



America Makes



Standardization Roadmap for Additive Manufacturing

VERSION 2.0

PREPARED BY THE
America Makes & ANSI Additive Manufacturing
Standardization Collaborative (AMSC)

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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. The AMSC was not chartered to write standards.

America Makes was established in 2012 and is the flagship Institute for [Manufacturing USA](#), the National Network for Manufacturing Innovation. America Makes is the nation's leading and collaborative partner in AM and three-dimensional (3D) printing technology research, discovery, creation, and innovation. It is managed and operated by the [National Center for Defense Manufacturing and Machining](#) (NCDMM).

Founded in 1918, ANSI serves as the administrator and coordinator of the United States private-sector voluntary standardization system. The Institute has a track record of convening stakeholders to define standardization needs that address national and global priorities in a variety of areas.

The catalyst for the AMSC was the recognition that a number of standards developing organizations 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.

This *Standardization Roadmap for Additive Manufacturing, Version 2.0* is an update to version 1.0 of this document published in February 2017. 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 the industrial additive manufacturing market, especially for aerospace, defense, and medical applications.

The roadmap has identified a total of 93 open gaps and corresponding recommendations across five 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; and 5) maintenance. Of that total, 18 gaps/recommendations have been identified as high priority, 51 as medium priority, and 24 as low priority. A "gap" means no *published* standard or specification exists that covers the particular issue in question. In 65 cases, additional research and development (R&D) is needed.

As with the earlier version of this document, the hope is that the roadmap will be broadly adopted by the standards community and that it will facilitate a more coherent and coordinated approach to the future development of standards and specifications for additive manufacturing.

To that end, it is envisioned that the roadmap will continue to be promoted in the coming year. The roadmap may be updated in the future to assess progress on its implementation and to identify emerging issues that require further discussion.

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Summary of Major Changes from Version 1.0

High-Level Structural and Content Changes

- Updates were made to the Introduction, especially sections 1.3, 1.4, and 1.5
- Polymers content has been expanded throughout section 2, and other content has been introduced, resulting in a number of the changes described below.

Renamed/Repositioned Roadmap Sections/Subsections (8)

- Section 2.1.4.1 renamed Design for As-Built Assembly
- Section 2.2.1.3 renamed Characterization of Powders
- Section 2.2.1.3.9 AM Process Specific Metal Powder Specifications (previously 2.2.1.4)
- Section 2.2.2.7 renamed Precursor Material Handling: Use, Re-use, Mixing, and Recycling Feedstock
- Section 2.2.4.2 renamed Material Properties
- Section 2.3.2.7 renamed NASA Marshall Space Flight Center (MSFC) Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals (previously 2.3.2.6)
- Section 2.5 renamed Maintenance and Repair
- Section 2.5.8 renamed Surface Preparation for Additive Repair (previously 2.5.7)

Substantially Revised Roadmap Sections/Subsections (36)

- Section 2.1.2 Design Guides: Design Guides for Post-processing
- Section 2.1.4.3 Design for Medical: Design of Lattice Structures
- Section 2.1.5 Design Documentation: In-Process Monitoring
- Section 2.1.5 Design Documentation: Documentation of New Functional Features and Surface Features
- Section 2.2.1.2 Storage, Handling and Transportation (metals)
- Section 2.2.1.3.8 Hollow Particles and Hollow Particles with Entrapped Gas
- Section 2.2.2.3 Machine Calibration and Preventative Maintenance
- Section 2.2.2.4 Machine Qualification
- Section 2.2.2.9 Environmental Health and Safety: Protection of Machine Operators
- Section 2.2.2.11 In-Process Monitoring
- Section 2.2.3.2 Heat Treatment (metals, polymers)
- Section 2.2.3.3 Hot Isostatic Pressing (HIP) (metals)
- Section 2.2.3.4 Surface Finish (Surface Texture) (metals, polymers)
- Section 2.2.3.6 Post-curing Methods (polymers)
- Section 2.2.4.2 Material Properties
- Section 2.2.4.3 Component Testing
- Section 2.2.4.4 Biocompatibility & Cleanliness of Medical Devices
- Section 2.2.4.6 Design Allowables

- Section 2.3.2.1 U.S Food and Drug Administration (FDA) Guidance on Technical Considerations for AM Devices
- Section 2.3.2.5 Composite Materials Handbook-17 (CMH-17) and Metallic Materials Properties Development and Standardization (MMPDS) Handbook
- Section 2.3.2.7 NASA Marshall Space Flight Center (MSFC) Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals (previously 2.3.2.6)
- Section 2.3.2.8 ASME Y14.46 (previously 2.3.2.7)
- Section 2.3.3.1 Aerospace Industry: Processes or Procedures
- Section 2.3.3.2 Defense Industry: Harmonizing Q&C Terminology for Process Parameters
- Section 2.3.3.2 Defense Industry: Machine Operator Training and Qualification
- Section 2.3.3.3 Medical Industry: Qualification & Certification of the Finished Device
- Section 2.3.3.3 Medical Industry: Resorbable Materials
- Section 2.3.3.3 Medical Industry: Material Control Data and Procedures
- Section 2.3.3.3 Medical Industry: Qualification and Control of Suppliers
- Section 2.3.3.3 Medical Industry: Validation of Sterilization Processes
- Section 2.4.2 Common Defects Catalog Using a Common Language for AM Fabricated Parts
- Section 2.4.3 Test Methods or Best Practice Guides for NDE of AM Parts
- Section 2.4.4 Dimensional Metrology of Internal Features
- Section 2.5.1 Introduction
- Section 2.5.3 Standard Repair Procedures (previously 2.5.2)
- Section 2.5.6 Standards for Tracking Maintenance Operations

New Roadmap Sections/Subsections (15)

- Section 1.5.10 MTConnect Institute*
- Section 2.1.3 Design Tools: Standardized Design for Additive Manufacturing (AM) Process Chain
- Section 2.1.7 Design for Anti-counterfeiting
- Section 2.2.1.4 Characterization of Material Extrusion Feedstock (Filaments & Pellets)
- Section 2.2.1.5 Characterization of Liquid Feedstock
- Section 2.2.2.12 Anti-Counterfeiting
- Section 2.2.3.2 Heat Treatment: Polymers
- Section 2.3.2.3 Nadcap Program*
- Section 2.3.2.9 Underwriters Laboratories
- Section 2.3.3.3 Medical Industry: Sterilization of Tissue Engineered Products
- Section 2.3.3.4 Electronic and Electrical Products Industry
- Section 2.4.6 NDE of Polymers and Other Non-Metallic Materials
- Section 2.4.7 NDE of Counterfeit AM Parts
- Section 2.4.8 NDE Acceptance Criteria for Fracture Critical AM Parts
- Section 2.5.2 Maintenance and Sustainment of Machines*

Withdrawn Roadmap Sections/Subsections (1)

- Section 2.3.2.2 Lockheed Martin AM Supplier Quality Checklist Overview*

*New or withdrawn roadmap sections that caused subsequent sections to be renumbered

Gap Analysis Changes

- 89 gaps were identified in roadmap version 1.0. Using a traffic light analogy, the status of progress on these is:
 - 49 gaps are Green (moving forward)
 - 2 more gaps are partially Green and partially Not Started or Unknown
 - 2 gaps are Yellow (delayed)
 - 0 gaps are Red (at a standstill)
 - 2 gaps have been Closed
 - 5 gaps have been Withdrawn
 - 29 gaps are Not Started or Unknown
- 42 gaps have been substantially revised in roadmap version 2.0
- 11 new gaps are identified in roadmap version 2.0
- 93 gaps are open. Of these:
 - 16 are High priority (should be addressed in 0-2 years)
 - 1 (Gap FMP1) is High for Metals and Polymers and Low for Ceramics
 - 1 (Gap FMP4) is High for Material Specifications and Medium for Data Requirements, Statistical Analysis, and Test Methods
 - 51 are Medium priority (should be addressed in 2-5 years)
 - 24 are Low priority (should be addressed in 5+ years)
- 65 gaps require research and development

Closed Gaps (2)

- Gap D11: Design for 3D Printed Electronics
- Gap D24: An Acquisition Specification

Withdrawn Gaps (5)

- Gap D25: Configuration Control of Digital Part Design
- Gap PC17: Motion Control
- Gap FMP2: Coupon Testing
- Gap QC11: Process Validation for Pigments and Processing Aid Materials
- Gap M2: Using AM to Print Tools

Substantially Revised Gaps (42)

- Gap D2: Decision Support: Additive Processes
- Gap D7: Design Guide for Post-processing
- Gap D8: Machine Input and Capability Report
- Gap D12: Imaging Consistency
- Gap D13: Image Processing and 2D to 3D Conversion

- Gap D14: Designing to be Cleaned
- Gap D15: Design of Test Coupons
- Gap D17: Contents of a TDP
- Gap D19: Organization Schema Requirement and Design Configuration Control
- Gap D22: In-Process Monitoring
- Gap D23: Documentation of New Functional and Complex Surface Features
- Gap D26: Design for Measurement of AM Features/Verifying the Designs of Features such as Lattices, etc.
- Gap PM1: Flowability
- Gap PM3: Particle Size and Particle Size Distribution
- Gap PM4: Particle Morphology
- Gap PM5: Metal Powder Feedstock Sampling
- Gap PM6: Hollow Particles and Hollow Particles with Entrapped Gas
- Gap PC2: Machine Calibration and Preventative Maintenance
- Gap PC5: Parameter Control
- Gap PC9: Environmental Conditions: Effects on Materials
- Gap PC14: Environmental Health and Safety: Protection of Machine Operators
- Gap PC16: In-Process Monitoring
- Gap P1: Post-processing Qualification and Production Builds
- Gap P4: Surface Finish
- Gap P5: Use of Post-cure to Reduce Toxic Gases from Uncured Polymer Feedstock
- Gap P6: Guidelines for Post-curing AM Plastics to Address Outgassing and Offgassing
- Gap FMP1: Material Properties
- Gap FMP2: Cleanliness of Medical AM Parts
- Gap FMP4: Design Allowables
- Gap QC2: AM Part Classification System for Consistent Qualification Standards
- Gap QC3: Harmonizing Q&C Terminology for Process Parameters
- Gap QC4: Process Approval for DoD-procured Parts
- Gap QC5: Machine Operator Training and Qualification
- Gap QC12: Resorbable Materials
- Gap QC15: Sterilization of Anatomical Models
- Gap NDE2: Standard for the Design and Manufacture of Artifacts or Phantoms Appropriate for Demonstrating NDE Capability
- Gap NDE4: Dimensional Metrology of Internal Features
- Gap M1: AM Analysis in RCM and CBM
- Gap M3: AM Level of Repair Analysis
- Gap M4: Physical Inspection of Parts Repaired Using AM
- Gap M5: Model-Based Inspection
- Gap M8: Surface Preparation for Additive Repair

New Gaps (11)

- New Gap D27: Standardized Design for Additive Manufacturing (DFAM) Process Chain
- New Gap D28: Specification of Surface Finish
- New Gap PM8: Use of Recycled Polymer Precursor Materials
- New Gap PM9: Characterization of Material Extrusion Feedstock (Filaments & Pellets)
- New Gap PM10: Sampling of Open Liquid Feedstock System
- New Gap P7: Heat Treatment (HT)-Polymers
- New Gap QC16: Sterilization of Tissue Engineered Products
- New Gap NDE6: NDE of Polymers and Other Non-Metallic Materials
- New Gap NDE7: NDE of Counterfeit AM Parts
- New Gap NDE8: NDE Acceptance Criteria for Fracture Critical AM Parts
- New GAP M9: Laser Based Additive Repair

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Summary Table of Gaps and Recommendations

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
Design								
1.	2.1.2	Design Guides: General Guides for AM	Gap D1: Decision Support: Additive vs. Subtractive. 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.	TBD	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.). Update: No standards are planned or in development. Commercial tools are available. SME and its ITEAM (Independent Technical Evaluation of Additive Manufacturing) are developing the RAPID Additive Manufacturing Platform (RAMP). The Additive Manufacturing Equipment and Materials Repository, a core aspect of RAMP, was released in beta, with beta testing continuing during the summer of 2018. The SAM-CT demo evaluation application will utilize RAMP. Application providers are being encouraged to develop additional additive manufacturing evaluation applications.	Medium	Green (SME) in terms of a tool providing general guidance, though not a standard	ISO/ASTM, AWS, SAE, SME
2.	2.1.2	Design Guides: General Guides for AM	Gap D2: Decision Support: Additive Processes. 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 2017, ISO/ASTM published ISO/ASTM 52910-17, Standard Guidelines for Design for Additive Manufacturing (work item previously known as ASTM WK38342). 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.	Yes. R&D is needed to identify trade-off criteria.	Continue work to complement what has been published in ISO/ASTM 52910:2017. Focus on identification of trade-off criteria between processes. There is still a need to develop a standard for reporting process inputs and capabilities. Update: The gap statement and recommendation have been updated in light of the publication of ISO/ASTM 52910-17.	Medium	Green. Gap partially closed in relation to standards with the publication of ISO/ASTM 52910-17.	National labs and government agencies for the R&D. ISO/TC 261 & ASTM F42 for the standards work.
3.	2.1.2	Design Guides: Process-Specific Guides for AM	Gap D3: Process-Specific Design Guidelines. There are no available AM process-specific design guidelines. The design guidelines currently being developed by JG 57 are process-specific design guidelines under joint development by ASTM F42 and ISO/TC 261. ASTM and ISO identify 7 types of AM processes, meaning that 6 AM processes do not have guidelines under development.	No, for the guidelines on PBF. Not yet determined for the other six processes.	Complete work on the ISO/ASTM JG 57 design guidelines for PBF. Develop guidelines for the six other AM processes defined in ISO/ASTM 52900:2015, Additive manufacturing -- General principles – Terminology . Update: As noted in the text, ISO/ASTM JG 57 design guidelines are being developed for PBF-L for metals and polymers. Work on electron beam	Medium	Green (ISO/ASTM) for PBF. Green (AWS) for PBF and DED. Not Started for the other processes	ASTM F42/ISO TC 261 JG 57, AWS

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					continues. AWS D20.1 will address PBF and DED, as noted in the text.		defined in ISO/ASTM 52900.	
4.	2.1.2	Design Guides: Design Guides for Specific Applications	Gap D4: Design Guides for Specific Applications. As industry fields mature in particular AM applications, best practices should be recorded.	TBD	<p>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.</p> <p>Update: ASME is working on design guides for pressure retaining equipment (e.g., pressure vessels). Other SDOs need to consult with their committees. Some of the SAE process specifications may address this.</p>	High	Green	ASME, SAE, ASTM F42/ISO TC 261, and potentially other SDOs et al. (e.g., manufacturers, industry consortia)
5.	2.1.2	Design Guides: Machine Customizable/ Adaptive Guides for AM	Gap D5: Support for Customizable Guidelines. 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. Guidelines on how to extend process and application guidelines would allow users to further adapt and specify to fit individual needs.	Yes. Customizable guidelines require understanding process/machine/design characteristics and subsequent tradeoffs.	<p>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.</p> <p>Update: ASTM WK54856, <i>New Guide for Principles of Design Rules in Additive Manufacturing</i>, has an expected release date of late 2018/early 2019.</p>	Medium	Green	ISO/ASTM
6.	2.1.2	Design Guides: Machine Customizable/ Adaptive Guides for AM	Gap D6: Software-encodable/Machine-readable Guidelines. In addition to design guidelines, complementary efforts have been initiated under ASTM Committee F42 on Additive Manufacturing Technologies (F42) to support the development of standardized design rules. Guidelines that are in development rely heavily on graphics/drawings and narrative through natural language, leaving often subjective interpretations. ASTM WK54856, <i>New Guide for Principles of Design Rules in Additive Manufacturing</i> , under development in ASTM F42, aims to provide explicit constructs from which explicit design rules can be developed and customized. These constructs will also provide a machine interpretable language that will support software implementation. The	Yes. The identification of fundamental constructs should mirror key characteristics and decision criteria for designs, materials, and processes.	<p>Standardize a language that can be interpreted by both humans and machines so that design for AM can be simplified and communicated across platforms, and constraints can be encoded into design software.</p> <p>Update: This gap is being addressed by ASTM WK54856.</p>	Medium	Green	ASTM, ISO, ASME, IEEE-ISTO PWG

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
			standard has an expected release date of late 2018/early 2019.					
7.	2.1.2	Design Guides: Design Guide for Post-processing	Gap D7: Design Guide for Post-processing. There is a need for a design guide for post-processing.	Yes	Develop a design guide for post processing Update: ASME is not working on a design guide but ASME B46 Committee is working on measurement and characterization methods for AM surface finish. ISO/ASTM 52910-17, Standard Guidelines for Design for Additive Manufacturing 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.	Medium	Not Started	ASME B46, ASTM F42/ISO TC 261
8.	2.1.3	Design Tools: A Machine Input and Capability Report	Gap D8: 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.	No	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 D20 on neutral build format. Update: ASTM has a guide for storage of technical build cycle data which may address some of this.	Medium	Not Started	Consortium of industry, ISO/ASTM, IEEE-ISTO PWG
9.	2.1.3	Design Tools: A Requirement for an AM Simulation Benchmark Model/Part	Gap D9: AM Simulation Benchmark Model/Part Requirement. A standard for a process-specific AM benchmark model/part is needed to enable verification and validation (V&V) of applicable process simulation tools.	Yes. R&D is needed for characterizing processes using consistent, measurable and precise techniques.	Develop a standard for a process-specific AM simulation benchmark model/part. Canonical models that reproduce difficult-to-build features are needed for V&V. Update: An AM Bench Consortium led by NIST has been started.	Low	Yellow	NIST, America Makes, ASME V&V, ISO/ASTM
10.	2.1.3	Design Tools: Standardized Design for Additive Manufacturing (DFAM) Process Chain	NEW Gap D27: Standardized Design for Additive Manufacturing (DFAM) Process Chain. A standardized design is needed for AM process chain integrating key AM considerations/design tools in each design stage.	Yes	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 52910-2017, Standard Guidelines for Design for Additive Manufacturing 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	Medium	New	ASTM F42/ISO TC 261 JG 73, NIST

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					site-specific DFAM process and digitalization implementation.			
11.	2.1.4.1	Design for As-built Assembly	Gap D10: 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 may need to account for complexity of support structures, removal times, post-processing complexity, 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.	Yes. 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.	ISO 8887-1:2017 and other DFMA standards can be reviewed and further developed to address AM related issues. Update: None provided	Low	Not Started	R&D: Academia, industry, national laboratories. Standards: ISO, ASTM, AAMI, NEMA/MITA
12.	2.1.4.2	Design for Printed Electronics	Gap D11: Design for 3D Printed Electronics. There is a need to develop standards on design for 3D printed electronics.	No	Complete work on IPC-2292, Design Standard for Printed Electronics on Flexible Substrates . Update: IPC 2292 was published in March 2018. The IPC D-66A, 3D Printed Electronics Processes Task Group is in the early stages of developing a table of contents for a process guideline standard. This activity will take a considerable amount of time because there are so many processes, variables, materials, technologies, equipment, process environments, etc., to consider. 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 D4.	Medium	Closed, with the publication of IPC 2292.	IPC
13.	2.1.4.3	Design for Medical: Input Data (CT, MRI, Ultrasound scan and X-Ray))	Gap D12: 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 practices for developing these plans and key	No. The information is housed within individual institutions and could be combined through participation in clinical associations, consortiums or standards development organizations.	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. Update: An RSNA 3D Special Interest Group (SIG) is working on best practices, not a standard. ISO/ASTM NP 52916, Additive manufacturing --	Medium	Green	RSNA (Radiological Society of North America), ASTM F42/ISO TC 261 JG 70, DICOM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
			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.		Data formats -- Standard specification for optimized medical image data from ISO/TC 261 JG 70 deals with imaging quality. This is a secondary priority for the DICOM WG.			
14.	2.1.4.3	Design for Medical: Data Processing	Gap D13: 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.	Yes. 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.	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. 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 NP 52916, Additive manufacturing -- Data formats -- Standard specification for optimized medical image data from ISO/TC 261 JG 70 covers this gap. An RSNA SIG is also looking at this.	Medium	Green	Methods: NEMA/MITA, ASME V&V 40, ASTM F4, ASTM F42/ISO TC 261. Phantoms: NIST, FDA, RSNA
15.	2.1.4.3	Design for Medical: Design of Lattice Structures	Gap D14: Designing to be Cleaned. Currently there are no design guidelines for medical devices to assure cleanability after production. When designing a medical device, cleanability must be evaluated at different stages for a number of reasons: 1. To ensure manufacturing residues/contact materials encountered during the manufacturing process can be removed 2. To ensure that unmelted/unsintered AM material from the manufacturing process can be removed 3. For devices that are to be sterilized prior to use, to ensure that 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, to ensure the device can be adequately cleaned and sterilized prior to subsequent uses 5. For reusable devices, to ensure that the device materials can be maintained for the specified number of cleaning cycles	Yes, in terms of ways to determine what parts are likely to be cleanable before they are made	Develop design guidelines to provide general design limits and recommendations that achieve both needed surface structure and allow adequate cleaning. See also Gap FMP3 and Gap QC15. Update: AAMI and ASTM have an interest and are meeting. FDA is also looking at this.	Medium	Not Started	AAMI, ASTM F4, ASTM F42/ISO TC 261, ISO/TC 198, ASME (surface metrology), FDA

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
16.	2.1.4.3	Design for Medical: Design of Lattice Structures	Gap D15: Design of Test Coupons. No standards are available for the design of test coupons for additively-manufactured porous structures.	Yes. Effects on what is in the build and how well can you replicate your feature of interest.	Standards are needed for the design of test coupons for additively-manufactured porous structures. Update: ASTM F4 is looking at this.	Low	Green	ASTM F4 and F42
17.	2.1.4.3	Design for Medical: Design of Lattice Structures	Gap D16: 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, there are no guidelines on considerations when validating their performance.	Yes	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. Update: ASME Y14.46 discusses the specification of functionally graded materials. New efforts are focusing on verification of lattice FGM specifications.	Low	Not Started	ASTM F4 and F42, SAE AMS-AM, ASME, ISO/TC 261 JG 67
18.	2.1.5	Design Documentation: Technical Data Package (TDP) Content	Gap D17: Contents of a TDP. The contents of a TDP 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.	Yes	Develop a standard (or revise MIL-STD-31000A , Technical Data Packages) to describe all required portions of a TDP and adopt them into a formal standard. The standard should address at a minimum: <ul style="list-style-type: none"> • 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 • Tailorable and non-tailorable build parameters • Cybersecurity requirements (if necessary) • Long term archival and retrieval process (including acquisition) Update: NIST has been involved in developing a number of component standards with various SDOs. DoD is pushing for a standard that defines the contents of a TDP to cover DoD products. DoD is in the process of updating 31000A2 revision B. ASME Y14.47, <i>Model Organization Schema Practices</i> , is based on Appendix B of MIL-STD-31000A. It should be available by the second quarter of 2018. DoD representatives are involved in the development of Y14.47 and Y14.46, which has a section specific to AM data packages. SAE G-33’s SAE EIA649C, Configuration Management Standard , targeted for publication in the third quarter of 2018, provides guidance on specification control. There is a joint WG for digital product definition and data management under ASTM/ISO (JG 73).	High	Green	ASME Y14.46, ASME Y14.47, ASTM F2/ISO TC 261, DoD AFRL, NIST, SAE G-33

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
19.	2.1.5	Design Documentation: New Dimensioning and Tolerancing Requirements	Gap D18: New Dimensioning and Tolerancing Requirements. Although ASME Y14.41, Digital Product Definition Data Practices and other standards provide some capability in addressing some of the challenges in documenting AM designs, significant gaps still remain. ASME Y14.46 will address these gaps.	No	Complete work on ASME Y14.46. See also Gap D26 on measurement of AM features/verifying the designs of features such as lattices, etc. Update: ASME Y14.46-2017, Product Definition for Additive Manufacturing [Draft Standard for Trial Use] has been published and items within the standard related to this gap are still under development pending final approval. ASME Y14.48 on Universal Direction may also be relevant but that will not be available for another year or two. NIST provides a vice chair of the Y14 subcommittee 46.	High	Green	ASME Y14.46, ASME Y14.48, NIST
20.	2.1.5	Design Documentation: An Organization Schema Requirement and Design Configuration Control	Gap D19: Organization Schema Requirement and Design Configuration Control. 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.	No	ASME Y14.47, <i>Model Organization Schema Practices</i> , formerly known as Y14.41.1 may partially address this gap but AM related aspects need to be further developed. This standard should be available by the second quarter of 2018. 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. Update: As noted in the recommendation.	High	Green	ASME Y14.47, ISO/TC 10, ASTM F42/ISO TC 261 JG 73, NIST, SAE G-33
21.	2.1.5	Design Documentation: A Neutral Build File Format	Gap D20: Neutral Build File Format. No published or in development standards or specifications have been identified that incorporate build path or feedstock into a neutral file format. Further, 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 AM file format, which will help to better enable qualification of a design. However, the unique technologies of the different vendors could make such an effort challenging.	Yes	Develop a new standard for the computer-interpretable representation and exchange of additive manufacturing product information that can represent all of the applicable slice files, build path, and feedstock, as well as the other applicable parameters into a single file format. This file would be used to exchange data between AM vendors and have the capability to be used instead of both the job files and material perimeter sets. This file format could make use of standard image formats and capture enough information to facilitate size, orientation and color normalization in post-processing of data. See also Gap D8 on machine input and capability report. Update: None provided	Low	Not Started, or Unknown	ISO/TC 184/SC4, ISO/TC 261/ASTM F42, consortium of industry, IEEE-ISTO PWG
22.	2.1.5	Design Documentation: New Terminology in	Gap D21: New Terminology in Design Documentation. While some AM terminology standards already exist, they do not include certain terms referred to in design	No	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	Medium	Green	ASME, ISO/ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
		Design Documentation	documentation. Terminology in a TDP needs to be clear.		standards such as ISO/ASTM 52900:2015, Additive manufacturing -- General principles – Terminology . Update: ASME Y14.46-2017, Product Definition for Additive Manufacturing [Draft Standard for Trial Use] 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. Since Y14.46 is a draft standard for trial use, comments are being accepted and there may be significant changes to the draft standard.			
23.	2.1.5	Design Documentation: In-Process Monitoring	Gap D22: In-Process Monitoring. 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). No standardized data models or documentation have been identified for in-process monitoring and analytics. Given the current state of the technology, this is not surprising.	Yes. R&D is needed to understand what in-process monitoring data is needed for verification and validation of the part. Research efforts have been undertaken that are devoted to the development of predictive computational models and simulations to understand the dynamics and complexity of heat and phase transformations. Although computational models and simulations are promising tools to understand the physics of the process, lack of quantitative representation of their prediction accuracy hinders further application in process control and optimization. Due to this reason, it is very challenging to select suitable models for the intended purpose. Therefore, it is important to study and investigate the degree of accuracy and uncertainty associated with AM models.	Develop standards for predictive computational modeling and simulation tools that link measured in-process monitoring data with product properties, quality, and consistency, as an important aspect of innovative structural design (NIST, 2013). See also Gap PC16 on in-process monitoring to obtain a layer-by-layer (3D) file or quality record showing the as-built part is defect-free or contains no critical flaws, or exhibits an in-family (nominal) response when interrogated during the build. Update: Office of Naval Research (ONR) is also researching this through their Quality Made program. NIST is developing a publicly available schema for metals that may apply.	Medium	Green	ASTM F42, ASME, IEEE-ISTO PWG
24.	2.1.5	Design Documentation: Documentation of New Functional Features and Surface Features	Gap D23: 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.	No	ASME Y14.46 should consider an annex describing a method to document functional and complex geometric features. Update: As noted in the recommendation. ASME Y14.46-2017, Product Definition for Additive Manufacturing [Draft Standard for Trial Use] has been published.	Low	Green	ASME
25.	2.1.5	Design Documentation: Documentation of New Functional	NEW Gap D28: 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	Yes	ASME should continue its work to develop ASME B46.1-2009, Surface Texture (Surface Roughness, Waviness, and Lay) , to address specification requirements of AM surface finishes.	Medium	New	ASME

