)
ID	Identification
IEC	International Electrotechnical Commission
IEDO	Industrial Efficiency and Decarbonization Office
IEEE	Institute of Electrical and Electronics Engineers
IETF	Internet Engineering Task Force
IGA	Intergranular attack
IGO	Intergranular oxidation
IMDRF	International Medical Device Regulators Forum
INL	Advanced Test Reactor at Idaho National Laboratory
IPC	Association Connecting Electronics Industries
IQ	Installation qualification
IQI	Image Quality Indicators
ISFA	International symposium on flexible automation
ISMS	Information security management systems
ISO	International Organization for Standardization
ISTO	Industry Standards and Technology Organization (IEEE)
IT	Information technology
JMADD	Joint Metals Additive Database Definition
KPV	Key process variables
LANL	Los Alamos National Laboratory
LCC	Life Cycle Cost
LORA	level of repair analysis
MAPOD	Model-assisted POD
MASAAG	U.K Military Aircraft Structural Airworthiness Advisory Group
MCAD	Mechanical computer-aided design
MDR	Meta data registries
MES	Manufacturing execution system
MIT	Massachusetts Institute of Technology
MITA	Medical Imaging & Technology Alliance
MMPDS	Metallic Materials Properties Development and Standardization (Handbook)
MOSA	Modular Open Systems Approach
MPIF	Metal Powder Industries Federation
MQTT	Message queuing telemetry transport
MR	Mixed reality

MRI	Magnetic resonance imaging
MRO	Maintenance, repair and operations
MRR	Manufacturing Readiness Review
MSR	Material selection requirements
MTDA	Montana Digital Academy
NASA	National Aeronautics and Space Administration
NAVSEA	Naval Sea Systems Command
NAWC	Naval Air Warfare Center
NCAMP	National Center for Advanced Materials Performance
NDE	Nondestructive evaluation
NDI	Nondestructive inspection
NDIA	National Defense Industrial Association
NDT	Nondestructive testing
NE	Nuclear Energy
NEI	Nuclear Energy Institute
NEMA	National Electrical Manufacturers Association
NFPA	National Fire Protection Association
NIH	National Institute of Health
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NNSA	National Nuclear Security Agency (DOE)
NRC	Nuclear Regulatory Commission
OBJ	Object file
OQ	Operational qualification
ORNL	Oak Ridge National Laboratory
OSHA	The Occupational Safety and Health Administration
OT	Operational technology
OTJ	On the job
PAEK	Polyaryl ether ketones
PBF	Power Bed Fusion
PBF-EB	Electron beam powder bed fusion
PBF-L	Laser based powder bed fusion
PBF-LB	Laser powder bed fusion
Pc	Peak Count
PC	Process control
PC	Production Certificate (see Q&C section)
PC	Polycarbonate (polymer)
PCB	Printed circuit boards
PCD	Process control documents
PCRT	Process compensated resonance testing
PDF	Portable Document Format

PEI	Polyetherimide (polymer)
PEKK	Polyether ketone ketone
PHM	Prognostics and Health Management
PJP	Plastics Jet Printing
PLA	Polylactic acid (polymer)
PLC	Programmable Logic Controller
PM	Powder metallurgy
PMC	Polymer matrix composites
POD	Probability of detection
PPP	Part Production Plan
PQ	Performance qualification
PRC	Product Representation Compact
PSDO	Partner standards developing organization (ASTM/ISO)
PT	Project team (ASME)
PT	Penetrant testing
PTB	Pressure Technology Book (ASME)
PWG	Printer Working Group
PWI	Preliminary work item (ISO)
Q&C	Qualification and certification
QA	Quality assurance
QC	Qualification and certification (ANSI AMSC)
QIF	Quality Information Framework
QMP	Qualified Material Process
QMS	Quality management system
QPC	Quality and process control
QPP	Qualified Part Process
R&D	Research and development
R&R	Repeatability and reproducibility
Ra	Roughness
RCM	Reliability Centered Maintenance
RFI	Request for information
ROI	Regions of interest
RPN	Risk priority number
RQI	Representative quality indicators
Rsm	Mean profile spacing
RSNA	Radiological Society of North America
RT	Radiographic testing
RUS	Resonant ultrasonic spectroscopy
S/N	Serial number
SABIC	SABIC
SAE	SAE International

SAR	Source Approval Request
SDO	Standards development organization
SIG	Special Interest Group (RSNA)
SLA	Stereolithography
SLM	Selective laser melting
SLS	Selective laser sintering
SMR	Small modular reactor
SPC	Statistical process control
STD	Standard
STEP	Standard for the Exchange of Product Data
STL	Stereolithography / standard tessellation language
SYSCOM	Systems Command (DoD)
T&I	Testing and inspection
TAA	Type Airworthiness Authorities
TC	Technical committee
TCR	Transformational Challenge Reactor
TDP	Technical data packages (defense sector)
Tg	Glass transition temperature
TGA	Thermogravimetric analysis
TMA	Thermomechanical analysis
TR	Technical report (ASTM, ISO)
TRISO	TRi-structural ISOtropic
TS	Technical specification (ISO)
UA	Unified architecture
UID	Unique Identification
UL	Underwriters Laboratory
UNS	Unified numbering system
URL	Uniform resource locator
USP	United States Pharmacopeia
UT	Ultrasonic testing
V&V	Verification and validation
V3	Version 3 (ANSI AMSC)
VDI	The Association of German Engineers
VOC	Volatile organic chemicals
VR	Virtual reality
VRML	Virtual Reality Modeling Language
VT	Visual testing
VVUQ	Verification, validation and uncertainty qualification
WAAM	Wire arc AM
WG	Working group
WK	Work item (ASTM)

X3D	Extensible 3D
XCT	X-ray computed tomography
XML	Extensible markup language

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