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
		Features and Surface Features	adequately specify surface finish requirements.					
26.	2.1.5	Design Documentation: An Acquisition Specification	Gap D24: An Acquisition Specification. A specification is needed to procure AM parts from third parties.	No	ASTM should complete work on WK51282, New Guide for Additive Manufacturing, General Principles, Requirements for Purchased AM Parts. Update: ISO/ASTM 52901, Additive manufacturing - General Principles - Requirements for Purchased AM Parts was published in 2017. WK51282 was the earlier ASTM work item.	Medium	Closed	ISO/ASTM
27.	2.1.6	Design Verification and Validation	Gap D26: Design for Measurement of AM Features/Verifying the Designs of Features such as Lattices, etc. As noted in Gap D18, 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 helices or other complex shapes, or internal features that are not compatible with common methods such as Go/NoGo 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.	Yes, investigation of high resolution radiographic and ultrasonic methods and the maximum achievable resolution and accuracy for GD&T of complex AM designs.	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. Update: A standard on methods to verify that complex AM parts meet design requirements is needed. ASME Y14.46-2017, Product Definition for Additive Manufacturing [Draft Standard for Trial Use] 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 52910-17, Standard Guidelines for Design for Additive Manufacturing 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.”	Medium	Not Started	ISO/TC 261/ASTM F42, ASTM E07.01, ASTM E07.02, ASME B89, ASME Y14.46, ISO/TC 10
Process and Materials – Precursor Materials								
28.	2.2.1.3.1	Precursor Materials: Characterization of Powders: Chemical Composition: Polymers	NEW 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 recycle from commercial sources, and post-consumer recycle. Recycled feedstock, depending on its source and usage level, can introduce problems in the printing or end-use	Yes, to determine the acceptable limits and other constraints of incorporating reprocessed materials. This may be machine, material, and/or application specific.	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.	Low	New	ASTM F42/D20, SAE AMS-AM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
			application due to the recycle's thermal/mechanical history, consistency and composition.					
29.	2.2.1.3.2	Precursor Materials: Characterization of Powders: Flowability	Gap PM1: Flowability. Existing standards for flowability do not account for the range of conditions that a powder may encounter during shipment, storage, and the AM process.	Yes. R&D is needed to measure and quantify flowability, especially with powder bed processing.	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. Recommend also completion of ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder , which points to published standards for flowability tests along with consideration of how the state of the powder would affect the flowability measurement. See also Gap PC12 on precursor material flow monitoring. Update: As noted in the text, ASTM WK55610 and ISO/ASTM DIS 52907 are in development. Completion of those work items may partially but not fully address the gap.	Medium	Green	ASTM F42/ISO TC 261, NIST, ASTM B09, ASTM E29
30.	2.2.1.3.3	Precursor Materials: Characterization of Powders: Spreadability	Gap PM2: Spreadability. There is no known description of spreadability or standard for how to quantitatively assess powder spreadability.	Yes. R&D is needed to measure and quantify spreadability, as well as to correlate powder characteristics with spreadability.	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. Update: There are no ASTM standard test methods for spreadability.	Medium	Not Started, or Unknown	ASTM F42/ISO TC 261, NIST, universities, ASTM B09, ASTM E29
31.	2.2.1.3.5	Precursor Materials: Characterization of Powders: Particle Size and Particle Size Distribution	Gap PM3: Particle Size and Particle Size Distribution. While current standards for measurement of particle size and particle size distribution exist for powder metallurgy and can be leveraged for AM powders, the reliability and repeatability of different testing methodologies is currently unacceptable.	Yes. Validation of various measurement techniques for reliability, repeatability, and correlation is required, possibly defining best measurement techniques for different build systems.	See R&D needed. For metal PBF, recommend completion of ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder , which points to published standards for particle size analysis and discusses advantages and limitations of each referenced test method. Update: As noted, ISO/ASTM DIS 52907 is in development as JG 66. Completion of this work item may partially but not fully address the gap.	Medium	Green	ASTM F42/ISO TC 261 JG 66, ASTM B09, ASTM E29
32.	2.2.1.3.6	Precursor Materials: Characterization of Powders: Particle Morphology	Gap PM4: Particle Morphology. No standards exist giving users of AM criteria for use of a particular powder feedstock based on the powder morphology.	Yes. R&D is needed to measure and quantify particle morphology.	Based on the results of R&D, a standard may be needed to define accepted test methods 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	Low	Green	NIST, ASTM F42/ISO TC 261 JG 66, ASTM B09, ASTM E29

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					<p>into account the density of the powder. Recommend completion of ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder, which points to published standards for describing particle morphology.</p> <p>Update: As noted, ISO/ASTM DIS 52907 is in development as JG 66.</p>			
33.	2.2.1.3.7	Precursor Materials: Characterization of Powders: Feedstock Sampling	Gap PM5: Metal Powder Feedstock Sampling. While existing powder metallurgy standards may be leveraged for AM use, they require tailoring for AM-specific situations. For example, sampling practices for 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.	Yes, with respect to the re-use of powder during the build. See also Gaps PC7, PC10 and PC11.	<p>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 re-use of powder.</p> <p>Update: SAE AMS7003, Laser Powder Bed Fusion Process was published in June 2018 and addresses this issue. For metals specifically, members of MPIF's Association for Metal Additive Manufacturing (AMAM) technical committee reviewed MPIF Standard Test Method 01, Method for Sampling Metal Powders (2016) and noted that challenges with standardizing powder sampling include variations for different powder alloy systems, additive manufacturing technologies, and the importance of powder purity to the application. ASTM B09 is currently reviewing the MPIF Std. Test Method 01. For polymers, there may be interest from ASTM D20 working in conjunction with ASTM F42.</p>	High	Green	NIST, SAE AMS-AM, ASTM B09, MPIF, ASTM D20 (for polymers), ASTM F42, ASTM E29
34.	2.2.1.3.8	Precursor Materials: Characterization of Powders: Hollow Particles and Hollow Particles with Entrapped Gas	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.	Yes. R&D is needed to establish the impact of hollow powder particles, if any.	<p>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. Recommend completion of ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder and include measurement standards for powder internal porosity.</p> <p>Update: None provided</p>	Low	Unknown	For R&D: NIST, ASTM, America Makes, Oak Ridge National Laboratory, universities. For standards: ASTM F42/ISO TC 261, SAE, ASTM B09, ASTM E29
35.	2.2.1.3.9	Precursor Materials: Characterization of Powders: AM Process-Specific Metal Powder Specifications	Gap PM7: AM Process-Specific Metal Powder Specifications. There is a need to develop AM process-specific metal powder specifications to ensure that a competitive supply of metal powder is available for procurement purposes. Further, vendors should be encouraged to use these industry powder specifications when testing their equipment and advertising final material properties.	Yes. 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	Develop AM process-specific metal powder specifications to facilitate procurement of metal powders for use in AM machines. These specifications should describe the acceptable ranges of all relevant powder parameters that would impact the suitability of a given powder to be used in a given AM machine, and the effect it would have on final material properties.	Medium	Green	ISO/ASTM, SAE AMS-AM, AWS, industry OEMs

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
				3) Flow Rate 4) Tap Density 5) Angle of Repose 6) Shear Stress 7) Chemistry 8) Specific Surface Area	Update: ASTM WK58219, New Guide for Additive Manufacturing - Feedstock Materials-Creating Feedstock Specifications for Metal Powder Bed Fusion , is in development. SAE AMS7001, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 62Ni - 21.5Cr - 9.0Mo - 3.65 Nb has some of the parameters defined and was published in June 2018.			
36.	2.2.1.4.5	Precursor Materials: Characterization of Material Extrusion Feedstock (Filaments & Pellets): Thermal Stability	NEW 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.	Yes, to define the specific requirements and evaluate if these can be addressed by existing systems and procedures and, if not, to develop new ones.	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.	Low	New	ASTM F42/D20, SAE AMS-AM
37.	2.2.1.5.3	Precursor Materials: Characterization of Liquid Feedstock: Feedstock Sampling	NEW 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.	Yes. 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.	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).	Low	New	ISO/ASTM, Industry OEMs
Process and Materials - Process Control								
38.	2.2.2.2	Process Control: Digital Format and Digital System Control	Gap PC1: Digital Format and Digital System Control. Existing process control standards do not adequately address digital format and digital system control.	Yes	Leverage NIST research and work with SDOs to ensure that AM process control standards include digital format and digital system control. Update: The ISO/TC 261/ASTM F42 JG 56 standard in development addresses digital data configuration control.	Medium	Green	NIST, ISO/ASTM JG 56, SAE, IEEE-ISTO PWG
39.	2.2.2.3	Process Control: Machine Calibration and Preventative Maintenance	Gap PC2: Machine Calibration and Preventative Maintenance. There are no known industry standards addressing machine calibration and preventative maintenance for additive manufacturing. Current users may not have established best practices or their own internal standards and may assume that the 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.	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	Complete work on standards in development addressing machine calibration and preventative maintenance. In addition, OEM and end user best practices should ensure adequate and recommended calibration and maintenance intervals that have been documented with data for different processes and machines. OEMs and SDOs should develop technical reports that incorporate case studies related to machine restart after maintenance. Standards should account for motion control components that guide measurement and remediation of error in positioning systems where possible in AM machines. OEMs should also take this into account when designing AM machines. Update: As noted in the text.	High. There is an urgent need to develop guidelines on day-to-day machine calibration checks.	Green	AWS D20, ASTM F42/ISO TC 261, SAE AMS-AM, NIST, OEMs, end users, experts in machine metrology

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
40.	2.2.2.3	Process Control: Machine Calibration and Preventative Maintenance	Gap PC3: Machine Health Monitoring. There are no known industry standards addressing 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.	Yes	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 . ¹ 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, Tracking Maintenance. Update: ASME has a non AM-specific project concerning Advanced Monitoring, Diagnostics, and Prognostics for Manufacturing Operations.	Low	Not Started, or Unknown	NIST, ISO, ASTM, AWS, IEEE-ISTO PWG, ASME
41.	2.2.2.4	Process Control: Machine Qualification	Gap PC4: Machine Qualification. Current users may not have considered the influence of machine control on resulting product quality and material properties beyond form and fit, including machine-to-machine variation (even between machines of the same make and model). While guidelines for machine qualification can be developed, a broader view of part-specific, process-specific, material-specific, and application-specific recommended practices is needed.	Yes	SDOs should develop qualification standards for AM machines to pass in order to provide a level of confidence that these machines can produce parts with the required material properties. In addition, SDOs should develop guidelines or technical reports that incorporate case studies of various part types and applications across materials. Additional research may be needed in relation to machine-to-machine variation and on key parameters. Update: As noted in the text.	Medium	Green	NIST, AWS, SAE AMS-AM, ASTM F42, NAVSEA, NASA MFSC
42.	2.2.2.5	Process Control: Parameter Control	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.	Yes. Develop and establish one verifiable key process parameter that combines both material and process parameters (such as power absorption coefficient or power ratio parameter, verifiable by melt pool geometry, as shown in the research) that is independent of material and machine brand. R&D is needed to verify the concept of power ratio as the single controlling parameter and its applicability to all materials and machine brands.	Develop a standard that identifies key build process parameters for AM machines, taking into account the different processes, materials, industry-specific applications, and machines involved. Complete work on AWS D20.1 . See also Gap QC3 on harmonizing Q&C terminology for process parameters. Update: As noted in the text, AWS D20.1 has been drafted. ASTM F42 process and materials standards cover the parameters for PBF and Inconel 625 but not the values. SAE AMS7100 is trying to address FDM process control including setting parameters for the aerospace industry. SAE AMS7003 includes	Medium	Green	AWS D20, ASTM F42, SAE AMS-AM, OEMs, IEEE-ISTO PWG

¹ <http://dx.doi.org/10.6028/NIST.IR.8012>

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					an appendix on PBF-L process characteristics but contains no values.			
43.	2.2.2.6	Process Control: Adverse Machine Environmental Conditions: Effect on Component Quality	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.	Yes	Develop standards and specifications to address external environmental factors that could negatively impact component quality. Update: None provided	Low	Unknown	OEMs, DoD for military-specific operational environments, ASTM
44.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Feedstock	Gap PC7: Recycle & Re-use of Materials. There are many practices in the materials industry of how to recycle, re-use, and revert materials in production. They are also highly material dependent. End users need to understand best practices for how to qualify their various precursor material streams.	Yes. Research should be conducted to understand the effects of mixing ratios of reused to virgin material.	Develop guidance as to how reused materials may be quantified and how their history should be tracked (e.g., number of re-uses, number of exposure hours [for a laser system], or some other metric). Guidelines for sieving reused powder prior to mixing must be created. Update: SAE is looking at it on the aerospace side. NIST has published one study on the subject on metals but more R&D is needed before you can build parts to be qualified.	High	Green	ASTM F42/ISO TC 261, ASTM D20, MPIF, NIST, SAE, trusted end user-group
45.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Feedstock	Gap PC8: Stratification. Powders used in additive manufacturing are composed of a distribution of particle sizes. Stratification may take place during container filling, transportation, or handling before and after being received by a user of powder. Users must know what conditioning is appropriate to ensure that the powder's particle size distribution is consistent and acceptable for the specific process. There is currently a lack of guidance in this area.	Yes. Research should be conducted to understand the effect of stratification on particle size distribution of as-received powder and mixed powder prior to being put into service. The results from this work can be used to guide the re-blending of powder before being put into service.	Develop guidelines on how to maintain OEM characteristics in new use and re-use powder scenarios. There is documented variability in the final part properties in various AM processes; the AM community must either rule out stratification of powder precursor material or provide guidelines for mixing of lots to achieve acceptable particle size distribution. Update: None provided	Medium	Unknown	NIST, trusted end user-group, ASTM
46.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Feedstock	Gap PC9: Environmental Conditions: Effects on Materials. AM materials can be sensitive to changes in environmental conditions including temperature, humidity, and ultraviolet radiation. Therefore, general guidance must be provided to ensure the environmental conditions in which the material is used and stored remain within acceptable ranges for all material types. Specific material packaging requirements are addressed in Section 2.2.1.3.9. No standards or specifications have been identified regarding this topic.	Yes	Develop guidance on the storage of AM materials so that AM materials are stored and used in environments with acceptable conditions. Research should be conducted to identify these ranges. Update: UL 3400, Outline of Investigation for Additive Manufacturing Facility Safety Management , is a document for the evaluation and certification of any additive manufacturing facility that uses powder as the initial form of feedstock material to print parts. It identifies the potential hazards within an AM facility, which includes environmental conditions. It does not provide specific reference to acceptable ranges for material storage within a facility. The effect of environmental conditions on AM materials can be dependent on a number of factors, which can vary by facility. UL 3400 provides guidance based on the requirements and conditions of the facility being evaluated. ASTM F42.06 is looking at	High	Green	ASTM F42/ISO TC 261, NIST, SAE, UL, Powder Manufacturer s/Suppliers

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					environmental conditions for storage via work item ASTM WK59813, New Guide for Hazard Risk Ranking and Safety Defense . SAE AMS7003, Laser Powder Bed Fusion Process , contains requirements for feedstock powder handling and storage plans.			
47.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Feedstock	Gap PC10: Re-use of Material that Has Not Been Processed. There is a lack of industry guidance on the re-use of material that has <u>not</u> been processed.	Yes	Develop a standard for the re-use of material that was not processed but is already within the system (e.g., for inkjet it can be in the plumbing, the reservoirs, the printing heads, etc.). Update: None provided	Medium	Unknown	ISO/ASTM
48.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Feedstock	Gap PC11: Re-use of Material that Has Been Processed. There is a lack of industry guidance on the re-use of material that was already processed.	Yes	Develop a standard for re-use of material that was already processed and cannot be reused as precursor material. For inkjet, there are two concerns: Material that was jetted but not polymerized and material that was polymerized to some extent (waste from each processed layer or the actual support material). Example: non-polymerized material that was jetted can be reused as material to fill bulky areas of the model (by filtering, re-jetting, and polymerizing). Update: None provided	Low	Unknown	ASTM
49.	2.2.2.8	Process Control: Precursor Material Flow Monitoring: Directed Energy Deposition (powder)	Gap PC12: Precursor Material Flow Monitoring. There is no known standard for defining: <ul style="list-style-type: none"> • Method of DED process powder flow monitoring • Location of monitoring • Accuracy of flow monitoring • Standardized calibration process of flow 	Yes	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. Update: None provided	Medium	Unknown	NIST, ISO/ASTM
50.	2.2.2.8	Process Control: Precursor Material Flow Monitoring: Inkjet (Material Jetting)	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.	Yes	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: <ul style="list-style-type: none"> • 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 	Low	Unknown	NIST, OEMs, ASTM, IEEE-ISTO PWG

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					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. Update: None provided			
51.	2.2.2.9	Process Control: Environmental Health and Safety: Protection of Machine Operators	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. Typical hazards to be addressed include: guarding from moving parts that are not protected from contact; chemical handling (liquids, powders, wires); 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). See Gaps P5 and P6 in section 2.2.3.6 related to health and safety, specifically to toxic gases/vapors from polymers.	Yes	Recommend creating a standard addressing EHS issues relative to additive machines (power, laser, handling, air quality, etc.). Physical measurement of operator exposure to AM materials is one of the most critical needs and can be leveraged from existing industry standards. As noted in the text, research is underway. Update: UL has published UL 3400, 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. ASTM WK59813, New Guide for Hazard Risk Ranking and Safety Defense , is being developed to cover risks associated with different types of AM technologies and the recommended PPE and safety measures. ISO/TC 261 has a Working Group on <i>Environment, health and safety</i> (ISO/TC 261/WG 6), and two Joint Groups with ASTM F42 on AM: <i>EH&S for 3D printers</i> (ISO/TC 261/JG 68) and <i>EH&S for use of metallic materials</i> (ISO/TC 261/JG 69).	High	Green	ASTM F42/ISO TC 261, UL, ASSP, B11, LIA (Z136), ISO/TC 262
52.	2.2.2.10	Process Control: Configuration Management: Cybersecurity	Gap PC15: Configuration Management: Cybersecurity. Best practices for maintaining and controlling the programming environment for additive processes are needed to ensure repeatable product quality.	Yes	Develop best practices to protect digital files used in the AM process. See also Gap M7 on cybersecurity for maintenance. Update: None provided	Medium	Unknown	America Makes, NIST, UL, IEEE-ISTO PWG
53.	2.2.2.11	Process Control: In-Process Monitoring	Gap PC16: In-Process Monitoring. No published standards have been identified that address 1) the conversion of in-process monitoring data into an accurate 3D file representing the part manufactured, or 2) the use of in-process monitoring data to self-monitor and self-calibrate processing equipment. 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. A standard guide is being developed in ASTM E07 (WK62181) that covers conversion of in-process monitoring data into an accurate 3D file representing the part manufactured, based on real-time	Yes. Seamless incorporation of sensor-based monitoring techniques into the build without interfering with the build is nontrivial. While commercial based systems have been developed (for example, visible-spectrum layer-wise imaging; co-axial melt pool monitoring (visible or near-infrared); infrared, off-axis thermography; single-point, and off-axis pyrometry and/or photodetectors), other techniques (for example, spectroscopic measurements of plume; high speed visible-spectrum imaging (stationary view); single-point surface profilometry; and in-situ laser	Issue standards on in-process monitoring of 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, density, hot spots, defect state). See also Gap D22 on the use of physics-based models and simulation tools (analytics). Update: ASTM E7.10 is developing a draft guide WK62181 on in-process monitoring covering commercial based systems (visible-spectrum layer-wise imaging; co-axial melt pool monitoring (visible or near-infrared); infrared, off-axis thermography; single-point, off-axis pyrometry and/or photodetectors). Potentially, other techniques that	Medium, given the relatively low TRL state of the art	Yellow	ASTM E07.10

Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization	
		measurement of part dimensions, surface finish, density, hot spots, or defect state during the build. Ideally, the information gathered during in-process monitoring is used to evaluate part acceptance, as a go/no-go before expensive post-processing operations are performed, and/or to guide NDE performed on the part after build.	ultrasonic or AE monitoring) are lower TRL and warrant additional R&D.	show promise will be included (spectroscopic measurements of plume; high speed visible-spectrum imaging (stationary view); single-point surface profilometry; and in-situ laser ultrasonic or AE monitoring). The goal of WK62181 is to obtain a layer-by-layer (3D) file or quality record showing the as-built part is defect-free or contains no critical flaws, or exhibits an in-family (nominal) response when interrogated during the build. WK62181 does not address control of equipment functions such as feedstock supply, process conditions, or process parameters (no known gap), or physics-based models or simulation tools used in prognostics or diagnostics (see Gap D22).				
Process and Materials – Post-processing								
54.	2.2.3.1	Post-processing: Introduction	Gap P1. Post-processing Qualification and Production Builds. No known standards have been issued that require consistent post-processing to be applied for qualification and production builds.	Yes	Guideline standards should be issued that require consistent post-processing for the various AM processes to be applied for qualification and production builds. These standards should be process and material specific and should seek to define minimum best practices for qualification and production builds, along with reporting requirements. Update: For metals, AWS D20.1 is in development and SAE AMS7000 was published in June 2018. For polymers, ASTM F42/ISO TC 261 JG 55 is in development for material extrusion.	Medium	Green	AWS D20, ASTM F42/ISO TC 261 JG 55, SAE
55.	2.2.3.2	Post-processing: Heat Treatment (Metals, Polymers): Metals	Gap P2: Heat Treatment (HT)-Metals. The existing and in-development ASTM 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. In this example, both processes are considered to be the same regarding HT requirements, when in reality PBF-EB is performed at much higher temperature and may not require residual stress relief and produce a more uniform microstructure. Heat treatment requirements for metals made with non-powder processes such as directed energy deposition using wire feedstock, sheet lamination, etc., are currently not addressed in any standards except for titanium-6Al-4V via DED. There are currently no standards on heat treatments designed to reduce anisotropy in properties. In cases where AM materials	Yes. R&D is needed to determine the optimized heat treatments for AM materials as a function of materials and process.	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 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. Update: SAE AMS7000, 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 , states that several thermal processing steps (stress relief and solution annealing) need to be performed in accordance with SAE AMS2774E, Heat Treatment, Wrought Nickel Alloy and Cobalt Alloy Parts. ASTM F3301-18, Standard for Additive Manufacturing – Post Processing Methods –	Medium	Green	R&D: universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE AMS-AM.

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
			requires HIP processing, the process may be modified to meet HT requirements as well, negating the need for additional HT standards.		Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion (formerly WK58233) addresses this.			
56.	2.2.3.2	Post-processing: Heat Treatment (Metals, Polymers): Polymers	NEW 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. There are currently no 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.	Yes. 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.	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.	Low	New	R&D: NIST, universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE AMS-AM.
57.	2.2.3.3	Post-processing: Hot Isostatic Pressing (HIP) (Metals)	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. 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.	Yes	Develop material specific standards based on R&D defined HIP parameters for AM with acceptance criteria for internal discontinuities. Some examples include the following: <ul style="list-style-type: none"> • 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 	Medium	Green	R&D: various entities. Standards: ASTM F42, SAE AMS-AM, possibly SAE AMEC

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					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 AMS7000 was published in June 2018 and SAE AMS AMEC is working on a HIP spec.			
58.	2.2.3.4	Post-processing: Surface Finish (Surface Texture) (Metals, Polymers)	Gap P4: 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. <ul style="list-style-type: none"> • ANSI/ASME Y14.36M-1996 (R2008), 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 micro-machining 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. 	Yes <ul style="list-style-type: none"> • 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) • Investigation of mechanical techniques such as shot peening or media blasting and their effect on fatigue life for AM materials 	Verify if there are certain measurement methods more appropriate to AM-unique features than a stylus approach such as laser or white light 3D scanning. If so, they should be reviewed for their use on AM materials and appropriate standards written. <ul style="list-style-type: none"> • 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. Update: In terms of R&D for metals, NIST is currently investigating several research topics related to surface texture of parts produced via laser powder bed fusion. Current research is focused on process-structure relationships and the identification of complex structures that result from the AM process in anticipation that better identification and definition of as-built surfaces will lead to stronger functional correlations for AM parts. To this end, current topic areas include: investigation of surface texture parameters beyond Ra (including both areal and profile parameters) to better define AM parts, variability of as-built surface texture (i.e., methods for describing changes in the as-built surface texture as position and orientation within the build chamber change), and use of XCT for determining surface texture.	Medium	Green for R&D (metals). Unknown for Standards (metals and polymers).	ISO/ASTM; ASME (B46 new project team 53 on surface finish), IEEE-ISTO PWG, NIST
59.	2.2.3.6	Post-processing: Post-curing Methods (Polymers)	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.	No	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.	Low	Not Started, or Unknown	ASTM D20, ISO/TC 261/ASTM F42

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					Update: None provided			
60.	2.2.3.6	Post-processing: Post-curing Methods (Polymers)	Gap P6: Guidelines for Post-curing AM Plastics to Address Outgassing and Offgassing. Guidelines for evaluating the outgassing and offgassing properties and the effects of post-polymerization treatments have not been evaluated, specifically for AM materials. The voids and entrapments that can form in this case warrant some method of evaluating AM plastics over traditional methods.	Yes, R&D may be needed to look at environmental conditions and health and safety aspects. Outgassing (thermal vacuum stability) and offgassing (toxicity) 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.	Extend existing methods with AM-specific recommendations. Update: None provided	Low	Not Started, or Unknown	ASTM E21.05, ASTM D20, ISO/TC 138, ISO/TC 261/ASTM F42
Process and Materials - Finished Material Properties								
61.	2.2.4.2	Finished Material Properties: Material Properties	Gap FMP1: Material Properties. Many machine manufacturers offer general values for parts made from select materials in their machines. However, these values are not statistically validated and do not have the pedigree required for material design. Standards for thermal properties and minimum mechanical properties that also contain qualification procedures cannot currently be produced for AM materials, given the current state of knowledge, for the reasons stated above. Testing standards modified for use with AM parts that are designed/built to be inhomogeneous are also not available at this time.	Yes	Develop standards that identify the means to establish minimum mechanical properties (i.e., AM procedure qualification requirements) for metals and polymers made by a given AM system using a given set of AM parameters for a given AM build design. Developing these standards will require generating data that currently doesn't exist or is not in the public arena. Qualification requirements to establish minimum mechanical properties for AM parts, both homogeneous and deliberately inhomogeneous, need to be developed. Update: Work in progress is noted in the text.	High (Metals, Polymers); Low (Ceramics)	Green	ASTM F42/ISO TC 261, SAE AMS-AM, AWS D20, CMH-17, MMPDS, NIST
62.	2.2.4.4	Finished Material Properties: Biocompatibility & Cleanliness of Medical Devices: Cleanliness of Medical AM Parts	Gap FMP3: Cleanliness of 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. For patient-contacting (both direct and indirect) devices this cleaning must allow the device to pass tests for biological reactivity such as cytotoxicity and inflammation as described in ISO 10993. They should also ensure that AM materials such as powder are removed before use. Residues left on the parts may include but are not limited to cooling fluids or AM materials (powder or uncured monomer), that may be stuck within small geometric features or lattice structures. There are no standardized protocols or acceptance criteria to reproducibly measure and evaluate the cleanliness of a part with relevant, risk-based acceptance criteria.	Yes. R&D is needed to establish standards which discern clean from uncleaned parts; specifically, to reliably distinguish unsintered, unmelted, and uncured material from the intended part.	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 F04 already has work in progress. Update: As noted, ASTM F04.15 is working on WK53082 and WK60265.	High	Green	AAMI, ASTM F04, ASTM F42/ISO TC 261, ISO, ISO/TC 150, ISO/TC 194

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
63.	2.2.4.6	Finished Material Properties: Design Allowables	Gap FMP4: Design Allowables. Current standards and underlying infrastructure/technology are not mature enough to support the development of design allowables. For metallic additively manufactured material, a guideline was published by the MMPDS Coordination Committee describing an exploratory study for developing a metallic design allowable entitled “11-40. Guidelines for Emerging Materials and Technologies.” This guideline includes potential procedures to publish design allowables in a handbook and illuminates the gaps that would need to be addressed before AM could be included. For polymer based additively manufactured materials, an FAA sponsored research program is currently developing statistical procedures for allowables that will eventually be submitted to CMH-17 for consideration to be published in a new volume.	Yes. Recommended R&D required to fill this gap includes the generation of a set of initial seed data and subsequent statistical analyses. The initial data may be developed via round robin testing and procedures to capture the multiple sources of variability inherent in AM materials and processes. These data should result from programs through public-private partnerships or government laboratories to ensure the sharing of information. Separate test programs must be developed for different material types as the distributions may not be the same across all materials (i.e., metallic, polymer, etc.). The generation of data and subsequent analyses will help define the minimum requirements and statistical methods necessary for additive materials.	<p>Multiple developments must take place prior to generation and acceptance of design allowables for additive materials.</p> <p>1. Material specifications: SDOs involved in developing and publishing material specifications should continue their efforts to adequately capture the relevant material parameters and minimum mechanical properties required for a specification. These specifications can be used in the future to support testing that will lead to the level of data needed to support design allowable basis values. Currently, the SAE AMS-AM Committee is actively developing specifications for lot acceptance of metallic and polymer additive materials. ASTM F42.05 may also have interest.</p> <p>2. Data requirements and statistical analyses: Established organizations, such as MMPDS and CMH-17, should be involved in establishing the methodology required for deriving the allowables through a statistical process that takes into account the variability and parameters associated with additively manufactured materials. The MMPDS General Coordinating Committee, CMH-17 Executive Group, and/or other steering groups of organizations familiar with curating design allowable databases should develop guidelines on minimum data requirements and statistical processes. Although the key material/process parameters affecting allowables and in some cases the required test methods will differ, it is recommended to start with the currently available statistical analysis methods for metals and polymer composites as a baseline.</p> <p>3. Test methods: Test standards organizations, such as ASTM/ISO, should provide recommendations on established test methods with special considerations for AM materials. If necessary, new coupon or component test methods should be developed.</p> <p>Update: At this time, no publicly available methodology for design allowables of additively manufactured materials has been identified. However, the three sections listed above (Material Specifications, Data Requirements and Statistical Analyses, and Test Methods) are all being addressed throughout multiple SDOs and other programs. Material specifications are being generated by multiple SDOs at this time. SAE has a Data Management Sub-Committee currently defining guidelines to generate specifications minimum values for both metals and polymers. In addition to</p>	High (Material Specifications); Medium (Data Requirements and Statistical Analyses); Medium (Test Methods)	Green	ASTM F42/ISO TC 261, SAE AMS-AM, AWS, NASA, ASME BPVC, MMPDS, CMH-17, NIST

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					the work in progress noted in the text and gap statement, ASME's BPVC committee is looking at this. Regarding characterization methods for metals, the MMPDS coordinating committee has concerns that existing data requirements and statistical analysis methods are not sufficient. Their primary concern is the level of maturity of standards and specifications needed to ensure consistent properties. Polymer AM material test methods have similar issues; methods can either be adopted from plastic or polymer matrix composites methods, both of which may need modification.			
64.	2.2.4.7	Finished Material Properties: Microstructure	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.	Yes. NIST should help develop Calphad databases suitable for non-equilibrium solidification.	ASTM should develop a standard for characterization and acceptance criteria of AM microstructures (both identification and quantification). Update: Nothing started in terms of ASTM work.	Medium	Not Started, or Unknown	NIST, ASTM
Qualification & Certification (not covered elsewhere)								
65.	2.3.1	Qualification & Certification: Introduction: Q&C Terminology	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.	No	Compare how the terms qualification, certification, verification and validation are used by industry sector. Update as needed existing quality management system standards and other terminology standards to harmonize definitions and encourage consistent use of terms across industry sectors with respect to AM. Update: In discussions between the AMSC advisory group and the SDOs, there was a general sense that relevant AM terminology could be captured in the ISO/ASTM 52900 document to the extent possible. However, that document does not currently address the disparities on Q&C terminology discussed here. As a general matter, ASME has been coordinating AM terminology activity with ASTM. SAE has noted the challenges of coming to consensus on terminology and has been using the ASTM definitions when they exist but coming up with new terms for aerospace applications when a term is not defined. ASTM has offered to convene a virtual meeting with the SDOs and technical experts to discuss terminology. America Makes could help to promote such collaboration. This would be a step forward though it may not solve the issue of getting different sectors to adopt the same terminology.	High	Green	ASTM F42/ISO TC 261, AAMI, ASME, SAE
66.	2.3.3.1	Qualification & Certification: Aerospace Industry: Parts/Products	Gap QC2: AM Part 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. A common classification system for AM parts by	No	A technical report describing existing classification systems for AM parts would be useful. It could include the recommended minimum process and part qualification requirements commensurate with part risk for each classification level.	High	Green	ASTM F42/ISO TC 261, AWS, DoD, FAA, NASA, SAE

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
			industry sector is needed to provide consistent evaluation criteria for AM part risk. This should include a definition of criticality levels. Consistent risk criteria provide the basis for consistent expectations and levels of qualification rigor. Examples of classification systems can be found in NASA's MSFC-STD-3716, Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals , and the draft AWS D20.1 standard, which utilizes the part classification system identified in AWS D17.1/D17.1M:2017-AMD1, Specification for Fusion Welding of Aerospace Applications . Any industry requiring rigorous AM part qualification and system certification would benefit from a common part classification system.		Update: ASTM F42.01 will explore developing this technical report. This will require coordination between the SDOs and relevant federal agencies. It may also be application-specific (e.g., spaceflight, military, etc.) This is more a harmonization issue. Procurement and level of testing required need to be addressed. The primary beneficiaries will be industry.			
67.	2.3.3.2	Qualification & Certification: Defense Industry: Harmonizing Q&C Terminology for Process Parameters	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.	No	Develop standardized terminology for process parameters for use across all AM equipment. Potentially, incorporate these into ISO/ASTM 52900:2015, Additive manufacturing - General principles - Terminology . See also Gap PC5 on parameter control. Update: As noted in the text.	Medium	Green	ASTM F42/ISO TC 261 JG 51, AWS D20, SAE AMS-AM, IEEE-ISTO PWG
68.	2.3.3.2	Qualification & Certification: Defense Industry: Process Approval for DoD-procured Parts	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.	Yes	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. Update: DoD is holding AM business model workshops, the agenda for which includes developing an AM contracting guide for the Navy/DoD. None provided vis a vis work by the SDOs.	Medium	Yellow	ASME, ASTM F42/ISO TC 261, DoD, Industry, SAE, Service SYSCOMS
69.	2.3.3.2	Qualification & Certification: Defense Industry: Machine Operator	Gap QC5: Machine Operator Training and Qualification. There is a need for standards or guidelines outlining AM training requirements.	No	Recommendation: Develop AM operator training and qualification standards or guidelines. Training should cover the various AM materials and processes available in the market and be performance based to ensure consistent AM part quality. Develop additional standards for artisanal levels of competency and experience, delineating	Low	Green	NASA, SAE, AWS, OEMs, UL, ASTM F42/ISO TC 261, AAMI

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
		Training and Qualification			an individual's expertise in the field or subsets of the AM field. Update: As noted in the text.			
70.	2.3.3.3	Qualification & Certification: Medical Industry: Data Output from Imaging Sources	Gap QC6: Importing Ultrasound Data. The DICOM standard needs to be more widely promoted and may need to be revised to enable data to be imported from any ultrasound equipment similar to the CT scan or MRI data. There is a concern that the data coming from the ultrasound may not be providing adequately detailed images but this cannot be assessed until the interoperability concerns are eliminated.	Yes	Promote and potentially revise the DICOM standard for importing data from ultrasound equipment. Use cases are obstetrics and pre-natal diagnosis. CP 1071 correction proposals should be approved. This relates to codes for cardiac ultrasound data target sites. Update: ISO/ASTM NP 52916, Additive manufacturing -- Data formats -- Standard specification for optimized medical image data , is being developed by ASTM F42 and ISO/TC 261 as JG 70.	Medium	Green	DICOM, IEEE, ASTM F42/ISO TC 261 JG 70
71.	2.3.3.3	Qualification & Certification: Medical Industry: Data Acquisition for 3D Modeling: Protocols for Image Accuracy	Gap QC7: Protocols for Image Accuracy. 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.	Yes. More R&D is needed on data for image accuracy before a standard can be developed.	Develop standard protocols for acquiring data for 3D modeling to ensure image accuracy. 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. Update: ISO/ASTM NP 52916, Additive manufacturing -- Data formats -- Standard specification for optimized medical image data , is being developed by ASTM F42 and ISO/TC 261 as JG 70.	Medium	Green	DICOM, IEEE, ASME, ASTM F42/ISO TC 261, RSNA (Radiological Society of North America)
72.	2.3.3.3	Qualification & Certification: Medical Industry: Phantoms	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).	Yes	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. Update: The RSNA 3DP Special Interest Group (SIG) is developing best practices for phantoms.	Medium	Green	Biomedical Engineering Society, NEMA/MITA, ISO, ASTM, RSNA
73.	2.3.3.3	Qualification & Certification: Medical Industry: Personnel Training for Image Data Set Processing	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.	No	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. Update: The SME AM3DP medical WG has developed competency models and is working on a detailed body of knowledge (BOK) to help recruit skilled workers to the profession, along with training, curriculum development, and a certification program. ² The FDA is involved with	High	Green	SME, RSNA, ASTM F42/ISO TC 261

² <http://sme.org/am3dpjobmodel/>

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
					SME and RSNA. There is no separate interest at the federal level; certifications happen at the state level.			
74.	2.3.3.3	Qualification & Certification: Medical Industry: Quality, Verification, and Validation of Medical Product 3D Models	Gap QC10: Verification of 3D Model. There are currently no standards for the final verification of a 3D model before it is approved for AM for the intended purpose (e.g., surgical planning vs. implantation; cranial replacement piece; cutting guides which have a low tolerance for anatomical discrepancy).	Yes, in terms of tolerances	Develop standards for verification of the 3D model against the initial data. Ideally, they should identify efficient, automatable methods for identifying discrepancies. Update: ASTM F42/ISO 261 are looking at image quality as part of the model verification. ASME V&V 40 addresses verification and validation in computational modeling of medical devices. This issue requires cooperation between clinical societies, the FDA and industry. It may also be a general, not only medical, concern.	High	Green	ASTM F42/ISO TC 261, NEMA/MITA, AAMI, ASME, NIST, ACR
75.	2.3.3.3	Qualification & Certification: Medical Industry: Resorbable Materials	Gap QC12: Resorbable Materials. Testing of degradation of the new resorbable metals/polymers in living tissues cannot be adequately achieved using existing standards.	Yes, in terms of rate and amount of degradation for new polymers and resorbable metals.	Develop guidance on how to test the degradation of new resorbable metals/polymers to support material selection for AM. Update: None provided	Medium	Green	ASTM F4, ISO, ISO/TC 150, ISO/TC 194
76.	2.3.3.3	Qualification & Certification: Medical Industry: Material Control Data and Procedures	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.	Yes	A standard or specification describing a data set for material pedigree, recommended testing, and handling procedures would simplify evaluation of material suitability. Update: None provided	Low	Unknown	Material providers, ASTM
77.	2.3.3.3	Qualification & Certification: Medical Industry: Patient Imaging Files and Segmentation	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. There is no group or entity that oversees segmentation within a clinical setting. RSNA has a special interest group that may set standards for segmentation and/or 3D printing. DICOM WG 17 also is looking at this.	No	There is a need to create an augmented file specification for 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. Update: DICOM is addressing most of this. They will have public comment by the end of 2018, with a target for the first update being made by the second quarter of 2019.	Medium	Green	RSNA, DICOM, ASTM
78.	2.3.3.3	Qualification & Certification: Medical Industry: Validation of Sterilization Processes	Gap QC15: Sterilization of Anatomical Models. Anatomical models are frequently made in a healthcare setting and their final use may differ from the initial intended use. For instance, a surgeon may determine that a model patient education may be useful for reference in the operating room during the surgical procedure. If the models enter the sterile field they would require sterilization and the effects of sterilization on the	No. Procedures and protocols for determining appropriate materials, sterilization cycles, and validation tests are already available but may not be implemented in healthcare settings.	Develop guides and best practices to help identify critical parameters and apply existing standards in a clinical setting. Update: The SME medical group is working on a biocompatibility worksheet for use with both models and surgical guides. This will not be a standard, but a guide of considerations.	Low	Unknown	R&D: OEMs. Guidance: AAMI, AOAC International, ASTM, ISO, PDA, USP, RSNA 3DP SIG.

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
			geometric fidelity of the model should be assessed. If they are to come into contact with the patient the effects of sterilization on the materials are especially important. While many standards and industry best practices exist, the healthcare facilities may not have relevant experience.					
79.	2.3.3.3	Qualification & Certification: Medical Industry: Sterilization of Tissue Engineered Products	NEW Gap QC16: Sterilization of Tissue Engineered Products. 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 can help decrease the risks of contamination with best practices but not provide defined measures to ensure the sterility or assess contamination in a tissue engineered product.	Maybe. 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 tissue engineered products.	Develop and validate standard methods of sterilizing and verifying the sterility of tissue engineered products, especially those that can be applied in healthcare settings.	Medium	New	R&D: OEMs, FDA, BioFabUSA. Standards: AAMI, ISO, ASTM, AATB.
Nondestructive Evaluation (NDE)								
80.	2.4.2	Nondestructive Evaluation: Common Defects Catalog Using a Common Language for AM Fabricated Parts: Terminology	Gap NDE1: Terminology for the Identification of AM Flaws Detectable by NDE Methods. An industry driven standard needs to be developed, with input from experts in metallurgy, NDE, and additive manufacturing fabrication, to identify flaws or flaw concentrations with the potential to jeopardize an AM object's intended use. Many flaws have been identified but more effort is needed to agree on flaws terminology, providing appropriate names and descriptions.	No	Develop standardized terminology to identify and describe flaws, and typical locations in a build. Update: As noted in the text.	High	Green	ASTM E07, ASTM F42/ISO TC 261, SAE AMS K, ASME BPVC, AWS D20, NIST
81.	2.4.2	Nondestructive Evaluation: Common Defects Catalog Using a Common Language for AM Fabricated Parts: Defect Catalog and Equipment Standardization	Gap NDE2: Standard for the Design and Manufacture of Artifacts or Phantoms Appropriate for Demonstrating NDE Capability. No published standards exist for the design or manufacture of artifacts or phantoms applicable to calibrating NDE equipment or demonstrating detection of naturally occurring flaws (lack of fusion, porosity, etc.), or intentionally added features (watermarks, embedded geometrical features, etc.). Current standards under development, ISO/ASTM CD 52905 JG59 and ASTM WK47031, are partially addressing this with seeded defects and demonstration of NDT detectability. This standard should identify the naturally occurring flaws and intentional features. This standard should also include recommendations regarding the use of existing subtractive machined calibration standards or AM representative artifacts or phantoms.	No. This may not need R&D but it will require obtaining the knowledge necessary to state requirements and present supporting evidence, much like a round robin activity.	Complete work on JG59, JG60 and ASTM WK47031. Update: As noted in the text.	Medium	Green	ASTM F42/ISO TC 261

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
82.	2.4.3	Nondestructive Evaluation: Test Methods or Best Practice Guides for NDE of AM Parts	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 provide an introduction to nondestructive testing and inspection requirements.	Yes. Round robin testing is underway on ASTM WK47031 and ISO/ASTM CD 52905. A future need will be a precision and bias statement to generate standard test methods to accept/reject AM parts and in procurement of AM parts.	Complete work on ASTM WK47031, New Guide for Nondestructive Testing of Additive Manufactured Metal Parts Used in Aerospace Applications and ISO/ASTM CD 52905, Additive Manufacturing — Non-Destructive Testing and Evaluation — Standard Guideline for Defect Detection in Metallic Parts , proceeding as ISO/TC 261/JG 59. Update: ASTM WK47031 and ISO/TC 261/JG 59 are in development. ASME is also looking at NDE vis a vis its boiler and pressure vessel code.	High	Green	ASTM E07, ASTM F42/ISO TC 261, ASME, NIST
83.	2.4.4	Nondestructive Evaluation: Dimensional Metrology of Internal Features	Gap NDE4: Dimensional Metrology of Internal Features. The utility of existing and draft CT standards are needed for the dimensional measurement of AM internal features.	Yes	ASTM E07 should address the applicability of current and draft CT standards (E1570, E1695, WK61161, and WK61974) for measurement of internal features 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 D26, Measurement of AM Features/Verifying the designs of features such as lattices, etc. Update: As noted in the text.	Medium	Green	ASTM
84.	2.4.5	Nondestructive Evaluation: Data Fusion	Gap NDE5: Data Fusion. 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.	No	The following are needed to address the gap: <ul style="list-style-type: none"> • Specific industry standards for data fusion in AM NDT techniques • Expert education, training, and certification for AM data fusion in NDT Update: None provided	Medium	Unknown	ASTM
85.	2.4.6	Nondestructive Evaluation: NDE of Polymers and Other Non-Metallic Materials	NEW Gap NDE6: NDE of Polymers and Other Non-Metallic Materials. No published or in development standards or specifications have been identified for NDE of polymers and other non-metallic materials.	Yes. Research who uses AM Fused Filaments or pellets with PAI/Torlon and/or carbon fiber reinforced filaments with a high degree of fiber loading to see what they are anticipating for testing requirements for NDE for strength or structural qualities.	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 provide an introduction to nondestructive testing and inspection requirements for structural or load bearing polymers and other non-metallic materials. Use ASTM E2533-17e1 as a guideline when applicable.	Low	New	ASTM F42/ISO TC 261, ASTM E07, ASTM D20
86.	2.4.7	Nondestructive Evaluation: NDE of Counterfeit AM Parts	NEW Gap NDE7: NDE of Counterfeit AM Parts. There are no published or in development NDE standards for methods used to verify anti-counterfeiting methods.	Not at this time. Future R&D may be needed if an anti-counterfeiting method is developed which cannot be verified by existing NDE methods or standards.	Develop NDE methods and standards for anti-counterfeiting that are not addressed by existing methods or standards.	Low	New	ASTM F42/ISO TC 261, ASTM E07, SAE AMS-AM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
87.	2.4.8	Nondestructive Evaluation: NDE Acceptance Criteria for Fracture Critical AM Parts	NEW Gap NDE8: NDE Acceptance Criteria for Fracture Critical AM Parts. There is a need for an industry standard that establishes NDE acceptance classes for fracture critical AM parts.	Yes. Well-characterized samples should be fabricated with controlled loadings of technologically important AM defects in order to conduct effect-of-defect studies.	Develop an industry standard that establishes different degrees of flaw concentrations for quality acceptance. Fabricate effect-of-defect samples with the appropriate level of fidelity, i.e., sufficient similarity between the defect state in sacrificial samples (for example, ASTM E8 compliant dogbones) with natural flaws in actual production parts.	Medium	New	ASTM F42 / ISO TC 261 JG 59, ASTM E07, ASTM E08 on Fracture and Fatigue
Maintenance and Repair								
88.	2.5.2	Maintenance and Repair: Maintenance and Sustainment of Machines	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.	No	Update SAE JA1012 , a guide to provide analytics for AM trade-offs in RCM and CBM*. Update: SAE G-11M, Maintainability, Supportability and Logistics Committee, will consider inclusion of analytics for AM trade-offs in the next update of JA1012_201108 .	Medium	Not Started	SAE, ISO, ASTM
89.	2.5.3	Maintenance and Repair: Standard Repair Procedures	NEW 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.	No	Ensure that laser based additive repair processes are included in AWS D20.1.	Low	New	AWS, SAE AMS-AM
90.	2.5.3	Maintenance and Repair: Standard Repair Procedures	Gap M3: AM Level of Repair Analysis. Standards for AM LORA are needed. In performing a repair versus discard analysis, the use of AM can change the LORA decision due to shifts in factors relating to logistics delay time, spares availability, cost of spares, etc. Trade space would address reduction of time and increase in skill set (e.g., for qualified printer operators).	No	Update SAE AS1390, Level of Repair Analysis (LORA) , to include impact of AM on trade space of repairs. Update: SAE's LCLS (Life Cycle Logistics Supportability) Committee plans to include AM in the upcoming revision of AS1390. Although the LCLS Committee has not opened a Work in Progress for AS1390, a team is working on revisions and has agreed to include AM. The SAE G-11M Committee is in the process of reorganizing but the chair has the AMSC requests on his radar. In addition, AMS2680C is currently under revision.	Medium	Green	SAE LCLS, SAE AMS-B, ISO, ASTM
91.	2.5.4	Maintenance and Repair: Standard Technical Inspection Processes	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.	No	Update SAE JA1011/1012 to include an inspection process for additive manufacturing repairs. 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_200908 and JA1012_201108 .	Medium	Not Started	SAE, ISO/ASTM
92.	2.5.5	Maintenance and Repair: Model-Based Inspection	Gap M5: Model-Based Inspection. Standard practices for model-based inspection methods using AM are needed for repair assessments and scheduling.	No	Develop standard practices for assessing level of damage for end-use parts. Update: No updated provided.	Medium	Not Started, or Unknown	ASME, ISO/ASTM, Dimensional Metrology Standards Consortium
93.	2.5.6	Maintenance and Repair: Standards for Tracking	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.).	No	• Develop a standard for tracking maintenance operations to ensure a printer is ready when needed. See also Gap PC3 on machine health monitoring.	Medium	Unknown	AWS, ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Status of Progress	Organization
		Maintenance Operations			<ul style="list-style-type: none"> Develop a standard to address emergency repair/limited life parts for urgent cases in the field. Update: None provided			
94.	2.5.7	Maintenance and Repair: Cybersecurity for Maintenance	Gap M7: Cybersecurity for Maintenance. In support of on-site repairs, guidance is needed that addresses cybersecurity considerations for maintenance and repair of parts that have 3D models ready to print. Secure storage in a database should ensure that only authorized personnel can download files and print parts.	Yes	Guidance is needed to ensure the integrity and safe storage of AM files as maintenance and repair operations may take place in an uncontrolled environment. See also gap PC15 on configuration management: cybersecurity. Update: None provided	Medium	Not Started, or Unknown	NIST, NEMA/MITA, NDIA JWG, ASTM, IEEE-ISTO PWG
95.	2.5.8	Maintenance and Repair: Surface Preparation for Additive Repair	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.	Yes	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. Update: None provided	Medium	Not Started, or Unknown	ASTM, SAE, ISO

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1. Introduction

Additive Manufacturing (AM), sometimes referred to as three-dimensional (3D) 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 the past several years, particularly in the aerospace, defense, and medical sectors 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. In the medical field, AM technologies are being used to create new, patient-specific, life-saving, medical devices. The industrial sector, like medical, is also driven by AM-enabled designs for unique performance 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 Situational Assessment for AM

The AM industry began with the patenting and commercialization of Stereolithography (SLA) by 3D Systems in 1986. In the early 1990s, Selective Laser Sintering (SLS) and Fused Deposition Modeling (FDM) were patented and commercialized by DTM Corporation and Stratasys, Inc., respectively. Applications for polymer AM materials and processes began with rapid prototyping and gradually transitioned to include end use parts as improvements to materials, processes, and machines occurred.

Over time, 3DP technologies began transitioning from polymers to metals. In 2009, the ASTM committee F42 was formed. In 2012, a public-private partnership came into existence as [America Makes](#). With these developments, 3DP has been branded “additive manufacturing” and become known by all. Call it an overnight success, thirty years in the making.

Established as part of an Obama Administration initiative to promote advanced manufacturing and bring high tech jobs to the “rust belt,” America Makes is the first pilot institute of [Manufacturing USA](#), previously known as the National Network for Manufacturing Innovation. Headquartered in Youngstown, Ohio, America Makes is today the nation’s leading collaborative partner in AM and 3DP technology research, discovery, creation, and innovation. It is managed and operated by the [National Center for Defense Manufacturing and Machining](#) (NCDMM), which delivers optimized manufacturing solutions that enhance the quality, affordability, maintainability, and rapid deployment of existing and yet-to-be developed defense systems.

According to the Wohlers Report 2018, the AM market continues to grow rapidly, with an 80% increase from 2016-17 in the number of metal AM systems sold. The number of companies that produced and sold AM systems (machines that sell for more than \$5,000) also increased from 97 in 2016 to 135 in 2017.³ Companies investing in AM technologies cut across sectors from aerospace to medical, athletic footwear to automotive.⁴

1.2 Roadmap Background and Objectives

In the 1st quarter of 2016, America Makes commissioned the [American National Standards Institute](#) (ANSI) to lead a program to identify which AM standards and specifications have been published, or are being drafted, and where standards and specifications are needed. Thus, the [America Makes & ANSI Additive Manufacturing Standardization Collaborative](#) (AMSC) was born. 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), were instrumental in the formation of this collaborative.

America Makes 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 it 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.

³ Scott, Clare, “Wohlers Report 2018 Details Overall 3D Printing Industry Growth, Major Gains in Metals,” *3DPrint.com*, dated March 27, 2018, <https://3dprint.com/208122/wohlers-report-2018/>

⁴ Huff, Ray and Wohlers, Terry, “AM Continues Rapid Ascent, Targets New Markets,” *Advanced Manufacturing Now*, dated March 30, 2018, <http://advancedmanufacturing.org/am-continues-rapid-ascent-targets-new-markets/>

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 to maintain 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.

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 which to date has been largely dependent on OEM proprietary specifications.

The roadmap can thus be viewed as a tool designed to help focus resources in terms of participation by stakeholders in the planning and development of industry-wide standards and related research and development (R&D) activities to the extent R&D needs are identified. It is assumed that those reading the document are directly affected stakeholders who have an understanding of AM technologies.

The roadmap’s focus is the industrial AM market, especially for the aerospace, defense, and medical sectors. This is largely a reflection of the subject matter expertise of those who participated in its development. That said, this document may have application to other industry sectors such as energy and industrial gas turbines, automotive, etc. For example, following the release of the initial draft roadmap for public comment, ANSI was contacted by the American Petroleum Institute (API), an ANSI accredited SDO, who expressed interest in the topic and agreed to canvass its membership and gauge their interest. Readers are encouraged to take note of gaps and recommendations that may not be specific to their industry sector.

In terms of what can be deemed out of scope, the consumer desktop 3D printing market is generally not addressed in this report.

1.3 How the Roadmap Was Developed

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

Following a phase 1 kickoff meeting on March 31, 2016, the working groups held online meetings every two weeks to make an inventory of existing standards, conduct the gap analysis, and draft the roadmap. On September 26, 2016, a second face-to-face meeting was held to review the first draft of the roadmap. In conjunction with the issuance of subsequent drafts, and review and comment periods, the working groups further refined the document and finalized it for publication. Throughout the process, the America Makes Additive Manufacturing Standards, Specs, and Schemas Advisory Group ("Advisory Group") served as a steering committee for the project.

The [*Standardization Roadmap for Additive Manufacturing, Version 1.0*](#), was published in February 2017, representing the culmination of the AMSC's work in its first year. The roadmap was promoted at industry events and the Advisory Group also met with the principal SDOs involved in the project to track their progress to implement the recommendations contained in the roadmap.

A kickoff meeting to launch phase 2 of the AMSC's work was held on September 7, 2017. As a major goal for phase 2 was to expand the discussion of standards needs for polymers and other materials besides metals, a special working group on polymers was established and did a wholesale review of the document's content. A medical working group begun in phase 1 was also formalized and continued to evaluate the document's content from the perspective of the medical community. Outreach efforts were also undertaken to engage other industry sectors such as ground vehicle/heavy equipment, energy, industrial and commercial machinery, and electronics. All of the working groups undertook to provide updates on gaps identified in phase 1 and to identify potentially overlooked gaps. The roadmap was released for public comment on April 6, 2018. Following the review of submitted comments by the working groups, the document was finalized for publication.

1.4 Roadmap Structure

A summary of major changes from the roadmap version 1.0 can be found immediately following the Executive Summary in this document. Following that is a table summarizing the gaps, recommendations, and priorities by issue as described in more detail in section 2. Chapter 3 briefly describes next steps.

Chapter 2 of the roadmap provides the context and explanation for why specific issues were considered important and subsequently assessed as part of this 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 phase 1 retain their original numbering and now include a descriptor of the status of progress since the release of version 1.0 of the roadmap. The status of progress is 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 1.0 are also summarized in a narrative update statement. New gaps for version 2.0 are identified as such, starting with the next number in sequence from version 1.0 for a particular section.

Each gap has been assessed and ranked using the criteria described in Figure 1 below as being high, medium, or low priority. In terms of taking action to address the priorities, the desired timeframes are as follows: high priority (0-2 years), medium (2-5 years), and low (5 + years).

Criteria (Make the <u>C</u>-<u>A</u>-<u>S</u>-<u>E</u> for the Priority Level)	Scoring Values
<u>C</u>riticality (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
<u>A</u>chievability (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
<u>S</u>cope (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
<u>E</u>ffect (Return on Investment) - What impact will the completed project have on the AM 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)	

Figure 1: AMSC Prioritization Matrix

This roadmap is supplemented by the [AMSC Standards Landscape](#), a table of standards that are directly or peripherally related to the issues described in the roadmap.

1.5 Overview of SDOs in the AM Space

The development of AM standards and specifications is a collaborative activity that engages a wide array of subject matter experts from the private and public sectors including industry, government, academia,

professional societies, and SDOs. Below is an overview of the work of several SDOs listed alphabetically whose scope of work directly or indirectly relates to AM standardization.

1.5.1 Association for the Advancement of Medical Instrumentation (AAMI)

The Association for the Advancement of Medical Instrumentation (AAMI) is the leading developer of standards for medical devices globally. In addition to American National Standards, AAMI publishes guidance documents (Technical Information Reports) that address medical device production and use. AAMI also administers 17 U.S. Technical Advisory Groups (TAGs) and 10 international secretariats for International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) committees or subcommittees addressing medical technology.

Over the decades AAMI has produced a large body of standards that govern aspects of the design and manufacture of medical devices (quality systems, risk management, materials testing, process control, sterilization, residual management, etc.). AAMI standards focus on enhancing the safety and efficacy of medical devices and are widely referenced or recognized by regulatory frameworks around the world.

The distinct nature of additive manufacturing and the ability to create unique or customized devices add challenges to ensuring the safety and efficacy of products. AAMI is very interested in determining what guidance might be developed for applying existing standards to additive manufacturing, as well as what new standards or controls may be necessary.

1.5.2 American Society of Mechanical Engineers (ASME)

ASME Committee Efforts to Address Additive Manufacturing

ASME Y14 Subcommittee 46 Product Definition for Additive Manufacturing

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=100749850>

Charter: To develop and standardize systems and indications to promote uniform practices for product definition for Additive Manufacturing (AM); to create a broadly accepted standard that incorporates, expands, or refines international practices and symbology to enable AM product definition data sets to be created, interpreted, and consumed on a global basis.

Document: [ASME Y14.46-2017, Product Definition for Additive Manufacturing \[Draft Standard for Trial Use\]](#)

This document addresses Product Definition Requirements that are specific to Additive Manufacturing. This standard covers definitions of terms and features unique to additive manufacturing technologies with recommendations for their uniform specification in product definition data sets and in related documents.

ASME Y14 Subcommittee 41.1 on 3D Model Data Organization Schema

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=100688394>

Document: [ASME Y14.47-201x, Model Organization Schema Practices](#)

This standard establishes a schema for organizing 3D model and other associated information within the context of a digital product definition data set for the purpose of conveying a product definition that enables a Model-Based Enterprise (MBE). This standard contains no requirements pertaining to drawing graphic sheets. The schema defines a common practice to improve design productivity and to deliver consistent data content and structure to consumers of the data. This particular schema need not be followed verbatim as long as the producer of the digital product definition data provides a map of the content of the 3D model into the schema.

ASME Y14 Subcommittee 48 on Universal Direction and Load Indicators

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=102068063>

Charter: Standardization of methods to unambiguously define and specify directions, directional requirements, loads, and loading requirements in product definition data sets.

This standard provides symbolic methods to unambiguously delineate directions, directional requirements, loads, and loading requirements in product definition data. It will define standard methods of specifying linear and non-linear directions, the direction of gravity, point loads, pressure differentials, and other types of directional and loading requirements, and the relationships of directions and loads to datum reference frames associated to products.

ASME B46 Project Team on Additive Manufacturing

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=102019836>

This document explains how to find parameters that can describe the topography of AM parts so that they can correlate with and discriminate between processing and performance parameters.

Specification of surface topographies should reflect their influence on performance and be capable of correlating with process parameters. The surfaces created by additive manufacturing are distinctly different from those created by traditional methods. What has been learned about specifying topographies for processing and performance with traditional manufacturing is of little help for recommending surface texture characterization parameters for additive manufacturing that can be valuable for product and process design.

ASME V&V Subcommittee 50, Verification and Validation of Computational Modeling for Advanced Manufacturing

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=101978604>

Charter: To provide procedures for verification, validation, and uncertainty quantification in modeling and computational simulation for advanced manufacturing.

V&V for Additive Manufacturing is a focused topic area to explore V&V issues in a context. It is on a scale that this nascent group can engage with and make progress on. There is real opportunity to potentially engage with the software industry that is creating the first AM commercial models and help define best practices based on lessons learned in prior ASME V&V efforts.

ASME New Committee on Advanced Monitoring, Diagnostic, and Prognostic Technologies for Manufacturing

ASME is in the process of establishing a new committee to address advanced monitoring, diagnostic, and prognostic technologies for manufacturing.

These guidelines would allow manufacturers to determine: 1) the most appropriate data to collect from a manufacturing operation; 2) an efficient strategy to collect the identified data; 3) the recommended approach to organize, store, and contextualize the data; 4) the ideal analyses to apply to the data; 5) the V&V of these analyses; and 6) the dissemination of these results across the manufacturing facility to promote more effective decision-making with respect to updating control and maintenance strategies.

ASME Board Pressure Technology Codes and Standards (BPTCS)/Board on Nuclear Codes and Standards (BNCS) Special Committee on Use of Additive Manufacturing for Pressure Retaining Equipment

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=101029283>

Charter: To develop a technical baseline to support development of a proposed BPTCS standard or guideline addressing the pressure integrity governing the construction of pressure retaining equipment by the additive manufacturing process. Construction, as used in this Charter, is limited to materials, design, fabrication, examination, inspection, testing and quality control.

This standard will focus on the fabrication of pressure retaining equipment using the AM process.

The initial phase in this process is to review current standards developed by SDO's (e.g. ASTM, AWS, ISO) to develop baseline material performance characteristics to ensure control of material properties during the AM fabrication process, followed by the design and fabrication of simple shapes, followed by design and fabrication of more complex shapes, and complete pressure vessels using the AM process. Testing

will be used to compare the mechanical properties of AM fabricated parts with standard fabricated parts to evaluate differences in leakage, burst strength, and fatigue life.

The final phase (phase 5) will be the development of an ASME standard or guideline on the use of additive manufacturing for the construction of pressure retaining equipment.

ASME Committee Efforts Relevant to Additive Manufacturing

ASME Y14 Subcommittee 41, Digital Product Definition Data Practices

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=C64045910>

Document: [ASME Y14.41-2012, Digital Product Definition Data Practices](#)

This standard establishes requirements and references documents applicable to the preparation and revision of digital product definition data, hereafter referred to as data sets. This standard defines exceptions and additional requirements to existing ASME standards for using product definition digital data sets or drawing graphic sheets in digital format, hereafter referred to as drawing graphic sheets.

ASME B89 Project Team 4.23, CT Measuring Machines

Document: [ASME B89.4.23-201x, X-ray Computed Tomography \(CT\) Performance Evaluation Standard](#)

This standard specifies the dimensional measurement accuracy of industrial X-ray computed tomography (CT) systems for point-to-point length measurements of homogeneous materials. Medical CT instruments are outside the scope of this standard. This standard is applicable to dimensional measurements made at the surface of the workpiece, i.e., at the workpiece material – air interface, including those of internal cavities. The evaluation of workpieces composed of multiple materials or of “density gradient” measurements, e.g., gradual density variations within the material, is outside the scope of this standard.

ASME Y14.5, Dimensioning and Tolerancing

Committee Webpage:

<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=C64041000>

Document: [ASME Y14.5-2009, Dimensioning and Tolerancing](#)

This standard establishes rules, definition, requirements, defaults and recommended practices for stating and interpreting dimensioning, tolerancing, and related requirements for use on engineering drawings, models defined in digital data files and in related documents.

Y14.5 provides essential 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.

1.5.3 ASTM International (ASTM)

ASTM International is a globally recognized leader in the development and delivery of voluntary consensus standards. Today, [over 13,000 ASTM standards](#) are used around the world to improve product quality, enhance health and safety, strengthen market access and trade, and build consumer confidence. ASTM's leadership in international standards development is driven by the contributions of its members: more than 30,000 of the world's top technical experts and business professionals representing 140 countries. Working in an open and transparent process and using ASTM's advanced IT infrastructure, ASTM members create the test methods, specifications, classifications, guides and practices that support industries and governments worldwide.

[Through more than 140 technical standards-writing committees](#), ASTM serves a broad range of industries: metals, construction, petroleum, consumer products and many more. When new industries — like nanotechnology, additive manufacturing and industrial biotechnology — look to advance the growth of cutting-edge technologies through standardization, many of them come to ASTM International. It is notable that ASTM test methods are required to have statements addressing precision and bias, statistically determined from round robin studies.

[ASTM International Committee F42 on Additive Manufacturing Technologies](#) was organized by industry in 2009. At present, the committee consists of 625+ individuals and organizations representing 27 countries. The committee is dedicated to the promotion of knowledge, stimulation of research, and implementation of technology through the development of standards for additive manufacturing technologies. The work of the committee is coordinated with other ASTM technical committees and other national and international organizations having mutual or related interests.

The work program of F42 is significant, having approved 22 standards at the time of writing this roadmap section, with an additional 17 work items in various stages of development - <https://www.astm.org/COMMIT/SUBCOMMIT/F42.htm>. All standards fall under the F42 subcommittee structure of:

[F42.01](#) Test Methods

[F42.04](#) Design

[F42.05](#) Materials and Processes

[F42.06](#) Environment, Health, and Safety

[F42.91](#) Terminology

[F42.95](#) U.S. TAG to ISO/TC 261

Additional information about ASTM F42's joint work program with ISO/TC 261 can be found at the end of this section and in section 1.5.7.

Other ASTM Technical Committees identified by the AMSC as having work relevant to AM include:

B09: ASTM International Committee B09 on Metal Powder & Metal Powder Products has jurisdiction over standards on metal powder characterization such as flow characteristics, particle size distribution,

sampling and densities. Many AM parts are made using metal powders specifically manufactured for this purpose. For a listing of the standards under the jurisdiction of B09 and its sub-committees, visit: <http://www.astm.org/COMMIT/SUBCOMMIT/B09.htm>.

E04: ASTM International Committee E04 on Metallography has jurisdiction over the development of standard methods for the preparation of specimens for, but not limited to: metallographic procedures; photomicrography; microhardness testing; grain size measurements; determining inclusion content of metals; quantitative metallography; X-ray metallography including diffraction analysis, texture and orientation determinations, residual stress measurements, and microradiography; electron metallography utilizing transmission electron microscopy, scanning electron microscopy, electron diffraction, and microprobe analysis; field ion microscopy; and ion microprobe and Auger analysis. The Committee also works with the International Center for Powder Diffraction Data, Joint Committee on Powder Diffraction Standards (JCPDS), which Committee E04 sponsors. Additional information for Committee E04, along with a list of current and proposed standards, is available at: <http://www.astm.org/COMMITTEE/E04.htm>

E07: ASTM International Subcommittee E07.10 on Specialized NDT Methods, housed under Committee E07 on Nondestructive Testing, is concerned with the development of nondestructive testing by methods of emerging and specialized technologies, and as such, this subcommittee has taken on the activities of nondestructive testing for additively manufactured parts. A list of standards and work items found under Subcommittee E07.10 can be found at: <https://www.astm.org/COMMIT/SUBCOMMIT/E0710.htm>. The current focus of the subcommittee is on [ASTM WK47031, New Guide for Nondestructive Testing of Additive Manufactured Metal Parts Used in Aerospace Applications](#). Information on the scope of this work item can be found at: <https://www.astm.org/DATABASE.CART/WORKITEMS/WK47031.htm>. The subcommittee has also developed an internal roadmap in expectation of the future development of nondestructive testing standards in support of additively manufactured parts.

E08: Fatigue and Fracture develops standards that focus on the fatigue and fracture of materials and structures that are manufactured from conventional manufacturing technologies. The emergence of additive manufacturing has the committee looking at its current fatigue testing standards to determine if they need to be modified if test specimens are built using AM. There are many details involved in making an AM build that will affect fatigue resistance, and these details need to be brought into the current standards. Standardization is a key and vital element to establish trust in components fabricated using AM, and many industries are rapidly moving forward with the use of AM. Subcommittees E08.05 on Cyclic Deformation and Fatigue Crack Formation and E08.06 on Crack Growth Behavior are leading the effort in Committee E08 as they pursue standards activities in AM. More information is available at: <https://www.astm.org/COMMIT/SUBCOMMIT/E08.htm>

E28: ASTM International Committee E28 on Mechanical Testing focuses on the development of standards that involve the measurement of mechanical properties typically in metallic materials. The various E28 subcommittees address ductility, flexure, uniaxial testing, indentation hardness, and impact testing. E28 also addresses the calibration of mechanical testing machines and instruments used to

determine mechanical properties. These standards can be used to evaluate the mechanical properties of additively manufactured materials, and are also used to compare a traditional material versus an additively manufactured material. Information on all of the E28 subcommittees and their standards can be found at: <http://www.astm.org/COMMIT/SUBCOMMIT/E28.htm>.

E29: ASTM International Committee E29 on Particle and Spray Characterization has jurisdiction over standards used for characterizing solid and liquid particles and for the apparatus and techniques required for such purposes. E29 relates to additive manufacturing in the sense that many AM machines spray particles during the manufacturing process. For a listing of the standards under the jurisdiction of E29 and its sub-committees, visit: <http://www.astm.org/COMMITTEE/E29.htm>.

F04.12: Subcommittee on Metallurgical Materials, housed under Committee F04 on Medical and Surgical Materials and Devices, is concerned with defining and determining the properties and characteristics of metallurgical materials in order to develop standard specifications, test methods, classifications and performance requirements for medical and surgical materials and devices. A list of standards and work items found under Subcommittee F04.12 can be found at: <https://www.astm.org/COMMIT/SUBCOMMIT/F0412.htm>. F04.12 maintains liaison with Committee F42.

Partner Standards Developing Organization (PSDO) Agreement between ASTM International and ISO

Signed in 2011 by the ASTM president the ISO Secretary General (<http://www.astmnewsroom.org/default.aspx?pageid=3108>), this agreement is an enabler of jointly developed standards in the AM space between ASTM F42 on Additive Manufacturing Technologies and ISO TC261 on Additive Manufacturing.

The PSDO agreement speaks to:

- fast tracking the adoption process of an ASTM International standard as an ISO final draft international standard;
- formal adoption of a published ISO standard by ASTM International;
- maintenance of published standards; and
- publication, copyright, and commercial arrangements.

At the time of writing of this roadmap section, the PSDO had produced 5 joint ISO/ASTM standards (below), with additional joint standards projects under development.

1. [ISO/ASTM52900-15, Standard Terminology for Additive Manufacturing – General Principles – Terminology](#)
2. [ISO/ASTM 52901:2017, Additive manufacturing - General principles - Requirements for purchased AM parts](#)
3. [ISO/ASTM52915-16, Standard Specification for Additive Manufacturing File Format \(AMF\) Version 1.2](#)

4. [ISO/ASTM52921-13, Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies](#)
5. ISO/ASTM 52911-1, *Additive manufacturing – Technical Design Guideline for Powder Bed Fusion –Part 1: Laser-based Powder Bed Fusion of Metals*
6. ISO/ASTM 52911-2, *Additive manufacturing – Technical Design Guideline for Powder Bed Fusion – Part 2: Laser-based Powder Bed Fusion of Polymers*

The ISO TC261 work program contains the 6 joint standards (above), 3 additional standards, and 16 other work items in various stages of development. See:

http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=629086.

On October 6, 2016, ASTM F42 and ISO/TC 261 announced a new standards development framework (Figure 2) that they agreed to under which standards can be developed at three levels:

- general standards (e.g., concepts, common requirements, guides, safety);
- standards for broad categories of materials (e.g., metal powders) or processes (e.g., powder bed fusion); and
- specialized standards for a specific material (e.g., aluminum alloy powders), process (e.g., material extrusion with ABS), or application (e.g., aerospace, medical, automotive).

The announcement noted that the structure does not confine the scope of work for any standards organization but provides a framework in which the majority of standards needs can be met. A companion guidance document is also being developed to accompany this structure.

Additive Manufacturing Standards Structure

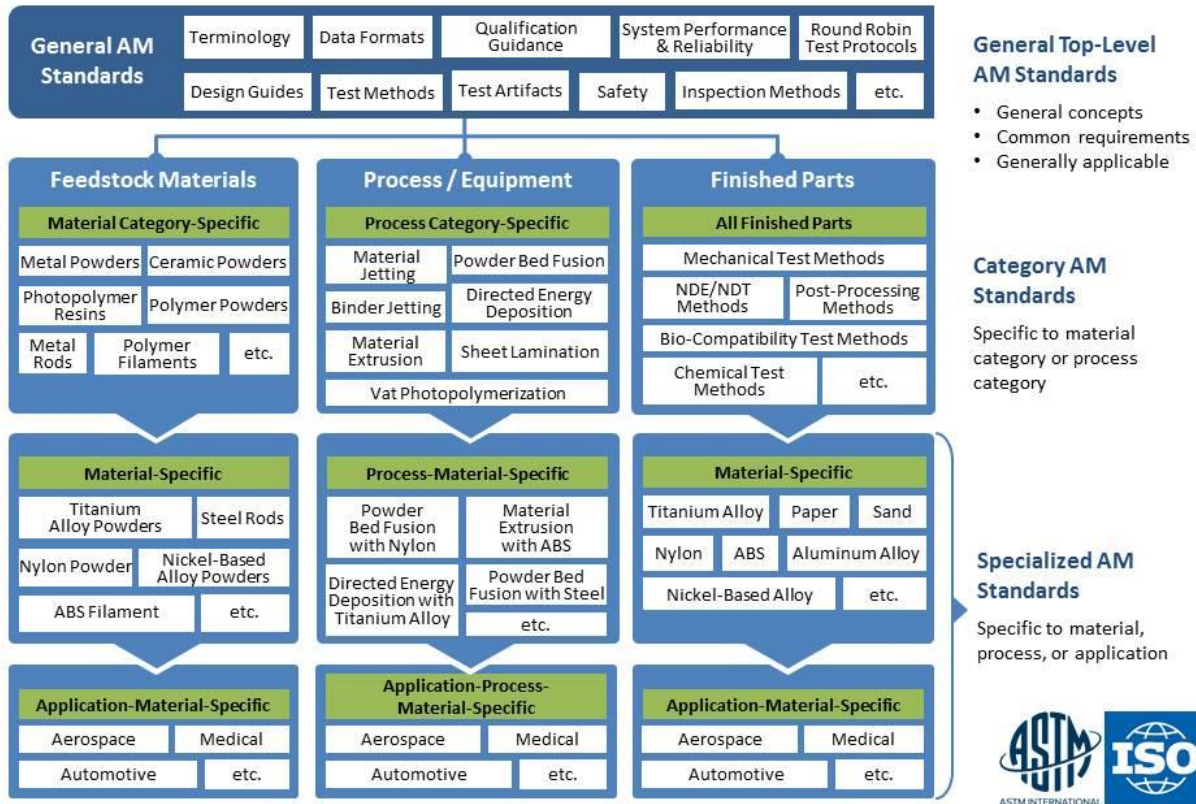


Figure 2: Standards structure approved by ASTM F42 and ISO TC261. Used with permission of NIST.

European Standards (ENs)

3 standards have also been approved as ENs (CEN TC438)

[EN ISO/ASTM 52900:2017](#) (WI=00438005)

Additive manufacturing - General principles - Terminology (ISO/ASTM 52900:2015)

[EN ISO/ASTM 52915:2017](#) (WI=00438006)

Specification for additive manufacturing file format (AMF) Version 1.2 (ISO/ASTM 52915:2016)

[EN ISO/ASTM 52921:2016](#) (WI=00438001)

Standard terminology for additive manufacturing - Coordinate systems and test methodologies (ISO/ASTM 52921:2013)

10 more are under development:

[prEN ISO/ASTM 52900 rev](#) (WI=00438014)

Additive manufacturing - General principles – Terminology

[prEN ISO/ASTM 52901](#) (WI=00438017)

Additive manufacturing - General principles - Requirements for purchased AM parts (ISO/ASTM 52901:2017)

[prEN ISO/ASTM 52902](#) (WI=00438007)

Additive manufacturing -- General principles -- Standard test artifacts

[prEN ISO/ASTM 52903-2](#) (WI=00438008)

Additive Manufacturing - Standard Specification for Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 2 process – equipment

[prEN ISO/ASTM 52903-3](#) (WI=00438010)

Additive Manufacturing -- Standard Specification for Material Extrusion Based Additive Manufacturing of Plastic Materials -- Part 3: Final parts

[prEN ISO/ASTM 52905](#) (WI=00438009)

Additive manufacturing -- General principles -- Nondestructive testing of additive manufactured products

[prEN ISO/ASTM 52907](#) (WI=00438013)

Additive manufacturing - Technical specifications on metal powders

[prEN ISO/ASTM 52911-1](#) (WI=00438012)

Additive manufacturing - Technical Design Guideline for Powder Bed Fusion - Part 1: Laser-based Powder Bed Fusion of metals (ISO/ASTM DIS 52911-1:2017)

[prEN ISO/ASTM 52911-2](#) (WI=00438011)

Additive manufacturing - Technical Design Guideline for Powder Bed Fusion - Part 2: Laser-based Powder Bed Fusion of Polymers (ISO/ASTM DIS 52911-2:2017)

[prEN ISO/ASTM 52915 rev](#) (WI=00438015)

Specification for additive manufacturing file format (AMF) Version 1.2

Additive Manufacturing Center of Excellence (CoE) Partnership with EWI and Auburn University-NASA

ASTM International, with its partners EWI and jointly Auburn University-NASA, has established an Additive Manufacturing Center of Excellence (CoE) to facilitate collaboration and coordination between government, academia, and industry to advance AM standardization and expand ASTM and its partners' capabilities. The CoE's mission is to bridge standards development with R&D to better enable efficient development of standards, education and training, certification, and proficiency testing programs.

1.5.4 American Welding Society (AWS)

The American Welding Society (AWS) formed the D20 committee on additive manufacturing (AM) in 2013 to develop a standard that would integrate requirements for the additive manufacturing of metal components. The AWS D20 committee, which consists of volunteers working in various AM-related fields, has completed a draft of [AWS D20.1, Standard for Fabrication of Metal Components using Additive Manufacturing](#). AWS D20.1 is a comprehensive document that identifies requirements related to AM component design, machine qualification, procedure qualification, machine operator performance qualification, fabrication, and inspection. The draft AWS D20.1 standard implements a graded approach to qualification and inspection, with requirements determined by the criticality of the component. The scope of the draft AWS D20.1 standard includes both powder bed fusion (PBF) and directed energy deposition (DED) metal AM processes. The standard is anticipated to be available in 2019.

The AWS D20 committee has three active task groups: Qualification, Fabrication, and Inspection. The Qualification Task Group has drafted the AWS D20.1 clauses on AM machine and procedure qualification, and machine operator performance qualification. The AM machine and procedure qualification clause contains requirements to demonstrate the capability of an AM machine and procedure to produce a component that meets acceptance requirements. This clause includes requirements for qualification test piece design, testing, and acceptance; qualification variables for each AM process covered by AWS D20.1; and requalification requirements based on changes to the qualification variables. The performance qualification clause contains requirements intended to ensure that AM machine operators are capable of repeatedly fabricating acceptable AM components. This clause includes requirements related to topics such as AM machine operator training, written and practical examinations, and the demonstration of an acceptable build.

The Fabrication Task Group of the AWS D20 committee has drafted a clause containing requirements designed to ensure the successful fabrication of AM components. Examples of topics covered by this clause include requirements related to digital control plans, equipment calibration control plans, feedstock and build platform storage and cleanliness, environmental controls, the use of qualified procedures and personnel, build cycle interruptions, component identification, witness specimens, repairs, post-build processing, and build documentation packages.

The Inspection Task Group of the AWS D20 committee has drafted a clause containing requirements for the qualification of inspection personnel, nondestructive and destructive examination for qualification and production builds, and acceptance of qualification and production builds. The inspection requirements for AM builds are based on component classification. Acceptance criteria for mechanical properties and microstructure are established by the Engineer on a component basis. The evaluation of discontinuities is performed through volumetric inspection to a given set of acceptance criteria (similar to the inspection requirements of [AWS D17.1/D17.1M:2010-AMD1, Specification for Fusion Welding for Aerospace Applications - AMD](#)).

Since metal AM essentially involves the fabrication of components from weld metal, the AWS D20 committee considers that many existing AWS documents and standards are relevant to the development of requirements for metal AM components. These include [AWS B2.1/B2.1M:2014, Specification for Welding Procedure and Performance Qualification](#); [AWS D17.1/D17.1M:2010-AMD1, Specification for Fusion Welding for Aerospace Applications - AMD](#)); and various other materials, inspection, and process documents. AWS D20 also keeps up with related international work.

At the time of writing of this roadmap section, further related work was getting underway in ISO/TC 44/SC 14/WG 1, Additive Manufacturing in Aerospace, though this WG did not have any work items. There have also been activities in the International Institute of Welding, but no standards projects had been requested.

1.5.5 Institute for Electrical and Electronics Engineers (IEEE)

IEEE is the world's largest technical professional organization dedicated to advancing technology for the benefit of humanity. Through its highly cited publications, conferences, technology standards, and professional and educational activities, IEEE is the trusted voice in a wide variety of areas ranging from aerospace systems, computers, and telecommunications to biomedical engineering, electric power, and consumer electronics. Learn more at <http://www.ieee.org>.

The IEEE Standards Association (IEEE-SA), a globally recognized standards-setting body within IEEE, develops consensus standards through an open process that engages industry and brings together a broad stakeholder community. IEEE standards set specifications and best practices based on current scientific and technological knowledge. The IEEE-SA has a portfolio of over 1,200 active standards and over 650 standards under development. For more information visit <http://standards.ieee.org>.

Below are IEEE projects sponsored or jointly sponsored by the IEEE Computer/Standards Activity Board, the IEEE Consumer Electronics Society/Standards Board, and the IEEE Engineering, Medicine and Biology Society/Standards Committee that may be relevant to additive manufacturing.

The IEEE 3333 series is a multi-part standard, part one of which is published and parts 2-5 are in development.

Sponsored by: IEEE Computer Society/Standards Activity Board

Working Group: 3D Based Medical Application Working Group (C/SAB/3333-2_WG)

Chaired by: Young Lae Moon (Located in Korea)

Standard: IEEE 3333.2.1-2015 (Completed)

Title: [IEEE Recommended Practice for Three-Dimensional \(3D\) Medical Modelling](#)

Scope: This standard includes volume rendering and surface rendering techniques for three-dimensional (3D) reconstruction from two-dimensional medical images. Also, it contains a texturing method of 3D medical data for the realistic visualization.

Standardization related to medical services includes medical equipment utilizing two-dimensional images, three-dimensional medical data, and contents for diagnosis and treatment. Standardization

of medical contents, software, and hardware will enhance safety, economy, and quality of the 3D medical services.

Purpose: Medical images from hospitals consist of a 2D data set, providing information on the human body as sectioned slices. The human body has a morphological structure in 3D space. Therefore, to recognize human organs, a 3D reconstruction process is necessary to be performed using 2D slice. After this, its precise position and shape can be identified.

Medical 3D volume images are based on unprocessed 3D medical data, which contains a variety of medical information. It determines guidelines, standards of medical 3D technology, and 3D volume images' safety and quality. Additionally, these standards describe generation and practical use of medical 3D modeling for diagnostics and therapeutic applications.

Project: IEEE P3333.2.2

Title: [Standard for Three-Dimensional \(3D\) Medical Visualization](#)

Scope: This standard focuses on the demands arising when scientific results in the field of 3D medical visualization are applied for the construction of a software system. It is targeted to aid the clinical work of medical professionals.

This standard includes visualization techniques by the automated medical shape detection and reconstruction of three-dimensional (3D) models from two-dimensional medical images. Also it contains texturing of three-dimensional medical data for the intuitive visualization.

Purpose: Medical 3D data acquisition devices are increasingly available and able to provide accurate spatial information for the human body. Even though nowadays hardware capabilities and rendering algorithms have improved to the point that 3D visualizations can be rapidly obtained from acquired data, 3D reconstructions are not routinely used in most hospitals. This is because physicians are traditionally trained to gather information from 2D image slices, and because 3D volumetric images displayed on traditional devices are often of questionable value because of ambiguities in their interpretations. Therefore, this standard provides routine visualization techniques for three-dimensional medical images, so that medical images can be visualized from routine processes.

Project: IEEE P3333.2.3

Title: [Standard for Three-Dimensional \(3D\) Medical Data Management](#)

Scope: This standard includes medical 2D and 3D data management such as storage, compression for transfer, regulation for wired or wireless transfer, and search engine development for data retrieval.

Purpose: The purpose of this standard is to allow a standardized sharing method of 2D and 3D data with security for human-care managers and medical service providers to support the decision-making process.

Project: IEEE P3333.2.4

Title: [Standard for Three-Dimensional \(3D\) Medical Simulation](#)

Scope: This standard discusses the simulation of the movement of joints and subsequent changes of

skin, muscle, and neighboring structures. It defines joint range of motion, movement, and structure of skeleton, for rigging work.

Purpose: The purpose of this document is the standardization of three-dimensional medical simulations, which will help device development and related research.

Project: IEEE P3333.2.5

Title: [Standard for Bio-CAD File Format for Medical Three-Dimensional \(3D\) Printing](#)

Scope: This standard defines the Bio-CAD format for three-dimensional (3D) printing based on sectional scan image data containing surface and volumetric information. Standardization is related to medical 3D printing services, including anatomic, pathologic models, and medical instrument printing based on two-dimensional images, three-dimensional medical data, and other medical data.

Purpose: To establish the standardization of an accurate and optimized Bio-CAD file format system for medical 3D printing.

Status of Project: New project and in draft development

Sponsored by: IEEE Consumer Electronics Society/Standards Committee

Working Group: Consumer 3D Printing Working Group (CES/SC/C3DP)

Chaired by: Yu Yuan (Located in China)

Project: IEEE P3030

Title: [Standard for Consumer 3D Printing: Overview and Architecture](#)

Scope: This standard defines an architectural framework for consumer 3D printing, including descriptions of various domains (systems, services, devices, participants, etc.), definitions of domain abstractions, and identification of commonalities between different domains. The architectural framework for consumer 3D printing provides a reference model that defines relationships among various domains and common architectural elements. It also provides a blueprint for data abstraction, quality, protection, and safety.

Status of Project: New project and in draft development

Other Info: IEEE P3030 is focused on standards development to establish quality metrics and accuracy grades so that printed materials at the consumer level can be assembled faultlessly, while also addressing issues related to privacy, security, and control measures.

Sponsored by: IEEE Computer Society/Test Technology (C/TT)

Working Group: 3D-Test Working Group (C/TT/3DT-WG)

Chaired by: Erik Jan Marinissen (Located in Belgium)

Project: IEEE P1838

Title: [Standard for Test Access Architecture for Three-Dimensional Stacked Integrated Circuits](#)

Scope: The proposed standard is a 'die-centric' standard; it applies to a die that is intended to be part of a multi-die stack. The proposed standard defines die-level features that, when compliant dies are brought together in a stack, comprise a stack-level architecture. This enables transportation of control and data signals for the test of: (1) intra-die circuitry and (2) inter-die interconnects, in both (a) pre-stacking and (b) post-stacking situations, the latter for both partial and complete stacks in

pre-packaging, post-packaging, and board-level situations. The primary focus of inter-die interconnect technology addressed by this standard is through-silicon vias (TSVs); however, this does not preclude its use with other interconnect technologies such as wire-bonding.

The standard will consist of two related items.

1. 3D Test Wrapper Hardware – On-die hardware features that enable transportation of test (control and data) signals in pre-stacking and post-stacking (turn mode or elevator mode) configurations.
2. Description + Description Language – A description of the test wrapper features in a standardized human- and computer-readable language. This description should allow usage of the die within a multi-die stack for test and test access purposes.

The proposed standard does not mandate specific defect or fault models, test generation methods, or die-internal design-for-test, but instead focuses on generic test access to and between dies in a multi-die stack. The proposed standard is based on and works with digital scan-based test access and should leverage existing test access ports (such as based on IEEE Std 1149.x) and on-chip design-for-test (such as [IEEE 1500-2005](#)) and design-for-debug (IEEE P1687) infrastructure wherever applicable and appropriate.

The proposed standard is 'die-centric' and hence does not aim at 'stack/product-centric' challenges, solutions, and standards, such as the inclusion of boundary scan features for board-level interconnect testing. However, the proposed standard should not prohibit the application of such solutions.

Status of Project: New project and in draft development

IEEE P1838 public website: <http://grouper.ieee.org/groups/3Dtest>

Other info: There is a list of published status reports located in <http://grouper.ieee.org/groups/3Dtest/#StatusReports>.

Sponsored by: IEEE Consumer Electronics Society/Standards Committee

Working Group: 3DBP - 3D Body Processing

Chaired by: Luciano Oviedo

Project: IEEE P3141

Title: [*Standard for 3D Body Processing*](#)

Scope: This standard addresses the fundamental attributes that contribute to 3D body processing quality of experiences, as well as identifying and analyzing existing metrics and other useful information relating to these attributes. It defines a standardized suite of objective and subjective methods, tools and frameworks for assessing 3D body processing quality of experience attributes, and it specifies methods, tools and frameworks to facilitate standards-based interoperability, communication, security and comparison among 3D body processing technologies such as 3D/depth sensors, scanners, digitization, simulation and modeling, analytics and animation/visualization for solution providers as well as for consumer facing companies such as in retail, health/wellness, sports/athletics, medical industries.

Purpose: 3D body processing technologies are emerging as the next wave for how people interact and engage in a range of semi-to-fully immersive experiences to, for example, shop, play and learn. However, due to market and technology fragmentation, there is a lack of agreement from across the

ecosystem for how to align and deliver on quality of experiences as well as how to cope with gaps in interoperability, communication and security. This standard aims to establish a uniform means for deliberately designing and implementing immersive experiences by delivering the ability to evaluate the quality of experience for 3D body processing technologies for technology solution providers as well as for industries such as retail, health/wellness, sports/athletics and medical.

Status: New Project

Sponsored by: IEEE Engineering and Biology Society/Standards Committee

Working Group: Medical devices with measuring functions (EMB/Std Com/MDMF)

Chaired by: Almir Badnjevic

Project: IEEE P2727

Title: *Standard for General Vocabulary for Conformity Assessment of Medical Devices with Measuring Function*

Scope: The standard defines commonly-used terms used in the conformity assessment of medical devices with measuring function for legal metrology purposes.

Purpose: The purpose is to provide the framework for nomenclature in the field of medical device legal metrology and establish consistency in the use of the terms.

Sponsored by: IEEE Engineering and Biology Society/Standards Committee

Working Group: Medical Robots Working Group (EMB/Std Com/MRWG)

Chaired by: Jia Zheng

Project: IEEE P2730

Title: *Standard for Classification, Terminologies, and Definitions of Medical Robots*

Scope: The standard specifies the category, naming, and definition of medical robots.

Purpose: The purpose of this standard is to provide the industry a unified classification and definitions on medical robots that industry can leverage. Harmonization of these classification and definitions on medical robots promotes a common framework for the industry in the rapid development and deployment of medical robots the healthcare industry.

Sponsored by: IEEE Engineering and Biology Society/Standards Committee

Working Group: Intelligence Augmentation for Medical Imaging (EMB/Std Com/IA Medical Imaging)

Chaired by: Moira Schieke

Project: IEEE P2673

Title: *Standard for Patient Digital Biomedical Data Files with 3D Topological Mapping of Macroanatomy and Microanatomy for Use in Big Data and Augmented Intelligence Systems*

Scope: This standard provides a framework for organization and use of new patient biomedical files containing medical imaging and imaging biomarker information for use in big data cloud-based augmented intelligence systems. In addition, this standard defines 3D digital topological mapping of information and data to human macroanatomy and microanatomy. Included in this standard are requirements to assure compliance with ethical design and value-based design standards to assure

(1) patient data security with full access, sharing, and user control of their personal data; and (2) protection of the professional fiduciary relationships between physicians and patients.

Purpose: This standard, along with definitions, allows for precise communication among global experts of different domains that includes clinical medical imaging, artificial intelligence, and ethics for augmented intelligence systems that maintain a central role for the medical professional subject matter experts in managing and using image-based information. 3D digital topological mapping of this information and data to human macroanatomy and microanatomy including coordination with existing disease coding across global big data datasets will optimize its use for maximal societal benefit. This standard will assure systems integrate human-in-the-loop principles to assure accuracy, reliability, and clinical utility of generated information for safe optimal use in clinical decision-making.

Printer Working Group: An IEEE-ISTO Federation Member Program

The IEEE Industry Standards and Technology Organization (ISTO) was established in January 1999 as a federation of member alliance programs with the aim of supporting accelerated technology standards development and market adoption for industry. A global, 501(c)(6) not-for-profit corporation, ISTO offers a membership infrastructure and legal umbrella under which member alliances and trade groups can stand themselves up as legal operating entities.

The Printer Working Group (PWG) is a program of the IEEE-ISTO with members including printer and multi-function device manufacturers, print server developers, operating system providers, print management application developers, and industry experts. Originally founded in 1991 as the Network Printing Alliance, the PWG is chartered to make printers, multi-function devices, and the applications and operating systems supporting them, work better together.

The PWG enjoys an open standards development process. Everyone is welcome to contribute to the development of PWG documents and standards, serve as editors, and participate in interoperability tests. Members may additionally serve as officers in the various working groups. Voting members approve the documents and standards for publication and may serve as officers of the PWG.

The following Printer Working Group project may be directly relevant to additive manufacturing:

Sponsored by: IEEE-ISTO/ Printer Working Group (PWG)

Working Group: Internet Printing Protocol (IPP) Workgroup

Chaired by: Ira McDonald (High North) and Paul Tykodi (TCS)

Project: IPP 3D Printing Extensions

Title: PWG 5100.21-2017, [IPP 3D Printing Extensions v1.0 \(3D\)](#)

Scope: This specification defines an extension to the Internet Printing Protocol ([PWG 5100.12-2015, IPP 2.0, 2.1, and 2.2](#)) and IPP Everywhere (PWG 5100.14) that supports printing of physical objects by additive manufacturing devices such as 3D printers. The Internet Printing Protocol (IPP) workgroup has developed a modern, full-featured network printing protocol that is now the ubiquitous industry standard for 2D printing. IPP allows a print client to query a printer for its

supported capabilities, features, and parameters to allow the selection of an appropriate printer for each print job. IPP also provides job information prior to, during, and at the end of job processing.

Status of Project: Existing project, IPP 3D Printing Extensions v1.0 approved as PWG 5100.21-2017

IEEE-ISTO PWG public website: <http://www.pwg.org/>

There is a list of IEEE-ISTO PWG freely available standards at:

<http://www.pwg.org/standards.html>

There is more information about IPP Everywhere at:

<http://www.pwg.org/ipp/everywhere.html>

There is more information about IPP 3D Printing at:

<http://www.pwg.org/3d/index.html>

1.5.6 IPC – Association Connecting Electronics Industries (IPC)

IPC Mission Statement

IPC is a global trade association dedicated to furthering the competitive excellence and financial success of its members, who are participants in the electronics industry. In pursuit of these objectives, IPC will devote resources to management improvement and technology enhancement programs, the creation of relevant standards, protection of the environment, and pertinent government relations. IPC encourages the active participation of all its members in these activities and commits to full cooperation with all related organizations.

[IPC Printed Electronics Committee \(D-60\)](#)

The IPC Printed Electronics Committee (D-60) plans, guides and coordinates printed electronics standards development. These standards focus on electronics that use additive processes as either standalone technologies or as hybrid electronics.

Chaired by: Neil Bolding, MacDermid Enthone Electronics Solutions, and Daniel Gamota, Jabil

[Printed Electronics Design Subcommittee \(D-61\)](#)

This subcommittee is responsible for generating standards related to fundamental design considerations for printed electronics. Design considerations shall include information pertaining to material selection, layout configuration, assembly processes, tests, and in-service use.

Chaired by: Alan M Burk, ALMAX, and Richard Snogren, SAIC/Bristlecone LLC

Project: IPC-2292

Title: [Design Standard for Printed Electronics on Flexible Substrates](#)

Scope: This standard establishes specific requirements for the design of printed electronic applications and their forms of component mounting and interconnecting structures on flexible substrates. Flexible substrates, as pertain to this standard, are materials or devices which have some amount of flexibility or bendability (not rigid) but are not considered to be stretchable (e.g., fabrics, textiles, stretchable

polymers, etc.).

Status of Project: Published

Other Info: This group also published IPC-2291, *Design Guideline for Printed Electronics* in 2013. See Other Published Standards below.

[Printed Electronics Base Materials/Substrates Subcommittee \(D-62\)](#)

This subcommittee is responsible for generating standards for printed electronics base materials.

Chaired by: Scott E Gordon, DuPont Teijin Films, and Neil Bolding, MacDermid Enthone Electronics Solutions

Project: IPC-4921

Title: [Requirements for Printed Electronics Base Materials \(Substrates\)](#)

Scope: This standard establishes the classification system, qualification and quality conformance requirements for printed electronics base materials (substrates).

The standard defines the base material only and should not be used for substrates that have been post-processed and comprise defined features or structures (e.g., conductive traces).

Status of Project: Revision A published

[Printed Electronics Functional Materials Subcommittee \(D-63\)](#)

This subcommittee is responsible for generating standards related to additive materials applied to the surface of a substrate for printed electronics.

Chaired by: Josh Goldberg, Rogers Corporation

Project: IPC-4591

Title: [Requirements for Printed Electronics Functional Conductive Materials](#)

Scope: This standard establishes the classification system and the qualification and quality conformance requirements for functional conductive materials used in printed electronics applications.

Status of Project: Revision A published

[Printed Electronics Final Assembly Subcommittee \(D-64\)](#)

This subcommittee is responsible for generating standards related to the final printed electronics assembly. Final assemblies are considered to be functional electronic devices that are fabricated using printed electronics materials and processes.

Chaired by: Jeff Shubrooks, Raytheon Company, and Michael Jawitz, Orbital ATK

Project: IPC-6902

Title: *Qualification and Performance Specifications for Printed Electronics on Flexible Substrates*

Scope: This standard establishes and defines the qualification and performance requirements for printed electronic applications and their forms of component mounting and interconnecting structures on flexible substrates. Flexible substrates, as pertain to this standard, are materials or devices which have some amount of flexibility or bendability (not rigid) but are not considered to be stretchable (e.g., fabrics, textiles, stretchable polymers, etc.).

Status of Project: Working draft

Other Info: This group also published IPC-6901, *Application Categories for Printed Electronics* in 2015. See Other Published Standards below.

[Printed Electronics Terms and Definitions Task Group \(D-64a\)](#)

This task group defines terminologies used for the base materials, design and production of printed electronics. It covers printed electronics on flexible substrates, rigid substrates, 3D substrates, and rigid or flexible printed circuit boards.

Chaired by: Ken Gann, Lab Tech, and MaryAlice Gill, Jabil

Project: IPC-6903

Title: [Terms and Definitions for the Design and Manufacture of Printed Electronics](#)

Scope: This standard provides industry-approved terms and definitions for the design and manufacture of printed electronics.

Status of Project: Revision A published

[Printed Electronics Test Method Development and Validation Subcommittee \(D-65\)](#)

This subcommittee identifies, modifies as needed, creates as needed, and validates (by round-robin tests and other methods as appropriate) test and measurement methods specific to printed electronics, as a shared resource for other subcommittees operating under the D-60 committee. Once validated, test methods will be proposed and submitted for inclusion through the established process for IPC-TM-650.

Chaired by: Weifeng Liu, Flextronics International, and Neil Bolding, MacDermid Enthone Electronics Solutions

Project: IPC-9204

Title: [Guideline on Flexibility and Stretchability Testing for Printed Electronics](#)

Scope: This guideline describes flexibility and stretchability tests that may be used to evaluate printed electronics for flexible, stretchable and wearable applications.

Status of Project: Published

[Printed Electronics Processes Subcommittee \(D-66\)](#)

This subcommittee is responsible for developing standards on processes for the manufacture of printed electronics.

Chaired by: Neil Bolding, MacDermid Enthone Electronics Solutions

Project: IPC/SGIA-5222

Title: *Process Guideline for Screen Printing for Printed Electronics*

Scope: This document is an industry guideline for best practices related to screen printing specifically for printed electronics. This guideline covers prepress, stencil materials and processing, mesh types, printing equipment, substrate considerations, stencil exposure, printing materials (inks, adhesives, etc.), printing parameters, registration systems and testing for screen printing printed electronics.

The guideline also provides information on preparation, handling, processing, drying and curing of inks specific to screen printing.

Status of Project: Working draft

Other Info: This standard is being developed jointly with the Specialty Graphic Imaging Association (SGIA)

[3D Printed Electronics Processes Task Group \(D-66a\)](#)

This task group is developing an IPC guideline for 3D printed electronics processes.

Chaired by: Udi Zamwel, Nano Dimension, and Mike O'Reilly, Optomec

Project: IPC-7991

Title: *Process Guideline for 3D Printed Electronics*

Scope: This document is an industry guideline for best practices related to 3D printed electronics. This guideline covers equipment, design, substrates, printing materials, printing parameters, testing, quality and reliability for 3D printed electronics.

Status of Project: Working draft

Other Published Standards

[IPC-2291-2013, Design Guideline for Printed Electronics](#)

This guideline provides an overview of the design process flow for printed electronics based devices,

modules and units, and final products. The intent of IPC/JPCA-2291 is to establish a design process flow that will facilitate and improve the practice of printed electronics design.

[IPC- 6901-2015, Application Categories for Printed Electronics](#)

This standard establishes a market classification system and level classification system for printed electronics assemblies and provides a list of performance criteria and testing methods. It provides a standardized product category structure for designing and manufacturing printed electronics and assemblies which conform to industry-established performance metrics, as determined by accepted testing methods.

1.5.7 International Organization for Standardization (ISO)

[ISO/TC 261](#) is the ISO committee on Additive Manufacturing. Its scope is:

“Standardization in the field of Additive Manufacturing (AM) concerning their processes, terms and definitions, process chains (Hard- and Software), test procedures, quality parameters, supply agreements and all kind of fundamentals.”

Any standardization at the ISO level touching additive manufacturing is expected to be done in cooperation with ISO/TC 261, and preferably by it.

ISO/TC 261 was created in 2011. A few months later a partnership agreement with ASTM was finalized. As a result, ISO/TC 261 and [ASTM F42](#) are collaborating closely in the development and maintenance of standards on AM (which will be ISO/ASTM standards). A [Joint Plan for Additive Manufacturing Standards Development](#) was developed in 2013, which included a general structure/hierarchy of AM standards in order to achieve consistency of all projects started by one of the partners. This structure was revised in 2016 (see Figure 2 earlier in this document).

Initially, the agreement between ISO/TC 261 and ASTM F42 was implemented by identifying high priorities and the establishment of four Joint Groups (JGs) in which ASTM and ISO would develop standards. Subsequently, additional JGs were created. It was agreed by ISO/TC 261 and ASTM F42 that, if one organization starts to work on a new work item, it will invite the other organization to form a JG. Only if the other organization is not interested will the standard be developed “alone.”

The Joint Groups that have been established to date are:

ISO/TC 261/JG 51	Joint ISO/TC 261-ASTM F 42 Group: Terminology
ISO/TC 261/JG 52	Joint ISO/TC 261-ASTM F 42 Group: Standard test artifacts
ISO/TC 261/JG 55	Joint ISO/TC 261-ASTM F 42 Group: Standard Specification for Extrusion Based Additive Manufacturing of Plastic Materials
ISO/TC 261/JG 56	Joint ISO/TC 261-ASTM F 42 Group: Standard Practice for Metal Powder Bed Fusion to Meet Rigid Quality Requirements
ISO/TC 261/JG 57	Joint ISO/TC 261-ASTM F 42 Group: Specific design guidelines on powder bed fusion
ISO/TC 261/JG 58	Joint ISO/TC 261-ASTM F 42 Group: Qualification, quality assurance and post processing of powder bed fusion metallic parts
ISO/TC 261/JG 59	Joint ISO/TC 261-ASTM F 42 Group: NDT for AM parts

ISO/TC 261/JG 60	Joint ISO/TC 261-ASTM F 42 Group: Guide for intentionally seeding flaws in additively manufactured (AM) parts
ISO/TC 261/JG 61	Joint ISO/TC 261-ASTM F 42 Group: Guide for anisotropy effects in mechanical properties of AM part
ISO/TC 261/JG 62	Joint ISO/TC 261-ASTM F 42 Group: Guide for conducting round robin studies for additive manufacturing
ISO/TC 261/JG 63	Joint ISO/TC 261-ASTM F 42 Group: Test methods for characterization of powder flow properties for AM applications
ISO/TC 261/JG 64	Joint ISO/TC 261-ASTM F 42 Group: Solid modelling support
ISO/TC 261/JG 66	Joint ISO/TC 261-ASTM F 42 Group: Technical specification on metal powders
ISO/TC 261/JG 67	Technical report for the design of functionally graded additive manufactured parts
ISO/TC 261/JG 68	Joint ISO/TC 261-ASTM F 42 Group: EH&S for 3D printers
ISO/TC 261/JG 69	Joint ISO/TC 261-ASTM F 42 Group: EH&S for use of metallic materials
ISO/TC 261/JG 70	Joint ISO/TC 261-ASTM F 42 Group: Optimized medical image data
ISO/TC 261/JG 71	Joint ISO/TC 261-ASTM F 42 Group: Powder
ISO/TC 261/JG 72	Joint ISO/TC 261-ASTM F 42 Group: Machine
ISO/TC 261/JG 73	Joint ISO/TC 261-ASTM F 42 Group: Digital product definition and data management
ISO/TC 261/JG 74	Joint ISO/TC 261-ASTM F 42 Group: Personnel training
ISO/TC 261/JWG 5	Joint ISO/TC 261 - ISO/TC 44/SC 14 WG: Additive manufacturing in aerospace applications

New in this concept is the Joint Working Group ISO/TC 261/JWG 5. This Joint Working Group was created in September 2017 with the aim of capturing AM activities within ISO, but outside of technical committee ISO/TC 261. ISO/TC 261/JWG 5 is cross-committee cooperation between the two ISO technical committees

- ISO/TC 44/SC 14 "Welding and brazing in aerospace" and
- ISO/TC 261 "Additive Manufacturing" as well as
- ASTM F 42 "Additive Manufacturing Technologies"

Below is a list of the current work items of ISO/TC 261 (and finished projects) as of March 2018:

Reference	Document title	Committee	Status
ISO 17296-2:2015	<i>Additive manufacturing -- General principles -- Part 2: Overview of process categories and feedstock</i>	ISO/TC 261/WG 2	Published
ISO 17296-3:2014	<i>Additive manufacturing -- General principles -- Part 3: Main characteristics and corresponding test methods</i>	ISO/TC 261/WG 3	Published
ISO 17296-4:2014	<i>Additive manufacturing -- General principles -- Part 4: Overview of data processing</i>	ISO/TC 261/WG 4	Published
ISO/ASTM 52900:2015	<i>Additive manufacturing -- General principles -- Terminology</i>	ISO/TC 261/JG 51	Published

ISO/ASTM 52901:2017	<i>Additive manufacturing -- General principles -- Requirements for purchased AM parts</i>	ISO/TC 261	Published
ISO/ASTM 52910-17	<i>Standard Guidelines for Design for Additive Manufacturing</i>	ISO/TC 261	Published
ISO/ASTM 52915:2016	<i>Specification for additive manufacturing file format (AMF) Version 1.2</i>	ISO/TC 261	Published
ISO/ASTM 52921:2013	<i>Standard terminology for additive manufacturing -- Coordinate systems and test methodologies</i>	ISO/TC 261	Published
ISO/ASTM DIS 52900	<i>Additive manufacturing -- General principles -- Terminology</i>	ISO/TC 261/JG 51	Under development
ISO/ASTM DIS 52902	<i>Additive manufacturing -- Test artefacts -- Standard guideline for geometric capability assessment of additive manufacturing systems</i>	ISO/TC 261/JG 52	Under development
ISO/ASTM DIS 52903-1	<i>Additive manufacturing -- Standard specification for material extrusion based additive manufacturing of plastic materials -- Part 1: Feedstock materials</i>	ISO/TC 261/JG 55	Under development
ISO/ASTM CD 52903-2	<i>Additive manufacturing -- Standard specification for material extrusion based additive manufacturing of plastic materials -- Part 2: Process -- Equipment</i>	ISO/TC 261/JG 55	Under development
ISO/ASTM NP 52903-3	<i>Additive Manufacturing -- Standard Specification for Material Extrusion Based Additive Manufacturing of Plastic Materials -- Part 3: Part 3: Final parts</i>	ISO/TC 261/JG 55	Under development
ISO/ASTM PWI 52904	<i>Additive manufacturing -- Process characteristics and performance -- Standard practice for metal powder bed fusion process to meet critical applications</i>	ISO/TC 261/JG 56	Under development
ISO/ASTM NP 52905	<i>Additive manufacturing -- General principles -- Non-destructive testing of additive manufactured products</i>	ISO/TC 261/JG 59	Under development
ISO/ASTM DIS 52907	<i>Additive manufacturing -- Technical specifications on metal powders</i>	ISO/TC 261/JG 66	Under development
ISO/ASTM PWI 52908	<i>Additive manufacturing -- Post-processing methods -- Standard specification for quality assurance and post processing of powder bed fusion metallic parts</i>	ISO/TC 261/JG 58	Under development
ISO/ASTM PWI 52909	<i>Additive manufacturing -- Finished part properties -- Standard guideline for orientation and location dependence of</i>	ISO/TC 261/JG 61	Under development

	<i>mechanical properties for metal powder bed fusion</i>		
ISO/ASTM DIS 52911-1	<i>Additive manufacturing -- Technical design guideline for powder bed fusion -- Part 1: Laser-based powder bed fusion of metals</i>	ISO/TC 261/JG 57	Under development
ISO/ASTM DIS 52911-2	<i>Additive manufacturing -- Technical design guideline for powder bed fusion -- Part 2: Laser-based powder bed fusion of polymers</i>	ISO/TC 261/JG 57	Under development
ISO/ASTM NP TR 52912	<i>Design of functionally graded additive manufactured parts</i>	ISO/TC 261/JG 67	Under development
ISO/ASTM DIS 52915	<i>Specification for additive manufacturing file format (AMF) Version 1.2</i>	ISO/TC 261/JG 64	Under development
ISO/ASTM NP 52916	<i>Additive manufacturing -- Data formats - Standard specification for optimized medical image data</i>	ISO/TC 261/JG 70	Under development
ISO/ASTM PWI 52931	<i>Additive manufacturing -- Environmental health and safety -- Standard guideline for use of metallic materials</i>	ISO/TC 261/JG 69	Under development
ISO/ASTM NP 52932	<i>Additive manufacturing -- Environmental health and safety -- Standard test method for determination of particle emission rates from desktop 3D printers using material extrusion</i>	ISO/TC 261/JG 68	Under development
ISO/ASTM WD 52941	<i>Additive manufacturing -- System performance and reliability -- Standard test method for acceptance of powder-bed fusion machines for metallic materials for aerospace application</i>	ISO/TC 261/JWG 5	Under development
ISO/ASTM WD 52942	<i>Additive manufacturing -- Qualification principles -- Standard guideline for qualifying machine operators of powder bed based laser beam machines in aerospace applications</i>	ISO/TC 261/JWG 5	Under development

Please see the following link for regularly updated information about current ISO/TC 261 projects and completed standards:

http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=629086&development=on

ISO/TC 261 has established liaisons with the following ISO committees (as of March 2018):

IEC/TC 76	Optical radiation safety and laser equipment
ISO/IEC JTC 1	Information technology
ISO/TC 44	Welding and allied processes

ISO/TC 44/SC 5	Testing and inspection of welds
ISO/TC 44/SC 14	Welding and brazing in aerospace
ISO/TC 61	Plastics
ISO/TC 61/SC 9	Thermoplastic materials
ISO/TC 119	Powder metallurgy
ISO/TC 135	Non-destructive testing
ISO/TC 150	Implants for surgery
ISO/TC 156	Corrosion of metals and alloys
ISO/TC 184	Automation systems and integration
ISO/TC 213	Dimensional and geometrical product specifications and verification
ISO/TC 292	Security and resilience

In addition to that ISO/TC 261 has established liaisons with the following international organizations (as of March 2018):

ASTM	American Society for Testing and Materials
EFW	European Federation for Welding, Joining and Cutting

Apart from the work of ISO/TC 261, ISO/IEC JTC1, on information technology, has been looking at 3D printing. At the November 2016 JTC 1 plenary meeting, a Study Group (SG3) on 3D printing and scanning was established to understand the current state of standardization and to explore a possible role for JTC 1 in this area. At its meeting in Russia in October 2017, JTC 1 converted the SG into a Working Group (WG 12) reporting directly to JTC 1 under Resolution 11, dependent upon approval of a New Work Item Proposal (NWIP), *Information technology — 3D Printing and Scanning — Framework for Additive Manufacturing Service Platform (AMSP)*.

1.5.8 Medical Imaging & Technology Alliance (MITA) and Digital Imaging and Communications in Medicine (DICOM) of the National Electrical Manufacturers Association (NEMA)

The **Medical Imaging & Technology Alliance (MITA)**, a division of the **National Electrical Manufacturers Association (NEMA)**, is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. MITA is the leading standards-development organization for medical imaging equipment. These standards are voluntary guidelines that establish commonly accepted methods of design, production, testing and communication for imaging and cancer treatment products. Sound technical standards of this kind improve safety and foster efficiencies in how care is delivered. MITA may develop standards for image quality, phantoms and appropriate verification testing related to additive manufacturing in medicine.

Digital Imaging and Communications in Medicine (DICOM) is *the* international standard for medical images and related information, [ISO 12052:2017, Health informatics - Digital imaging and communication in medicine \(DICOM\) including workflow and data management](#). It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use. DICOM is

implemented in almost every radiology, cardiology imaging, and radiotherapy device (X-ray, CT, MRI, ultrasound, etc.), and increasingly in devices in other medical domains such as ophthalmology, pathology and dentistry. Since its first publication in 1993, DICOM has revolutionized the practice of radiology, allowing the replacement of X-ray film with a fully digital workflow. The DICOM Standard is a product of the international DICOM Standards Committee and its 31 Working Groups. MITA is the secretariat of DICOM and holds the copyright to the Standard.

DICOM Working Group 17 (3D Manufacturing) extends and promotes the use of DICOM in the creation, storage and management of 3D printing models in a healthcare setting, where the model is either (a) derived from medical images, or (b) expected to be compared / composited with medical images. WG-17 is preparing DICOM extensions to allow STL and several other AM file formats to be encapsulated inside DICOM wrappers to facilitate their management and distribution by PACS and VNA systems alongside the associated medical images.

The WG-17 scope also includes:

- Identify and maintain a roadmap of use cases and compatibility concerns to be addressed.
- Engage with, and liaise between, relevant stakeholders:
 - Clinical end-users of 3D printing
 - Vendors offering 3D modeling and printer control software for healthcare applications
 - Vendors of medical image acquisition, processing, and management equipment
 - Standards & professional organizations addressing 3D printing in general (e.g. SME, AMI)
- Facilitate including data relevant to the 3D printing imaging community in DICOM objects
- Provide best practice guidance and reference implementations to support the use of DICOM in 3D printing applications.

Many other DICOM objects (CT, MR, PET, Angiography, Ultrasound, X-Ray, Mammography, Endoscopy, Surface Scans, Segmentations, Implant Templates, etc.) are relevant to additive manufacturing as source data from which AM models are derived and as context for planning or simulating the use of AM parts.

1.5.9 Metal Powder Industries Federation (MPIF)

The Metal Powder Industries Federation (MPIF)⁵ is not-for-profit trade association, comprised as a federation of six trade associations, each of which is concerned with some aspect of powder metallurgy (PM): the Powder Metallurgy Parts Association (PMPA), Metal Powder Producers Association (MPPA), Powder Metallurgy Equipment Association (PMEA), Metal Injection Molding Association (MIMA), Refractory Metals Association (RMA) and the Association for Metal Additive Manufacturing (AMAM). It also includes other corporate members that may be end users or designers of PM parts and related products/material.

⁵ MPIF Test Method Standards (Published in: *Standard Test Methods for Metal Powders and Powder Metallurgy Products*)

MPIF standards cover five categories:

1. PM Terminology
2. Testing Procedures/Methods for Powder
3. Testing Procedure/Methods for Parts
4. Materials Standards Specifications for: PM structural parts; PM self-lubricating bearings; powder forged (PF) steel; and metal injection molded (MIM) parts
5. PM Press Safety Standards (ANSI/MPIF)

For the purposes of this document, information is primarily limited to test method standards development.

MPIF standards are developed to promote the advancement of the metal powder producing and consuming industries and are based on the *commonality* of practice within the powder metallurgy and particulate materials industries. MPIF Standards are intended to present and clarify PM technology so as to aid in the conduct of business.

Responsibility, Methodology & Approval Practice

Certain trade associations within MPIF have established standards committee and subcommittee activities composed of technical people who are responsible for developing standards within their area of expertise. These groups typically meet twice per year for face-to-face meetings (one-two days).

MPIF Standards Development Committee activities are populated on a volunteer-basis and financially supported by the various segments of the PM industry. These activities that provide standards development and input (and may include material specifications development/other activity) include:

- [MPIF Standards Committee](#) (conventional PM parts makers and powder producers)
- PM Self-Lubricating Bearings Subcommittee (bearings parts makers and powder producers)
- PF Subcommittee (PF parts makers and powder producers)
- [MIIMA Standards Committee](#) (MIM parts makers and powder producers)
- [MPPA Standards Committee](#) (conventional PM powder producers) – Maintenance and issuance of standardized methods of test for metal powders
- AMAM Standards Committee (AM parts makers, powder suppliers, and equipment/service providers)
- [ANSI B11.16-2014 \(MPIF #47\)](#), PM Press Safety Standards Subcommittee (safety personnel from PM compacting press-builders, end-user PM parts makers, and safety-related equipment suppliers)

MPIF standards development is based on the principle that standards follow (common industry practice); they do not lead.

MPIF test method standards comprise standard methods and practices/guides. These are developed as follows:

- A new standard is developed by the appropriate group when an existing need is identified within the industry by its members.
- Standardized practices/guides are developed to demonstrate the appropriate procedures to follow for achieving a certain task. Guides may reflect various industry practice(s). They may include procedures that demonstrate commonality of practice based on existing industry procedures that may be published in the literature (or by suppliers/producers). Guides may serve as a precursor to a future standardized method development.

New standards/guidelines and revisions to existing standards must be approved by the corporate voting members of MPIF as a whole, following established legal guidelines that include:

- no substantive issue(s), and
- approval by constituent association proposing new standard/revision for adoption.

The process of adoption/approval of proposed new standards or revisions to existing standards is conducted by letter ballot.

Precision Statements

Where practicable, Precision Statements (that demonstrate repeatability [r] and reproducibility [R]) are developed for the appropriate test method standard. Precision Statements are based on data reported from interlaboratory precision studies (ILS) conducted for this purpose and in accordance with [ASTM E691-16, Standard Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method](#).

Periodic Review

- MPIF Standards are subject to periodic review (typically on a 5-year review cycle).
- Standards may be revised at any time by the MPIF group responsible for their creation, subject to established approval practice.

Other

MPIF test method standards are comparable with, and may be harmonized with, other major standards developing organizations, e.g., ASTM and ISO.

MPIF Standard Test Methods for Metal Powders and Powder Metallurgy Products that Relate to Additive Manufacturing	
Definitions/Terms	
09	Terminology of Powder Metallurgy (Reprinted with permission from ASTM B243-13)
Testing of Metal Powders	
*** 01	Sampling Metal Powders

*** 02 Loss of Mass in a Reducing Atmosphere for Metal Powders (Hydrogen Loss)
*** 03 Flow Rate of Free-Flowing Metal Powders Using the Hall Apparatus
*** 04 Apparent Density of Free-Flowing Metal Powders Using the Hall Apparatus
*** 05 Sieve Analysis of Metal Powders
*** 06 Acid Insoluble Matter in Iron and Copper Powders
*** 28 Apparent Density of Non-Free Flowing Metal Powders Using the Carney Apparatus
*** 32 Average Particle Size of Metal Powders Using Air Permeability
*** 46 Tap Density of Metal Powders
*** 48 Apparent Density of Metal Powders Using the Arnold Meter
Testing of PM Products
42 Density of Compacted or Sintered Powder Metallurgy (PM) Products
43 Apparent Hardness of Powder Metallurgy Products
51 Microindentation Hardness of Powder Metallurgy Materials
54 Density of Impermeable Powder Metallurgy Materials
66 Total Carbon Content (Sample Preparation/Determination) of Powder Metallurgy (PM) Materials (Excluding Cemented Carbides)
Other Testing
*** 53 Volume of the Apparent Density Cup—Hall/Carney Apparatus
67 Sample Preparation for the Chemical Analysis of the Metallic Elements in PM Materials
69 Determination of the Porosity in Powder Metallurgy Products Using Automated Image Analysis

*** denotes standards under the jurisdiction of MPIF’s Metal Powder Producers Association

Referenced in [ASTM F3049-14, Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes](#)

1.5.10 MTConnect Institute (MTConnect)

Digital manufacturing depends on data from a diverse set of industrial equipment on the factory floor. Uniform, robust communications are part of the necessary infrastructure for modern business systems and 21st century analysis and decision-making. The MTConnect standard enables manufacturing equipment to provide structured, contextualized data with no proprietary format. With uniform data, developers and integrators can focus on useful, productive manufacturing applications rather than translation. MTConnect data sources include things like production equipment, sensor packages, and other hardware. Applications using MTConnect data provide more efficient operations, improved production optimization, and increased productivity. Scalable system architectures depend on standards. MTConnect provides domain-specific vocabulary and data models, is extensible, and integrates with other standards by design. The MTConnect Institute recently received its ANSI Standards Developer accreditation for future version releases; including extensions for additive manufacturing.

The MTConnect Institute efforts to extend the standard into additive manufacturing

Scope: Working Group (WG) on Additive Manufacturing: The Additive Manufacturing Working Group works to enhance the ways in which the MTConnect standard and schema handle data items that are specific to additive manufacturing machines and processes. The WG is prioritizing data items that are necessary across all ASTM F42-defined processes.

Purpose: To extend the MTConnect standard's data dictionary in order to support information transfer from a data source (i.e., additive manufacturing equipment) to an MTConnect agent and subsequently transfer those electronic documents from an MTConnect agent to a client software application. Given the increased demand for additive manufacturing equipment definitions and semantic information models, the WG was formed by industrial original equipment manufacturers (OEMs) and is being driven by the industrial community with a consensus-based approach.

1.5.11 SAE International (SAE)

SAE International is a global association of over 127,000 engineers and technical experts serving as the ultimate knowledge source for the mobility engineering profession. As the world's largest aerospace consensus standards developing organization, SAE maintains over 8,500 active aerospace technical standards utilized by the military and civilian aviation industry, government, and research stakeholders.

SAE International Additive Manufacturing Aerospace Standardization Activity

Established in July 2015, SAE AMS-AM, Additive Manufacturing, is a technical committee in SAE International's Aerospace Materials Systems Group responsible for developing and maintaining aerospace material and process specifications and other SAE technical reports for additive manufacturing, including precursor materials, additive processes, system requirements and post-build materials, pre-processing and post-processing, nondestructive testing, and quality assurance.

The objectives of the AMS-AM committee are to:

- Develop Aerospace Material Specifications (AMS) for the procurement of additive precursor and manufactured materials including metals, plastics, ceramics, composites, and hybrids made by additive technologies. When applicable, the material specification is tied to the appropriate shared material property database.
- Publish recommended practices, specifications, and standards for processing and fabrication of aerospace end products from AM materials.
- Further the adoption of industry sponsored material specifications through coordination with the [Metallic Materials Properties Development and Standardization \(MMPDS\) Handbook](#), [Composite Materials Handbook \(CMH-17\)](#), [ASTM Committee F42 on Additive Manufacturing](#), [AWS D20](#), [ASTM Committee E07.10 on Specialized NDT Methods](#), [Nadcap Welding Task Group](#), other AMS committees and associated organizations.

- Coordinate requirements for publishing data in shared material property databases with the MMPDS Emerging Technology Working Group for new metallic materials and CMH-17 for new polymer and composite materials.
- Establish a system to ensure material specifications are controlled and traceable to statistically substantiated data analyzed by documented procedures.

Given the unique certification requirements for critical aerospace applications, in October 2015, the Federal Aviation Administration (FAA) submitted a tasking letter to SAE requesting the development of specifications for additive manufacturing technologies that will support the FAA in preparing guidance material for AM certification. SAE's Aerospace Materials Specifications support the certification of aircraft and spacecraft critical parts by protecting the integrity of material property data and providing traceability within the supply chain. Industry consensus standards for additive manufacturing of aerospace parts are an enabler for the migration from part qualification to material qualification. An integral part of specification development is deriving specification minimum values for lot acceptance of the final AM processed material.

Over 300 global participants from more than 15 countries representing aircraft, spacecraft, and engine OEMs, material suppliers, operators, equipment/system suppliers, service providers, regulatory authorities, and defense agencies are active in the committee. There are currently six subcommittees: Metals, Polymers, Nondestructive Inspection, General, Data Management, and Regulatory Coordination.

In 2002, prior to the establishment of AMS-AM, SAE's AMS-G Committee on Titanium, Beryllium & Refractory Materials released the first additive manufacturing material specification, [AMS4999A, Titanium Alloy Direct Deposited Products 6Al - 4V Annealed](#). The document was revised in 2011 and subsequently transferred to AMS-AM in 2017.

Four initial material and process specifications were published in June 2018 which encompass the additive manufacture of aerospace parts from Ni-base Alloy 625 via the laser powder bed fusion process. As of June 2018, AMS-AM has 12 Works in Progress for aerospace metallic and non-metallic materials and processes specifications.

Metallic AM Specification Framework/Hierarchy

The AMS-AM Committee has adopted a framework for creating aerospace additive manufacturing metallic material and process specifications that is hierarchical in its structure. It starts with the final product material specification as the parent with supporting AM process and feedstock material specifications as child specifications (Figure 3). The material specifications are results oriented and contain the chemistry, microstructure, performance, and heat treatment requirements. Because AM materials are process intensive, additional supportive process specifications are included as requirements. The process specifications are not prescriptive but establish the necessary controls to ensure quality and consistency in the material produced by AM processes. The key requirement of the process specifications is the process control documentation (PCD), a collection of revision-controlled documents and procedures that are fixed and that are validated and substantiated through chemical,

metallurgical and mechanical testing protocols to demonstrate equivalency and repeatability. The fixed process is what is used to establish lot acceptance, quality control specification minimums.

The SAE AMS-AM material and process specifications are designed to work together to establish the typical requirements and controls for producing AM materials using AM processes. The parent material specification is very similar in structure and function as a conventional AMS material specification and establishes the requirements for chemistry, microstructure, mechanical properties, heat treatment and nondestructive inspection.

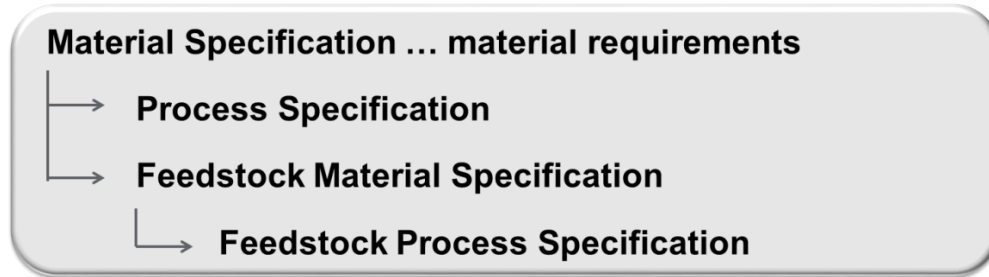


Figure 3: SAE AMS-AM Metals specification hierarchy

The feedstock material specification contains the material requirements, such as chemistry, and special manufacturing requirements for the feedstock material, such as melting method and gas environment. The process specifications establish the necessary controls to ensure consistency and quality of both the feedstock and the final AM processed material. Figure 4 provides an example of how requirements can be established and flowed down from the customer by purchase order, statement of work, contract, drawings, or other specifications.

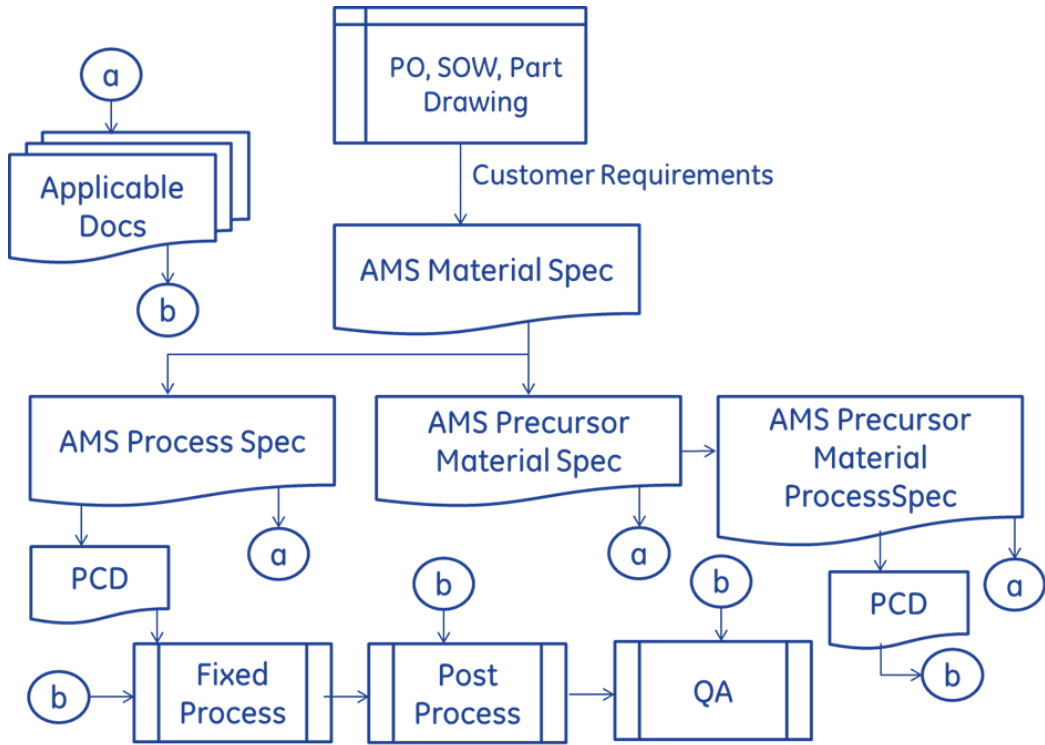


Figure 4: Flow diagram of control document precedence and customer requirements flow-down

Polymer AM Specification Framework/Hierarchy

SAE International’s AMS AM-P is a subcommittee of AMS-AM initiated in January 2017 at the request of the International Air Transport Association (IATA) to assist airlines utilizing additive manufacturing to produce cabin parts. The subcommittee’s documents will also support the broader aerospace industry’s interest in qualifying polymer AM parts. The initial three specifications under development provide technical requirements and quality assurance provisions for the Fused Deposition Modeling process and material feedstock characterization needed to produce high quality parts for aerospace applications utilizing Stratasys ULTEM™ 9085 and ULTEM™ 1010.

AMS AM-P is developing a unique specification framework applicable for both filled and unfilled polymers. Working closely with the National Institute for Aviation Research (NIAR) FAA-funded project to develop a framework for qualification of polymer-based AM materials, AMS AM-P industry specs will assist with the transition of the test data into shared databases such as CMH-17. The framework under development includes a base specification, which will include estimated values for selected mechanical properties, and in some cases, a detailed specification (or slash sheet), which will contain the statistically derived specification minimum values.

Aerospace Materials

As with any other conventional material, by establishing controls on the manufacturing process, consistent and predictable results can be attained in the material chemistry and microstructure, thereby

resulting in consistent and predictable properties and performance. The current SAE AMS-AM additive manufacturing specification strategy establishes controls on the input feedstock and AM process while relying on existing standards and specifications for commodity processes such as heat treatment and nondestructive inspection (NDI) as shown in Figure 5:

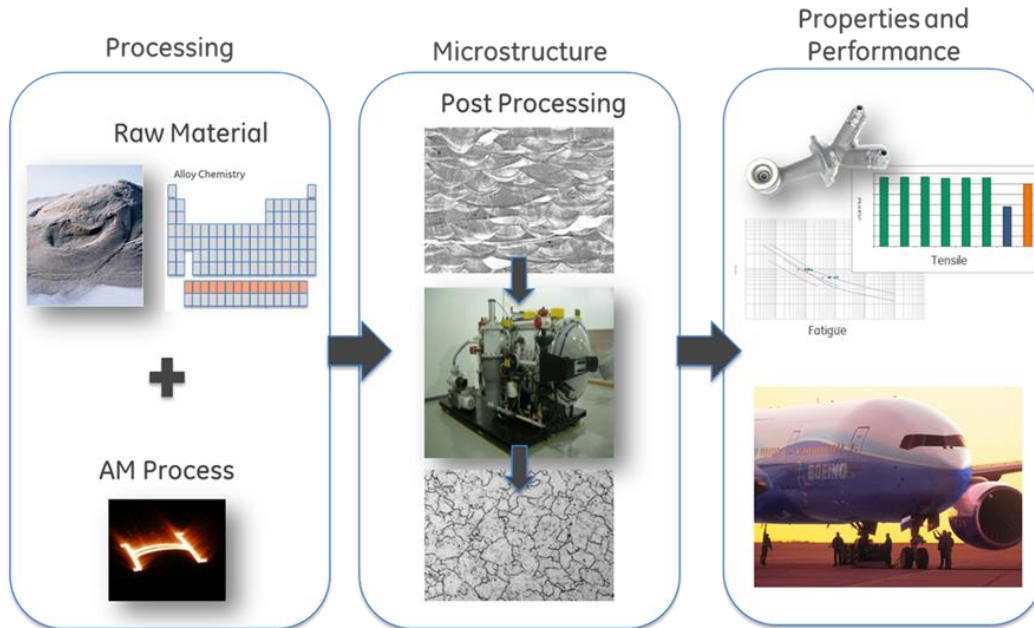


Figure 5

Additive materials cover a broad range of material forms: commodity metals with isotropic properties, commodity metals with anisotropic properties, tailored materials with anisotropic properties, and composite materials with anisotropic properties. The AMS-AM Committee’s initial projects will focus on commodity materials with isotropic properties and as experience is gained with tailored microstructures and hybrid and composite materials, AMS specifications will be developed for these more complex materials.

Data Management

The Data Management Subcommittee has finalized AM Metallic Data Submission Guidelines and is developing AM Polymers Data Submission Guidelines. The Guidelines will be used to establish statistically determined minimum values for the mechanical properties when the specified property (e.g., tensile yield and ultimate strength, elongation, compression yield strength, fracture toughness, modulus, Poisson’s Ratio, flex strength) is included in the AM material specification. Such values are not intended to be used in designing actual parts. The minimum values in the metallic specifications and detailed polymer specifications are to be used as lot acceptance for the final AM processed material. Since the purpose of the specification minimum values is to assess the consistency of the AM material being produced per the SAE AM process specification, the requirements for testing are dependent upon

the actual material and process specification under consideration. Specification minimum values are determined from coupons that meet the requirements of a defined SAE AMS-AM feedstock specification and the specimens produced to an established Process Control Document that complies with the requirements of the cognizant SAE AMS-AM process specification. The Guidelines define the minimum data requirements for lot release quality control specification minimum per machine manufacturer.

Current List of Published Standards from SAE AMS-AM

Published Standards – Metals Subcommittee

Project	Title
AMS7000	<i>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</i>
AMS7001	<i>Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 62Ni - 21.5Cr - 9.0Mo - 3.65 Nb</i>
AMS7002	<i>Process Requirements for Production of Powder Feedstock for Use in Laser Powder Bed Additive Manufacturing of Aerospace Parts</i>
AMS7003	<i>Laser Powder Bed Fusion Process</i>

Current List of Works in Progress within SAE AMS-AM

Works in Progress – Metals Subcommittee

Project	Title
AMS7004	<i>Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate- Ti6Al4V-Stress Relieved</i>
AMS7005	<i>Plasma Arc Directed Energy Deposition Additive Manufacturing Process</i>
AMS7006	<i>Alloy 718 Powder</i>
AMS7007	<i>Electron Beam Powder Bed Fusion Process</i>
AMS7008	<i>Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, Ni-Cr22-Fe18-Mo9-Co</i>
AMS7009	<i>Additive Manufacturing of Titanium 6Al4V with Laser-Wire Deposition - Annealed and Aged</i>
AMS7010	<i>Laser-Wire Directed Energy Deposition Additive Manufacturing Process</i>
AMS7011	<i>Additive Manufacture of Aerospace Parts from T-6Al-4V using the Electron Beam Powder Bed Fusion (EB-PBF) Process</i>
AMS7012	<i>17-4PH Powder for Additive Manufacturing</i>

Works in Progress – Polymers Subcommittee

Project	Title
AMS7100	<i>Fused Filament Fabrication Process</i>
AMS7100/1	<i>Fused Filament Fabrication - Stratasys Fortus 900mc Plus with Type 1, Class 1, Grade 1, Natural Material</i>
AMS7101	<i>Material for Fused Filament Fabrication</i>

AMS-AM Website

General Information on the AMS-AM Committee:

<http://www.sae.org/servlets/works/committeeHome.do?comtID=TEAAMSAM>.

Published documents are listed under the “Documents” tab on the metals and polymers subcommittee websites:

Metals: <http://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-M>

Polymers: <http://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-P>

Projects under development are listed under the “WIP” (Works in Progress) tab on the metals and polymers subcommittee websites:

Metals:

<http://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-M&inputPage=wlpS>

Polymers:

<http://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-P&inputPage=wlpS>

Additional SAE International Technical Committees with Interests in Additive Manufacturing

In addition to SAE’s AMS-AM, Additive Manufacturing Committee which specifically focuses on additive manufacturing, other SAE Technical Committees identified by the AMSC as having subject matter expertise relevant to AM include:

AMS Committee B, Finishes, Processes & Fluids prepares, coordinates, and revises documents related to processing technology, such as plating, brazing, coatings and compounds, through the participation of process suppliers, users, and interested government agencies. Committee activities shall provide a forum for the cooperative interchange of ideas and experience of the participants, resulting in the publication of specifications that embody sound, established aerospace industry practices and requirements to serve the suppliers and customers of aerospace processes. Areas of applicability to AM include heat treatment, hot isostatic pressing, and electron beam welding. For additional information, please visit: <http://www.sae.org/servlets/works/committeeHome.do?comtID=TEAAMSAB>.

AMS Committee G-8, Aerospace Organic Coatings provides a forum to address common concerns such as application, corrosion, environmental compliance, material compatibility, OSHA requirements, performance requirements, specifications, surface preparation, and test methods. For additional information, please visit: <http://www.sae.org/servlets/works/committeeHome.do?comtID=TEAAMSG8>.

AMS Committee K, Nondestructive Methods & Processes prepares, coordinates, and revises documents related to nondestructive testing technology, such as fluorescent penetrant, magnetic particle, X-ray, ultrasonic, and eddy current, through the participation of manufacturer's suppliers, users, airlines, and interested government agencies. For additional information, please visit: <http://www.sae.org/servlets/works/committeeHome.do?comtID=TEAAMSK>.

SMC G-33, Configuration Management Committee prepares practices, specifications, and standards dealing with technical data, drawing practices, and configuration management practices. It promotes understanding of configuration and data management principles and develops standards. For additional information, please visit: <http://www.sae.org/servlets/works/committeeHome.do?comtID=SMCG33>.

SMC G-41, Reliability Committee focuses on standards and handbooks that take a systems engineering approach to reliability that align best practices of reliability management, design and testing with reliability methods that provide the most value and the least risk in terms of achieving reliable products. The demand for highly-reliable systems/products prompted the development of ANSI/GEIA-STD-0009 (Reliability Program Standard for Systems Design, Development, and Manufacturing) and the corresponding handbook, TA-HB-009 (Reliability Program Handbook) that specifies a scientific approach to reliability design, assessment, and verification, coupled with integrated management and systems engineering. For additional information, please visit: <http://www.sae.org/servlets/works/committeeHome.do?comtID=TEASSTCG41>.

SMC LCLS, Life Cycle Logistics Supportability Committee focuses on standards and handbooks that facilitate the acquisition logistics process. By developing and maintaining supportability standards and handbooks, coalescing industry positions and preparing and coordinating positions on government policies and practices the committee is the industry innovation point for Logistics Product Data. Areas of applicability to AM include Level of Repair Analysis (LORA). For additional information, please visit: <http://www.sae.org/servlets/works/committeeHome.do?comtID=SMCLCLS>.

G-11M, Maintainability, Supportability & Logistics Committee addresses maintainability, supportability, and logistics tools, processes, procedures, and best practices. It provides an industry/government forum to review technology and investigates the interfaces with engineering design and development, support costs, maintainability, reliability, reparability, tooling, and diagnostics. Areas of applicability to AM include Reliability-Centered Maintenance (RCM) and Condition Based Maintenance (CBM). For additional information, please visit: <http://www.sae.org/servlets/works/committeeHome.do?comtID=TEAG11M>.

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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, and Maintenance. 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, 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 guidelines 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.

General Guides for AM

From the standards perspective, ASTM F42 and ISO TC261 have taken the lead in the development of design guidelines, though none currently exist as released standards.

Gap D1: Decision Support: Additive vs. Subtractive. 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: TBD

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.).

Priority: Medium

Status of Progress: Green (SME) in terms of a tool providing general guidance, though not a standard

Update: No standards are planned or in development. Commercial tools are available. SME and its [ITEAM](#) (Independent Technical Evaluation of Additive Manufacturing) are developing the RAPID Additive Manufacturing Platform (RAMP). The Additive Manufacturing Equipment and Materials Repository, a core aspect of RAMP, was released in beta, with beta testing continuing during the summer of 2018. The SAM-CT demo evaluation application will utilize RAMP. Application providers are being encouraged to develop additional additive manufacturing evaluation applications.

Organization: ISO/ASTM, AWS, SAE, SME

Gap D2: Decision Support: Additive Processes. 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 2017, ISO/ASTM published [ISO/ASTM 52910-17, Standard Guidelines for Design for Additive Manufacturing](#) (work item previously known as ASTM WK38342). 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.

R&D Needed: Yes. R&D is needed to identify trade-off criteria.

Recommendation: Continue work to complement what has been published in ISO/ASTM 52910-2017. 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: Medium

Status of Progress: Green. Gap partially closed in relation to standards with the publication of ISO/ASTM 52910-17.

Update: The gap statement and recommendation have been updated in light of the publication of ISO/ASTM 52910-17.

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

Process-Specific Guides for AM

ASTM and ISO plan to continue to jointly develop guidelines following the standards development framework they have agreed to (Figure 2). Accordingly, process-specific design guidelines are beginning to be developed. ISO/TC 261 and ASTM F42, via JG 57, are jointly developing technical design guidelines for laser-based powder bed fusion (PBF-L) for both metals ([ISO/ASTM DIS 52911-1](#), previously [ASTM WK59131](#)) and polymers ([ISO/ASTM DIS 52911-2](#), previously [ASTM WK59167](#)). These are similar in concept to an existing German standard VDI 3405. Work is ongoing for electron beam. There is another standard being contemplated on material extrusion. In addition, AWS is developing D20.1 which will address directed energy deposition (DED) and PBF processes.

Gap D3: Process-Specific Design Guidelines. There are no available AM process-specific design guidelines. The design guidelines currently being developed by JG 57 are process-specific design guidelines under joint development by ASTM F42 and ISO/TC 261. ASTM and ISO identify 7 types of AM processes, meaning that 6 AM processes do not have guidelines under development.

R&D Needed: No, for the guidelines on PBF. Not yet determined for the other six processes.

Recommendation: Complete work on the ISO/ASTM JG 57 design guidelines for PBF. Develop guidelines for the six other AM processes defined in [ISO/ASTM 52900:2015, Additive manufacturing -- General principles – Terminology](#).

Priority: Medium

Status of Progress: Green (ISO/ASTM) for PBF. Green (AWS) for PBF and DED. Not Started for the other processes defined in ISO/ASTM 52900.

Update: As noted in the text, ISO/ASTM JG 57 design guidelines are being developed for PBF-L for metals and polymers. Work on electron beam continues. AWS D20.1 will address PBF and DED, as noted in the text.

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

Design Guides for Specific Applications

Following the ASTM/ISO framework (Figure 2), 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.

Gap D4: Design Guides for Specific Applications. As industry fields mature in particular AM applications, best practices should be recorded.

R&D Needed: TBD

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

Status of Progress: Green

Update: ASME is working on design guides for pressure retaining equipment (e.g., pressure vessels). Other SDOs need to consult with their committees. Some of the SAE process specifications may address this.

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

Machine Customizable/Adaptive Guides for AM

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.

Gap D5: Support for Customizable Guidelines. 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. Guidelines on how to extend process and application guidelines would allow users to further adapt and specify to fit individual needs.

R&D Needed: Yes. Customizable guidelines require understanding process/machine/design characteristics and subsequent tradeoffs.

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: Medium

Status of Progress: Green

Update: ASTM WK54856, *New Guide for Principles of Design Rules in Additive Manufacturing*, has an expected release date of late 2018/early 2019.

Organization: ISO/ASTM

Gap D6: Software-encodable/Machine-readable Guidelines. In addition to design guidelines, complementary efforts have been initiated under [ASTM Committee F42 on Additive Manufacturing Technologies](#) (F42) to support the development of standardized design rules. Guidelines that are in development rely heavily on graphics/drawings and narrative through natural language, leaving often subjective interpretations. ASTM WK54856, *New Guide for Principles of Design Rules in Additive Manufacturing*, under development in ASTM F42, aims to provide explicit constructs from which explicit design rules can be developed and customized. These constructs will also provide a machine interpretable language that will support software implementation. The standard has an expected release date of late 2018/early 2019.

R&D Needed: Yes. The identification of fundamental constructs should mirror key characteristics and decision criteria for designs, materials, and processes.

Recommendation: Standardize a language that can be interpreted by both humans and machines so that design for AM can be simplified and communicated across platforms, and constraints can be encoded into design software.

Priority: Medium

Status of Progress: Green

Update: This gap is being addressed by ASTM WK54856.

Organization: ASTM, ISO, ASME, IEEE-ISTO PWG

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 6), 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.

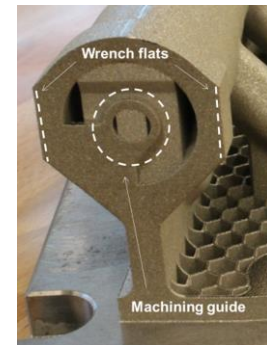


Figure 6: Hydraulic Manifold

- a. Has the design been optimized to reduce the need for support structure?
- b. If required for post-machining operations such as drilling, has a means to facilitate indexing been incorporated in the design?
- c. Have considerations for the fixturing of the part during post processing been incorporated in the design?
- d. 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?
- e. 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 are 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.

Published standards include:

- [ISO/ASTM 52910-17, Standard Guidelines for Design for Additive Manufacturing](#)

Standards in development include:

- **ASME B46 Project Team 52:** This is a relatively new effort started on 14 December 2015. It addresses Surface Finish in Additive Manufacturing.

Gap D7: Design Guide for Post-processing. There is a need for a design guide for post-processing.

R&D Needed: Yes

Recommendation: Develop a design guide for post processing

Priority: Medium

Status of Progress: Not Started

Update: ASME is not working on a design guide but ASME B46 Committee is working on measurement and characterization methods for AM surface finish. [ISO/ASTM 52910-17, Standard Guidelines for Design for Additive Manufacturing](#) 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.

Organization: ASME B46, ASTM F42/ISO TC 261

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.

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.

No published standards or standards in development have been identified.

Gap D8: 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: No

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 D20 on neutral build format.

Priority: Medium

Status of Progress: Not Started

Update: ASTM has a guide for storage of technical build cycle data which may address some of this.

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

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 understand and mitigate residual stress and process dependent deformation. There are a few simulation tools on the market in beta form but offered for sales and feedback. A standard for an AM benchmark model/part(s) to validate these simulation tools would benefit end users.

No published standards have been identified. ASTM is running an experimental protocol using a characterization tool (geometry and method) for AM. The tool is being developed as WK55297 by ASTM F42.

Gap D9: AM Simulation Benchmark Model/Part Requirement. A standard for a process-specific AM benchmark model/part is needed to enable verification and validation (V&V) of applicable process simulation tools.

R&D Needed: Yes. R&D is needed for characterizing processes using consistent, measurable and precise techniques.

Recommendation: Develop a standard for a process-specific AM simulation benchmark model/part. Canonical models that reproduce difficult-to-build features are needed for V&V.

Priority: Low

Status of Progress: Yellow

Update: An AM Bench Consortium led by NIST has been started.

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

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 52910-2017, Standard Guidelines for Design for Additive Manufacturing](#) 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.

The [NIST AM materials database](#), though not dealing with process chain per se, will aid in developing AM process chain.

Standards in Development

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.⁶ The guidelines cover saving and storing the build cycle data in order to meet quality system requirements.

NEW Gap D27: Standardized Design for Additive Manufacturing (DFAM) Process Chain. A standardized design is needed for AM process chain integrating key AM considerations/design tools in each design stage.

R&D Needed: Yes

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

⁶ 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>

can be expanded from [ISO/ASTM 52910-2017, Standard Guidelines for Design for Additive Manufacturing](#) 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: Medium

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

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 National Aeronautics and Space Administration (NASA) wrench⁷ 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.

⁷ <http://nasa3d.arc.nasa.gov/detail/wrench-mis>

Published standards related to this topic include:

- [ISO 8887-1:2017, Technical product documentation - Design for manufacturing, disassembling and end-of-life processing - Part 1: General concepts and requirements](#)
- [ASME Y14.46-2017, Product Definition for Additive Manufacturing \[Draft Standard for Trial Use\]](#)

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

Gap D10: 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 may need to account for complexity of support structures, removal times, post-processing complexity, 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. 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](#) and other DFMA standards can be reviewed and further developed to address AM related issues.

Priority: Low

Status of Progress: Not Started

Update: None provided

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

2.1.4.2 Design for Printed Electronics

The main effort in developing design standards for printed electronics is being led by Subcommittee D-61 out of IPC, which is the industry leading standards organization in printed circuit boards. The main document is [IPC-2292, Design Standard for Printed Electronics on Flexible Substrates](#), which establishes the specific requirements for the design of flexible printed electronic circuit applications and its forms of component mounting and interconnecting structures. The flexible materials used in the structures are comprised of insulating films, reinforced and/or non-reinforced, dielectric in combination with metallic

materials, conductive and non-conductive inks. These interconnecting structures may be single, double, or multilayer and can be comprised wholly of flexible substrates. This standard may also be used in conjunction with [IPC 2221B-2012, Generic Standard on Printed Board Design](#) and [IPC 2222A-2010, Sectional Design Standard for Rigid Organic Printed Boards](#) for the rigid sections of rigid-flex circuits as per [IPC 2223D-2016, Sectional Design Standard for Flexible Printed Boards](#). The D-61 Design Subcommittee is working in tandem with 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. See also roadmap section 1.5.6.

Gap D11: Design for 3D Printed Electronics. There is a need to develop standards on design for 3D printed electronics.

R&D Needed: No

Recommendation: Complete work on [IPC-2292, Design Standard for Printed Electronics on Flexible Substrates](#).

Priority: Medium

Status of Progress: Closed, with the publication of IPC 2292.

Update: IPC 2292 was published in March 2018. The [IPC D-66A, 3D Printed Electronics Processes Task Group](#) is in the early stages of developing a table of contents for a process guideline standard. This activity will take a considerable amount of time because there are so many processes, variables, materials, technologies, equipment, process environments, etc., to consider. 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 D4.

Organization: IPC

2.1.4.3 Design for Medical

AM has caused a revolution in healthcare delivery. New classes of 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 devices 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.

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

Gap D12: 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 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: No. 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.

Priority: Medium

Status of Progress: Green

Update: An RSNA 3D Special Interest Group (SIG) is working on best practices, not a standard. [ISO/ASTM NP 52916, Additive manufacturing -- Data formats -- Standard specification for optimized medical image data](#) from ISO/TC 261 JG 70 deals with imaging quality. This is a secondary priority for the DICOM WG.

Organization: RSNA (Radiological Society of North America), ASTM F42/ISO TC 261 JG 70, DICOM

Data Processing

Gap D13: 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. 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.

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: Medium

Status of Progress: Green

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 NP 52916, Additive manufacturing -- Data formats -- Standard specification for optimized medical image data](#) from ISO/TC 261 JG 70 covers this gap. An RSNA SIG is also looking at this.

Organization: Methods: NEMA/MITA, ASME V&V 40, ASTM F4, ASTM F42/ISO TC 261. Phantoms: NIST, FDA, RSNA

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, smoothing, and texturing functions are used to arrive at the final part to be manufactured.

Published standards for 3D modeling include the following:

- [P3333.2.1-2015, IEEE Recommended Practice for Three-Dimensional \(3D\) Medical Modeling](#)
 - This document describes the generation and practical use of medical three-dimensional (3D) modeling for diagnostics and therapeutic applications.
 - Volume rendering and surface rendering techniques for 3D reconstruction from two-dimensional (2D) medical images and a texturing method of 3D medical data for realistic visualization are included.

Standards in development for 3D modeling include the following:

- [P3333.2.2, Standard for Three-Dimensional \(3D\) Medical Visualization](#). In this document, 3D medical visualization is applied for the construction of a software system. It includes visualization techniques by automated medical shape detection and reconstruction of three-

dimensional (3D) models from two-dimensional medical images. It contains texturing of three-dimensional medical data for the intuitive visualization.

- [P3333.2.3, Standard for Three-Dimensional \(3D\) Medical Data Management](#). This standard in development deals with medical 2D and 3D data management, storage, compression for transfer, regulation for wired or wireless transfer, and search engine development for data retrieval.
- [P3333.2.4, Standard for Three-Dimensional \(3D\) Medical Simulation](#). This document includes:
 - standardization of three-dimensional medical simulations, which will help device development and related research;
 - simulation of the movement of joints and subsequent changes of skin, muscle, and neighboring structures;
 - a definition of joint range of motion, movement, and structure of skeleton for rigging work; and
 - a review of simulation devices such as haptic devices or software and hardware based on reality augmented equipment.

Design of Lattice Structures

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.

Published Standards include:

- [ANSI/AAMI/ISO 10993-1:2009 \(R2013\), Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process](#)
- [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.
- [ASTM F2971-13, Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing](#)
- [ASTM F3122-14, Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes](#)
- [ISO/ASTM 52901:2017, Standard Guide for Additive Manufacturing – General Principles – Requirements for Purchased AM Parts](#)
- [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)

Additionally, issues related to use of coupons for mechanical testing of AM devices are addressed in [ASTM F3122-14, Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes.](#)

Standards in development include:

- [ASTM WK60265, New Guide for Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder-bed Fusion](#)

Gap D14: Designing to be Cleaned. Currently there are no design guidelines for medical devices to assure cleanability after production. When designing a medical device, cleanability must be evaluated at different stages for a number of reasons:

1. To ensure manufacturing residues/contact materials encountered during the manufacturing process can be removed
2. To ensure that unmelted/unsintered AM material from the manufacturing process can be removed
3. For devices that are to be sterilized prior to use, to ensure that 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, to ensure the device can be adequately cleaned and sterilized prior to subsequent uses
5. For reusable devices, to ensure that the device materials can be maintained for the specified number of cleaning cycles

R&D Needed: Yes, in terms of ways to determine what parts are likely to be cleanable before they are made

Recommendation: Develop design guidelines to provide general design limits and recommendations that achieve both needed surface structure and allow adequate cleaning. See also Gap FMP3 and Gap QC15.

Priority: Medium

Status of Progress: Not Started

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

Organization: AAMI, ASTM F4, ASTM F42/ISO TC 261, ISO/TC 198, ASME (surface metrology), FDA

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. However, 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. Medical devices have complex geometries and contours and in addition may have lattice structures. One application where test coupons are frequently used is in the FDA evaluation of porous coatings for medical implants. Small sections of purpose-made porous coated material are tested to ensure that the manufacturing process obtains repeatable results within a specification that has been evaluated for safety. In the past, these coatings were sprayed or deposited on the surface of another part, which led to specific considerations for their wear adhesion and other properties. (See FDA Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements.) Test methods include abrasion testing and tensile testing of the coating/substrate interface.

As AM can allow the porosity to be designed into the part, which is then manufactured as a single piece, porous coating test methods may not be as relevant to evaluate porous AM structures. However, the use of test coupons to determine the capability and repeatability of the manufacturing process to make porous structures may still be useful. In addition, surface topography including at the nanoscale could impact the testing procedures. Therefore, there is a major challenge in designing test coupons for each production lot.

Gap D15: Design of Test Coupons. No standards are available for the design of test coupons for additively-manufactured porous structures.

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

Recommendation: Standards are needed for the design of test coupons for additively-manufactured porous structures.

Priority: Low

Status of Progress: Green

Update: ASTM F4 is looking at this.

Organization: ASTM F4 and F42

Gap D16: 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, there are no guidelines on considerations when validating their performance.

R&D Needed: Yes

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: Low

Status of Progress: Not Started

Update: ASME Y14.46 discusses the specification of functionally graded materials. New efforts are focusing on verification of lattice FGM specifications.

Organization: ASTM F4 and F42, SAE AMS-AM, ASME, ISO/TC 261 JG 67

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.

Technical Data Package (TDP) Content

TDPs 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 TDP. Additive manufacturing processes have not yet been standardized, and as a result the use of typical TDP content is not sufficient to procure parts made via these processes.

In terms of published standards, there is [MIL-STD-31000A, Technical Data Packages](#), though it is not AM-specific.

Gap D17: Contents of a TDP. The contents of a TDP 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

Recommendation: Develop a standard (or revise [MIL-STD-31000A, Technical Data Packages](#)) to describe all required portions of a TDP and adopt them into a formal standard. The standard should address at a minimum:

- 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
 - Tailorable and non-tailorable build parameters
 - Cybersecurity requirements (if necessary)
 - Long term archival and retrieval process (including acquisition)

Priority: High

Status of Progress: Green

Update: NIST has been involved in developing a number of component standards with various SDOs. DoD is pushing for a standard that defines the contents of a TDP to cover DoD products. DoD is in the process of updating 31000A2 revision B. ASME Y14.47, *Model Organization Schema Practices*, is based on Appendix B of MIL-STD-31000A. It should be available by the second quarter of 2018. DoD representatives are involved in the development of Y14.47 and Y14.46, which has a section specific to AM data packages. SAE G-33’s [SAE EIA649C, Configuration Management Standard](#), targeted for publication in the third quarter of 2018, provides guidance on specification control. There is a joint WG for digital product definition and data management under ASTM/ISO (JG 73).

Organization: ASME Y14.46, ASME Y14.47, ASTM F2/ISO TC 261, DoD AFRL, NIST, SAE G-33

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 related to this topic include:

- [ASME Y14.5, 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 essential 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, 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 issued the first version of this industrial standard on August 15, 2003 as ASME Y14.41-2003. It was immediately adopted by several industrial organizations, as well as the Department of Defense (DoD). ASME Y14.41 was revised and republished in May 2012 as ASME Y14.41-2012.
- [ASME Y14.46-2017, 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.

Standards in development include:

- ASME Y14 efforts are underway to specify universal direction and load indicator requirements. This 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 D18: New Dimensioning and Tolerancing Requirements. Although [ASME Y14.41, Digital Product Definition Data Practices](#) and other standards provide some capability in addressing some of the challenges in documenting AM designs, significant gaps still remain. ASME Y14.46 will address these gaps.

R&D Needed: No

Recommendation: Complete work on ASME Y14.46. See also Gap D26 on measurement of AM features/verifying the designs of features such as lattices, etc.

Priority: High

Status of Progress: Green

Update: [ASME Y14.46-2017, Product Definition for Additive Manufacturing \[Draft Standard for Trial Use\]](#) has been published and items within the standard related to this gap are still under development pending final approval. ASME Y14.48 on Universal Direction may also be relevant but that will not be available for another year or two. NIST provides a vice chair of the Y14 subcommittee 46.

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

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 SW, etc.) could result in materials properties that were not intended for the AM part design.

Gap D19: Organization Schema Requirement and Design Configuration Control. 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: No

Recommendation: ASME Y14.47, *Model Organization Schema Practices*, formerly known as Y14.41.1 may partially address this gap but AM related aspects need to be further developed. This standard should be available by the second quarter of 2018. 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

Status of Progress: Green

Update: As noted in the recommendation.

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

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. Also it does not scale well to high resolution and lattices. The AM File format (AMF) was developed with the assistance of ASTM; however, it has not been fully adopted throughout the industry. It does address some of the STL shortcomings; however, it is still not a complete solution. 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 Standard for the Exchange of Product model data file (STEP) 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.

It is extremely difficult to document many of the existing parameters and the laser track in a TDP. 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 related to this topic include:

- [ISO/ASTM 52915:2016, Specification for Additive Manufacturing File Format \(AMF\) Version 1.2.](#) The 2016 version of this standard revises the 2013 version.
- [ISO 10303-203:2011, Industrial automation systems and integration — Product data representation and exchange – Part 203: Application protocol: Configuration controlled 3D design of mechanical parts and assemblies.](#) Commonly referred to as STEP AP203 ("Standard for the Exchange of Product model data"), this non-AM-specific ISO standard "specifies the application protocol for configuration controlled three-dimensional design." This standard, along with ISO 10303-214, has been superseded by ISO 10303-242.
- [ISO 10303-242:2014, 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.](#)
- 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.

- 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 10303-238:2007](#) (also known as AP238).

Standards in development include:

- [ASTM WK48549, New Specification for AMF Support for Solid Modeling: Voxel Information, Constructive Solid Geometry Representations and Solid Texturing](#). ASTM F42.04 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.”

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 D20: Neutral Build File Format. No published or in development standards or specifications have been identified that incorporate build path or feedstock into a neutral file format. Further, 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 AM file format, which will help to better enable qualification of a design. However, the unique technologies of the different vendors could make such an effort challenging.

R&D Needed: Yes

Recommendation: Develop a new standard for the computer-interpretable representation and exchange of additive manufacturing product information that can represent all of the applicable slice files, build path, and feedstock, as well as the other applicable parameters into a single file format. This file would be used to exchange data between AM vendors and have the capability to be used instead of both the job files and material perimeter sets. This file format could make use of standard image formats and capture enough information to facilitate size, orientation and color normalization in post-processing of data. See also Gap D8 on machine input and capability report.

Priority: Low

Status of Progress: Not Started, or Unknown

Update: None provided

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

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 TDP.

Published standards addressing this topic include:

- [ISO/ASTM 52921:2013](#), *Standard terminology for additive manufacturing - Coordinate systems and test methodologies*, developed by ASTM F42.01 and adopted via a fast-track procedure by ISO/TC 261 under their PSDO cooperation agreement.
- [ISO/ASTM 52900:2015](#), *Additive manufacturing - General principles - Terminology*, developed by ISO/TC 261 and ASTM F42 in close cooperation under their PSDO cooperation agreement.
- [ASME Y14.46-2017, 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.

Gap D21: New Terminology in Design Documentation. While some AM terminology standards already exist, they do not include certain terms referred to in design documentation. Terminology in a TDP needs to be clear.

R&D Needed: No

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 52900:2015, Additive manufacturing -- General principles – Terminology](#).

Priority: Medium

Status of Progress: Green

Update: [ASME Y14.46-2017, Product Definition for Additive Manufacturing \[Draft Standard for Trial Use\]](#) 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. Since Y14.46 is a draft standard for trial use, comments are being accepted and there may be significant changes to the draft standard.

In-Process Monitoring

Additive manufacturing offers the capability to have significant in-process monitoring. The capability of in-process monitoring is expected to grow significantly 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. 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.

ASME is in the process of establishing a new committee to address advanced monitoring, diagnostic, and prognostic technologies for manufacturing.

A related gap (Gap PC16) is mentioned in 2.2.2 Process Control/2.2.2.11 Process Monitoring. PC16 involves converting in-process monitoring data into an accurate 3D file representing the manufactured part. 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).

Gap D22: In-Process Monitoring. 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](#)). No standardized data models or documentation have been identified for in-process monitoring and analytics. Given the current state of the technology, this is not surprising.

R&D Needed: Yes. R&D is needed to understand what in-process monitoring data is needed for verification and validation of the part. Research efforts have been undertaken that are devoted to the development of predictive computational models and simulations to understand the dynamics and complexity of heat and phase transformations. Although computational models and simulations are promising tools to understand the physics of the process, lack of quantitative representation of their prediction accuracy hinders further application in process control and optimization. Due to this reason, it is very challenging to select suitable models for the intended purpose. Therefore, it is important to study and investigate the degree of accuracy and uncertainty associated with AM models.

Recommendation: Develop standards for predictive computational modeling and simulation tools that link measured in-process monitoring data with product properties, quality, and consistency, as an important aspect of innovative structural design ([NIST, 2013](#)). See also Gap PC16 on in-process monitoring to obtain a layer-by-layer (3D) file or quality record showing the as-built part is defect-free or

contains no critical flaws, or exhibits an in-family (nominal) response when interrogated during the build.

Priority: Medium

Status of Progress: Green

Update: Office of Naval Research (ONR) is also researching this through their Quality Made program. NIST is developing a publically available schema for metals that may apply.

Organization: ASTM F42, ASME, IEEE-ISTO PWG

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, lightweighting, 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 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 include:

- [ASME Y14.46-2017, Product Definition for Additive Manufacturing \[Draft Standard for Trial Use\]](#), which establishes uniform TDP practices for AM.

Standards in development include:

- **ASME B46 Project Team 53.** This effort was started on December 14, 2015. It addresses Surface Finish in Additive Manufacturing.

Gap D23: 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: No

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

Priority: Low

Status of Progress: Green

Update: As noted in the recommendation. [ASME Y14.46-2017, Product Definition for Additive Manufacturing \[Draft Standard for Trial Use\]](#) has been published.

Organization: ASME

NEW Gap D28: 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.

R&D Needed: Yes

Recommendation: ASME should continue its work to develop [ASME B46.1-2009, Surface Texture \(Surface Roughness, Waviness, and Lay\)](#), to address specification requirements of AM surface finishes.

Priority: Medium

Organization: ASME

An Acquisition Specification

A specification will be required to procure AM parts from third parties.

Gap D24: An Acquisition Specification. A specification is needed to procure AM parts from third parties.

R&D Needed: No

Recommendation: ASTM should complete work on WK51282, *New Guide for Additive Manufacturing, General Principles, Requirements for Purchased AM Parts*.

Priority: Medium

Status of Progress: Closed

Update: [ISO/ASTM 52901, Additive manufacturing - General Principles - Requirements for Purchased AM Parts](#) was published in 2017. WK51282 was the earlier ASTM work item.

Organization: ISO/ASTM

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

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).

The Issue

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

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

- Guidelines for assessing the variations in material properties, microstructure, etc. of homogenous and functionally graded materials, such as how manufacturing parameters and post-processing affect the material properties.
 - This information would be useful when verifying that manufacturing parameters should result in the desired properties.
- 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
 - 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.

Published Standards

- Standardized material properties
 - Limited publications. ASTM F42 has published some material specifications, but their scopes include use of published properties in the design process. The properties are tensile only, and do not contain fatigue guidelines or thermal properties.

Committee	Standard	Title
ASTM F42	F2924-14	<i>Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion</i>
	F3001-14	<i>Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion</i>
	F3055-14a	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion</i>
	F3056-14e1	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion</i>
	F3184-16	<i>Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion</i>

- V&V that requires the definition and evaluation of unique features:
 - [ASME Y14.5-2009, Dimensioning and Tolerancing](#)
 - [ISO 17450-1:2011, – Geometrical product specifications \(GPS\) - General concepts - Part 1: Model for geometrical specification and verification](#) (ISO/TC 213)
 - [ASME B89.4.23, CT Measuring Machines \(SC4/B89\)](#)

- [ASME Y14.41-2012, Digital Product Definition Data Practices](#)
- 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. These tests can leverage methods available for castings, for example:

Committee	Standard	Title
ASTM E07.01	E1030/E1030M-15	<i>Standard Practice for Radiographic Examination of Metallic Castings</i>
	E1570-11	<i>Standard Practice for Computed Tomographic (CT) Examination</i>
	E1814-14	<i>Standard Practice for Computed Tomographic (CT) Examination of Castings</i>
ASTM E07.02*		
ASTM E08.05	E466-15	<i>Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials</i>
*There are numerous standard reference radiographs and digital reference images under the jurisdiction of ASTM E07.02 that may be useful when validating defects in AM parts.		

- 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 appropriate number of builds to validate a design for AM with respect to costs? 2) How much of the build volume needs to be captured?

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.

- Additional material specifications being developed by ASTM F42:

Committee	Standard	Title
ASTM F42	WK51329	<i>New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion1</i>

- ASME is also in the process of producing AM design guides, which may provide guidelines for design verification.

Committee	Standard	Title
ASME Y14, Subcommittee 46		<i>Product Definition for Additive Manufacturing</i>

Gap D26: Design for Measurement of AM Features/Verifying the Designs of Features such as Lattices, etc. As noted in Gap D18, 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 helices or other complex shapes, or internal features that are not compatible with common methods such as Go/NoGo 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, 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: Medium

Status of Progress: Not Started

Update: A standard on methods to verify that complex AM parts meet design requirements is needed. [ASME Y14.46-2017, Product Definition for Additive Manufacturing \[Draft Standard for Trial Use\]](#) 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 52910-17, Standard Guidelines for Design for Additive Manufacturing](#) 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.”

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

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.

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 Technical Data Package. Incorporating anti-counterfeiting at the design stage enables fast TDP compliance screening in the final product. Products that lack anti-counterfeiting measures may warrant additional scrutiny. See Process Control section 2.2.2.12 Anti-Counterfeiting and New Gap NDE7 in section 2.4.7 NDE of Counterfeit AM Parts.

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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 Introduction⁹

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, metal alloys, polymers, ceramics, and conductive inks which could vary greatly in their type, form, properties, and characteristics.

The technologies used to build a part will determine the physical form of the precursor materials, ranging from powder, wire, pellets, and filaments to liquids. 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 basic energy or no-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.). Conversely, no energy may be required during building, such as with binder jetting. In binder jetting, bonding of the precursor materials is performed as a post-processing operation.

⁹ The Precursor Materials working group defined the scope of this section as encompassing everything related to the precursor material until it leaves the facility where it was produced.

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 manufacturer or the business building the part. 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, wire or wire electrodes, or may be a commercial metal shape such as a plate or an existing manufactured shape, as used in repair, refurbishment, and returned-from-service applications. 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. Parts returned from service for repair or refurbishment pose the additional challenges of alloy identification and service history that may affect cleaning and preparation for AM refurbishment, as detailed within the Maintenance and Repair section of this roadmap.

Polymers

The precursor materials for additively manufactured polymer components are based on 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). The precursor material is in the form of powder for process (i), monofilaments or pellets for (ii), and liquid for (iii) and (iv).

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 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 monofilament 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.

In support of the development of polymer-based additive manufacturing, the National Institute of Standards and Technology (NIST) released in December 2016 the [Measurement Science Roadmap for Polymer-Based Additive Manufacturing](#), a guide that identifies future desired capabilities, challenges, and priority R&D topics in polymer-based AM. The report is the result of the “[Roadmap Workshop on Measurement Science for Polymer-Based Additive Manufacturing](#),” held June 9-10, 2016 at the NIST campus in Gaithersburg, Maryland. The workshop brought together nearly 100 AM experts from industry, government, national laboratories, and academia to identify measurement science challenges and associated R&D needs for polymer-based AM systems. Figure E-2 documents the primary challenges for polymer-based AM along with the priority roadmap topics within the categories of material characterization, process modeling, in-situ measurement, and performance.

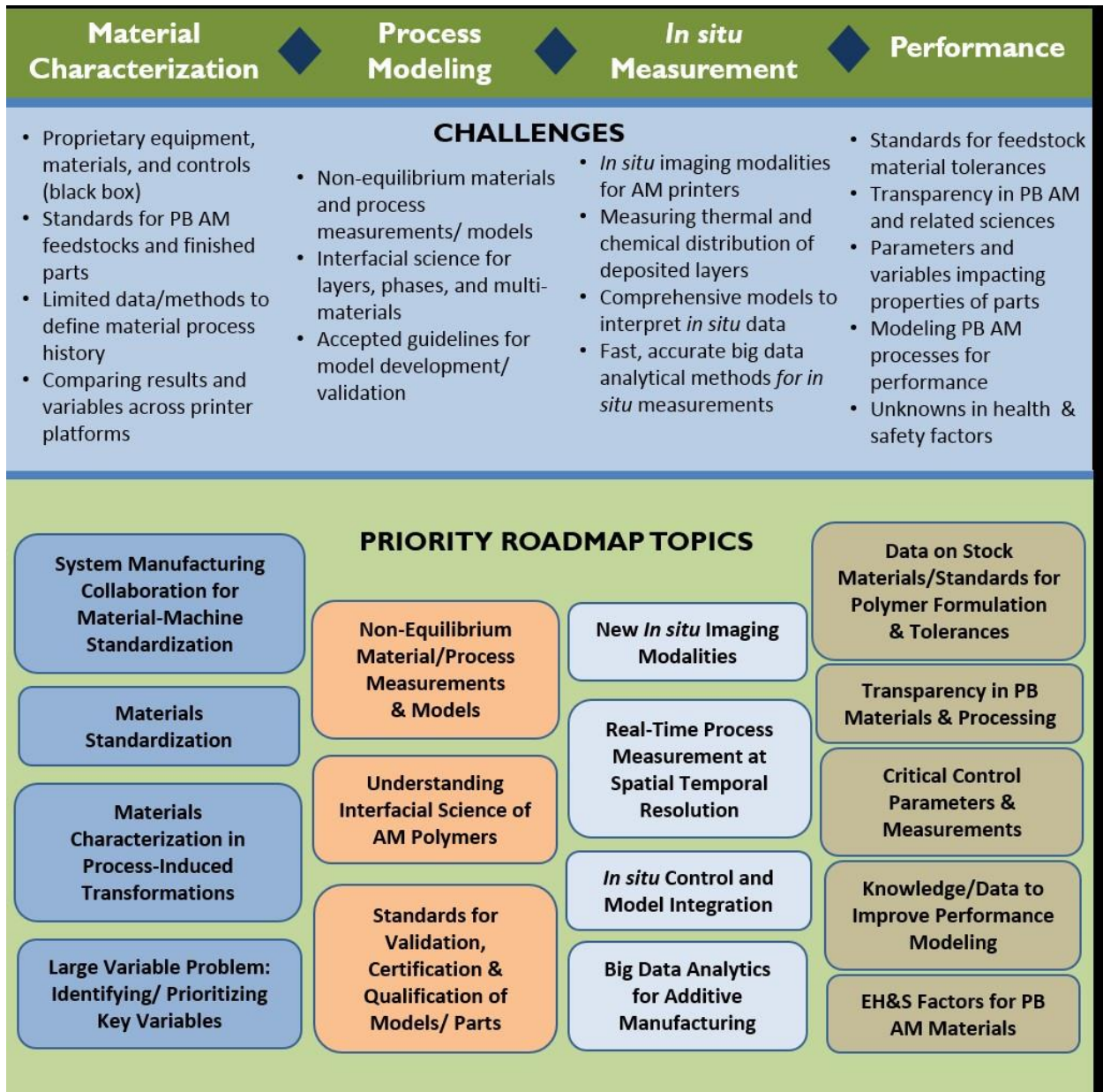


Figure E-2. Key Priority Topics and Challenges for Polymer-Based Additive Manufacturing
Used with permission of NIST¹⁰

¹⁰ From [Measurement Science Roadmap for Polymer-Based Additive Manufacturing](#)

2.2.1.2 Storage, Handling, and Transportation

Metals¹¹

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.

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 E2019-03\(2013\), Standard Test Method for Minimum Ignition Energy of a Dust Cloud in Air](#)
- [ASTM E1226-12a, Standard Test Method for Explosibility of Dust Clouds](#)
- [ASTM D1929-16, Standard Test Method for Determining Ignition Temperature of Plastics](#)
- DOT/UN Division 4.1 - Burning Rate Test
- DOT/UN Division 4.2 – Self-Heating Substances Test

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 69-2014, Standard on Explosion Prevention Systems, 2014 Edition](#)
- [NFPA 70-2017, National Electric Code \(NEC\) Softbound, 2017 Edition](#)
- [NFPA 77-2014, Recommended Practice on Static Electricity, 2014 Edition](#)
- [NFPA 91-2015, Standard for Exhaust Systems for Air Conveying of Vapors, Gases, Mists, and Particulate Solids, 2015 edition](#)

¹¹ This section does not discuss metal wire.

- [NFPA 499-2017, Recommended Practice for the Classification of Combustible Dusts and of Hazardous \(Classified\) Locations for Electrical Installations in Chemical Process Areas, 2017 edition](#)
- [NFPA 654-2017, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, 2017 edition](#)
- [NFPA 484-2015, Standard for Combustible Metals, 2015 Edition](#)
- [NFPA Fire Protection Handbook, 20th Edition](#)

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

ISO/TC 261 and ASTM F42 are considering the need for additional standards to address safety concerns specifically associated with additive manufacturing.

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 654-2017](#). In addition, [NFPA 652-2016, Standard on the Fundamentals of Combustible Dust](#) could also provide additional guidelines for proper handling of polymer dust.

See also Gap PC9 on environmental conditions: effects on materials.

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 includes 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

AM powder chemical characterization (including elemental composition, surface oxidation, 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 E322-12, Standard Test Method for Analysis of Low-Alloy Steels and Cast Irons by Wavelength Dispersive X-Ray Fluorescence Spectrometry](#)
- [ASTM E1085-16, Standard Test Method for Analysis of Low-Alloy Steels by Wavelength Dispersive X-Ray Fluorescence Spectrometry](#)
- [ASTM E572-13, Standard Test Method for Analysis of Stainless and Alloy Steels by Wavelength Dispersive X-Ray Fluorescence Spectrometry](#)
- [ASTM E353-14, Standard Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys](#)
- [ASTM E1019-11, Standard Test Methods for Determination of Carbon, Sulfur, Nitrogen, and Oxygen in Steel, Iron, Nickel, and Cobalt Alloys by Various Combustion and Fusion Techniques](#)
- [ASTM E2465-13, Standard Test Method for Analysis of Ni-Base Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry](#)
- [ASTM E2594-09\(2014\), Standard Test Method for Analysis of Nickel Alloys by Inductively Coupled Plasma Atomic Emission Spectrometry \(Performance-Based Method\)](#)
- [ASTM E2823-17, Standard Test Method for Analysis of Nickel Alloys by Inductively Coupled Plasma Mass Spectrometry \(Performance-Based\)](#)

- [ASTM E1479-16, Standard Practice for Describing and Specifying Inductively Coupled Plasma Atomic Emission Spectrometers](#)
- [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)
- [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 06, Method for Determination of Acid Insoluble Matter in Iron and Copper Powders](#)

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 E539-11, Standard Test Method for Analysis of Titanium Alloys by X-Ray Fluorescence Spectrometry](#)
- [ASTM E2371-13, Standard Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry \(Performance-Based Test Methodology\)](#)
- [ASTM E1941-10\(2016\), Standard Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis](#)
- [ASTM E1447-09\(2016\), Standard Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method](#)
- [ASTM E1409-13, Standard Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion](#)

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](#)
- [CSN EN 14242, Aluminium and aluminium alloys - Chemical Analysis - Inductively coupled plasma optical emission spectral analysis](#)

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.

NEW 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, 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.

Priority: Low

Organization: ASTM F42/D20, SAE AMS-AM

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.

Identified published standards not specific to AM include:

- [ASTM B213-17, 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](#)
- [ISO 4490:2014, 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](#)
- [ASTM D7891-15, Standard Test Method for Shear Testing of Powders Using the Freeman Technology FT4 Powder Rheometer Shear Cell](#)

- [ASTM D1895-17, Standard Test Methods for Apparent Density, Bulk Factor, and Pourability of Plastic Materials](#)

Identified standards in development include:

- Draft document [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
- Draft document [ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder](#), being jointly developed as JG 66 by ISO/TC261 and ASTM F42

Gap PM1: Flowability. Existing standards for flowability do not account for the range of conditions that a powder may encounter during shipment, storage, and the AM process.

R&D Needed: Yes. R&D is needed to measure and quantify flowability, especially with powder bed processing.

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. Recommend also completion of [ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder](#), which points to published standards for flowability tests along with consideration of how the state of the powder would affect the flowability measurement. See also Gap PC12 on precursor material flow monitoring.

Priority: Medium

Status of Progress: Green

Update: As noted in the text, ASTM WK55610 and ISO/ASTM DIS 52907 are in development. Completion of those work items may partially but not fully address the gap.

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

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.

Identified standards in development include:

- Draft document ISO/ASTM WK55610 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 [D6128-16](#), [D6773-16](#), and [D7891-15](#)).

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

R&D Needed: Yes. R&D is needed to measure and quantify spreadability, as well as to correlate powder characteristics with spreadability.

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: Medium

Status of Progress: Not Started, or Unknown

Update: There are no ASTM standard test methods for spreadability.

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

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.

Identified published standards include:

- [ISO 3923-1:2008, Metallic powders - Determination of apparent density - Part 1: Funnel method](#)
- [ISO 3953:2011, Metallic powders - Determination of tap density](#)
- [ASTM B527-15, Standard Test Method for Tap Density of Metal Powders and Compounds](#)
- [ASTM B212-17, Standard Test Method for Apparent Density of Free-Flowing Metal Powders Using the Hall Flowmeter Funnel](#)
- [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.

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, 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.

A number of applicable powder metallurgy standards exist 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 B215-15, Standard Practices for Sampling Metal Powders](#)
- [ASTM B822-17, Standard Test Method for Particle Size Distribution of Metal Powders and Related Compounds by Light Scattering](#)
- [MPIF Standard Test Method 32, Methods for Estimating Average Particle Size of Metal Powders Using Air Permeability](#)
- [ISO 9276 Parts 1-6, Representation of results of particle size analysis](#)
- [ISO 13320:2009, Particle size analysis - Laser diffraction methods](#)

Standards in development include:

- Draft document [ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder](#), being jointly developed as JG 66 by ISO/TC261 and ASTM F42

Gap PM3: Particle Size and Particle Size Distribution. While current standards for measurement of particle size and particle size distribution exist for powder metallurgy and can be leveraged for AM powders, the reliability and repeatability of different testing methodologies is currently unacceptable.

R&D Needed: Yes. Validation of various measurement techniques for reliability, repeatability, and correlation is required, possibly defining best measurement techniques for different build systems.

Recommendation: See R&D needed. For metal PBF, recommend completion of [ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder](#), which points to published standards for particle size analysis and discusses advantages and limitations of each referenced test method.

Priority: Medium

Status of Progress: Green

Update: As noted, ISO/ASTM DIS 52907 is in development as JG 66. Completion of this work item may partially but not fully address the gap.

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

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.

There are no AM-specific standards specifying how to quantitatively assess particle morphology. There is a specification for general powder metallurgy, [ASTM B243-17, 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.

Standards in development include:

- Draft document [ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder](#), being jointly developed as JG 66 by ISO/TC261 and ASTM F42

Gap PM4: Particle Morphology. No standards exist giving users of AM criteria for use of a particular powder feedstock based on the powder morphology.

R&D Needed: Yes. R&D is needed to measure and quantify particle morphology.

Recommendation: Based on the results of R&D, a standard may be needed to define accepted test methods 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. Recommend completion of [ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder](#), which points to published standards for describing particle morphology.

Priority: Low

Status of Progress: Green

Update: As noted, ISO/ASTM DIS 52907 is in development as JG 66.

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

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 2.2.2.7 on precursor material handling: use, re-use, mixing, and recycling powder.

In terms of published standards, there are:

- [ISO 3954:2007, Powders for powder metallurgical purposes—Sampling](#)
- [ASTM B215-15, Standard Practices for Sampling Metal Powders](#)
- [ASTM F3049-14, Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes](#), which references existing powder metallurgy sampling practices covered in ASTM B215
- [MPIF Standard Test Method 01, Method for Sampling Metal Powders \(2016\)](#), which has similarities to ASTM B215 [SAE AMS7003, Laser Powder Bed Fusion Process](#), contains requirements for feedstock powder handling and storage plan.

Gap PM5: Metal Powder Feedstock Sampling. While existing powder metallurgy standards may be leveraged for AM use, they require tailoring for AM-specific situations. For example, sampling practices for 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.

R&D Needed: Yes, with respect to the re-use of powder during the build. See also Gaps PC7, PC10 and PC11.

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 re-use of powder.

Priority: High

Status of Progress: Green

Update: [SAE AMS7003, Laser Powder Bed Fusion Process](#) was published in June 2018 and addresses this issue. For metals specifically, members of MPIF's Association for Metal Additive Manufacturing (AMAM)

technical committee reviewed [MPIF Standard Test Method 01, Method for Sampling Metal Powders \(2016\)](#) and noted that challenges with standardizing powder sampling include variations for different powder alloy systems, additive manufacturing technologies, and the importance of powder purity to the application. ASTM B09 is currently reviewing the MPIF Std. Test Method 01. For polymers, there may be interest from ASTM D20 working in conjunction with ASTM F42.

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

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.

In terms of published standards, there are:

- [ASTM B922-17, Standard Test Method for Metal Powder Specific Surface Area by Physical Adsorption](#)
- [ASTM B311-17, Test Method for Density of Powder Metallurgy \(PM\) Materials Containing Less Than Two Percent Porosity](#)
- [ISO 13947:2011, Metallic powders - Test method for the determination of non-metallic inclusions in metal powders using a powder-forged specimen](#)
- [ASTM B796-14, Standard test method for Nonmetallic Inclusion Content of Ferrous Powders Intended for Powder Forging \(PF\) Applications](#)
- [ASTM B923-10, Standard Test Method for Metal Powder Skeletal Density by Helium or Nitrogen Pycnometry](#)

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

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. 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. Recommend completion of [ISO/ASTM DIS 52907, Additive Manufacturing Technical Specifications on Metal Powder](#) and include measurement standards for powder internal porosity.

Priority: Low

Status of Progress: Unknown

Update: None provided

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

2.2.1.3.9 AM Process-Specific Metal Powder Specifications

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. However, there is a need for specifications to procure and accept metal powder so that compliance can be independently verified. SAE AMS-AM is developing AM powder standards for aerospace applications including [SAE AMS7001, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 62Ni - 21.5Cr - 9.0Mo - 3.65 Nb which was published in June 2018](#). In addition, ASTM F42 subcommittees for test methods ([F42.01](#)) as well as materials and processes ([F42.05](#)) are working in this area, having developed a draft (standard guide for creating feedstock specifications for metal powder bed fusion) that will most likely become a joint ISO/ASTM deliverable.

Gap PM7: AM Process-Specific Metal Powder Specifications. There is a need to develop AM process-specific metal powder specifications to ensure that a competitive supply of metal powder is available for procurement purposes. Further, vendors should be encouraged to use these industry powder specifications when testing their equipment and advertising final material properties.

R&D Needed: Yes. 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

Recommendation: Develop AM process-specific metal powder specifications to facilitate procurement of metal powders for use in AM machines. These specifications should describe the acceptable ranges of all relevant powder parameters that would impact the suitability of a given powder to be used in a given AM machine, and the effect it would have on final material properties.

Priority: Medium

Status of Progress: Green

Update: [ASTM WK58219, New Guide for Additive Manufacturing - Feedstock Materials-Creating Feedstock Specifications for Metal Powder Bed Fusion](#), is in development. [SAE AMS7001, Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 62Ni - 21.5Cr - 9.0Mo - 3.65 Nb](#), has some of the parameters defined and was published in June 2018.

Organization: ISO/ASTM, SAE AMS-AM, AWS, industry OEMs

2.2.1.4 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.

2.2.1.4.1 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.

Applicable standards and specifications include:

- [ASTM D4000, Standard Classification System for Specifying Plastic Materials](#)
- Specific ASTM Material classification documents (per D4000), for example:
- [ASTM D6779-17, Standard Classification System for and Basis of Specification for Polyamide Molding and Extrusion Materials \(PA\)](#)
- [ASTM D4101-17, Standard Classification System and Basis for Specification for Polypropylene Injection and Extrusion Materials](#)

Standards in development include:

- [SAE AMS7101, Material for Fused Filament Fabrication](#)

2.2.1.4.2 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.

2.2.1.4.3 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.

Applicable standards and specifications include:

- [ASTM D1238-13, Standard Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer](#)
- [ASTM D3418-15, 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 \(DMA T_g\) of Polymer Matrix Composites by Dynamic Mechanical Analysis \(DMA\)](#)

Standards in development include:

- [SAE AMS7101, Material for Fused Filament Fabrication](#)

2.2.1.4.4 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.

Applicable standards and specifications include:

- [ASTM D7191, Standard Test Method for Determination of Moisture in Plastics by Relative Humidity Sensor](#)
- [ASTM D6980, Standard Test Method for Determination of Moisture in Plastics by Loss in weight](#)

Standards in development include:

- [SAE AMS7101, Material for Fused Filament Fabrication](#)

2.2.1.4.5 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.

Applicable standards and specifications include:

- [ASTM D3895, Standard Test Method for Oxidative-Induction Time of Polyolefins by Differential Scanning Calorimetry](#)
- [ASTM D3012, Standard Test Method for Thermal-Oxidative Stability of Polypropylene Using a Specimen Rotator Within an Oven](#)

NEW 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.

R&D Needed: Yes, 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: Low

Organizations: ASTM F42/D20, SAE AMS-AM

2.2.1.5 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.

2.2.1.5.1 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.

2.2.1.5.2 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 or 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 D4212-16, Standard Test Method for Viscosity by Dip-Type Viscosity Cups](#)
- [ASTM D1084-16, Standard Test Methods for Viscosity of Adhesives](#)

2.2.1.5.3 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.

NEW 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. 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: Low

Organization: ISO/ASTM, Industry OEMs

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.

Existing process control standards include the following:

- [ASTM F3091/F3091M-14, Standard Specification for Powder Bed Fusion of Plastic Materials](#)
- [AWS D17.1/D17.1M:2010-AMD1, Specification for Fusion Welding for Aerospace Applications - AMD](#)
- [ASTM F3187-16, Standard Guide for Directed Energy Deposition of Metals](#)
- [SAE AMS7003, Laser Powder Bed Fusion Process](#)

Also relevant is auditing checklist AC7110/14, *Nadcap Audit Criteria for Laser and Electron Beam Metallic Powder Bed Additive Manufacturing*.

Process control standards in development include:

- ISO/ASTM PWI 52904, *Additive Manufacturing – Process Characteristics and Performance: Standard Practice for Metal Powder Bed Fusion Process to Meet Critical Applications*, being developed by ISO/TC 261 and ASTM F42 as JG 56), previously ASTM WK60906.
- [ISO/ASTM CD 52903-2, Additive manufacturing -- Standard specification for material extrusion based additive manufacturing of plastic materials -- Part 2: Process -- Equipment](#)
- [AWS D20.1, Standard for Fabrication of Metal Components using Additive Manufacturing](#)
- [ASME X-2019, Use of Additive Manufacturing for Pressure Retaining Equipment](#). Guideline standard under development by ASME with publication expected in 2019 to address manufacture of pressure retaining equipment using the additive manufacturing process. This “guide” is intended to initially address the use of laser and electronic beam powder bed fusion

to fabricate parts and items with emphasis on the final product produced using these two processes and the evaluation of the material properties of the finished product.

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 include [ISO/ASTM 52915:2016, Specification for Additive Manufacturing File Format \(AMF\) Version 1.2.](#)

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

Recommendation: Leverage NIST research and work with SDOs to ensure that AM process control standards include digital format and digital system control.

Priority: Medium

Status of Progress: Green

Update: The ISO/TC 261/ASTM F42 JG 56 standard in development addresses digital data configuration control.

Organization: NIST, ISO/ASTM JG 56, SAE, IEEE-ISTO PWG

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, 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.

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 include:

- [SAE AMS7003, Laser Powder Bed Fusion Process](#), includes requirements for a machine calibration and verification plan as well as an Appendix listing minimum measurement elements (metallic process).

Standards in development include:

- [AWS D20.1, Standard for Fabrication of Metal Components using Additive Manufacturing](#), contains requirements for the development of equipment calibration control plans.
- The ISO/TC 261/ASTM F42/JG 56 standard in development addresses periodic preventative maintenance. In addition, ASTM F42.01 and ISO jointly have about five artifacts in one standard, [ASTM WK55297, New Guide for Additive Manufacturing -- General Principles -- Standard Test Artefacts for Additive Manufacturing](#), that is nearing completion and that can be used for machine calibration and maintenance. [ISO/ASTM 52910-17, Standard Guidelines for Design for Additive Manufacturing](#), is also applicable.
- [SAE AMS7100, Fused Filament Fabrication Process](#), includes requirements for machine calibration procedures and preventative maintenance plans for the Fused Deposition Modeling process (polymer process).
- SAE AMS-AM plans to develop an aerospace recommended practice (ARP) for laser powder bed fusion machine calibration, metrology, and maintenance.

Gap PC2: Machine Calibration and Preventative Maintenance. There are no known industry standards addressing machine calibration and preventative maintenance for additive manufacturing. Current users may not have established best practices or their own internal standards and may assume that the 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.

R&D Needed: Yes. 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 addressing machine calibration and preventative maintenance. In addition, OEM and end user best practices should ensure adequate and recommended calibration and maintenance intervals that have been documented with data for different processes and machines. OEMs and SDOs should develop technical reports that incorporate case studies related to machine restart after maintenance. Standards should account for motion control components that guide measurement and remediation of error in positioning systems where possible in AM machines. OEMs should also take this into account when designing AM machines.

Priority: High. There is an urgent need to develop guidelines on day-to-day machine calibration checks.

Status of Progress: Green

Update: As noted in the text.

Organization: AWS D20, ASTM F42/ISO TC 261, SAE AMS-AM, NIST, OEMs, end users, experts in machine metrology

Gap PC3: Machine Health Monitoring. There are no known industry standards addressing 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

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](#).¹² 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, Tracking Maintenance.

¹² <http://dx.doi.org/10.6028/NIST.IR.8012>

Priority: Low

Status of Progress: Not Started, or Unknown

Update: ASME has a non AM-specific project concerning Advanced Monitoring, Diagnostics, and Prognostics for Manufacturing Operations.

Organization: NIST, ISO, ASTM, AWS, IEEE-ISTO PWG, ASME

2.2.2.4 Machine Qualification

To produce reproducible AM builds, it is necessary to ensure that the machine doing the build is qualified.

Published standards:

- [MSFC-STD-3716, Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals](#)
- [MSFC-SPEC-3717, Specification for Control and Qualification of Laser Powder Bed Fusion Metallurgical Processes](#)
- [ASTM F3301-18, Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion](#)
- For metals, [SAE AMS7003, Laser Powder Bed Fusion Process](#), includes requirements for machine calibration and machine approval.

Standards in development:

- [AWS D20.1, Standard for Fabrication of Metal Components using Additive Manufacturing](#), contains requirements for the fabrication and testing of PBF and DED standard qualification builds for AM machine qualification. Additionally, based on the category (i.e., criticality) of the part, the draft AWS D20.1 requires the fabrication of witness specimens along with each part build cycle to be tested to ensure that the machine is performing as expected.
- For polymers, [SAE AMS7100, Fused Filament Fabrication Process](#), includes requirements for machine calibration procedures and preventative maintenance plans for the Fused Deposition Modeling process (applicable to ULTEM 9085 and ULTEM 1010).
- NAVSEA is currently drafting a PBF specification that will address machine qualification as part of the manufacturing process prior to first article and production of a component or part.

Gap PC4: Machine Qualification. Current users may not have considered the influence of machine control on resulting product quality and material properties beyond form and fit, including machine-to-machine variation (even between machines of the same make and model). While guidelines for machine qualification can be developed, a broader view of part-specific, process-specific, material-specific, and application-specific recommended practices is needed.

R&D Needed: Yes

Recommendation: SDOs should develop qualification standards for AM machines to pass in order to provide a level of confidence that these machines can produce parts with the required material properties. In addition, SDOs should develop guidelines or technical reports that incorporate case studies of various part types and applications across materials. Additional research may be needed in relation to machine-to-machine variation and on key parameters.

Priority: Medium

Status of Progress: Green

Update: As noted in the text.

Organization: NIST, AWS, SAE AMS-AM, ASTM F42, NAVSEA, NASA MFSC

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, and between parts built with different AM machines of the same model. 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.

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.

No published standards have been identified.

AWS D20.1 has drafted extensive lists of process parameters (qualification variables) that must be controlled for a variety of metal AM processes. These processes include laser and electron beam powder bed fusion, and laser, electron beam, and arc directed energy deposition. The acceptability of the process parameters will be required to be demonstrated through the fabrication and testing of procedure qualification test pieces. Changes to the process parameters outside of a qualified range will

require full or partial requalification of the AM procedure. This philosophy is analogous to welding procedure qualification requirements.

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. Develop and establish one verifiable key process parameter that combines both material and process parameters (such as power absorption coefficient or power ratio parameter, verifiable by melt pool geometry, as shown in the research) that is independent of material and machine brand. R&D is needed to verify the concept of power ratio as the single controlling parameter and its applicability to all materials and machine brands.

Recommendation: Develop a standard that identifies key build process parameters for AM machines, taking into account the different processes, materials, industry-specific applications, and machines involved. Complete work on [AWS D20.1](#). See also Gap QC3 on harmonizing Q&C terminology for process parameters.

Priority: Medium

Status of Progress: Green

Update: As noted in the text, AWS D20.1 has been drafted. ASTM F42 process and materials standards cover the parameters for PBF and Inconel 625 but not the values. SAE AMS7100 is trying to address FDM process control including setting parameters for the aerospace industry. SAE AMS7003 includes an appendix on PBF-L process characteristics but contains no values.

Organization: AWS D20, ASTM F42, SAE AMS-AM, OEMs, IEEE-ISTO PWG

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.

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

Recommendation: Develop standards and specifications to address external environmental factors that could negatively impact component quality.

Priority: Low

Status of Progress: Unknown

Update: None provided

Organization: OEMs, DoD for military-specific operational environments, ASTM

2.2.2.7 Precursor Material Handling: Use, Re-use, 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 re-use of materials must meet the precursor material requirements. Similarly, handling of unused material is a critical enabler for product quality and re-use 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 section 2.2.1.3.7 on feedstock sampling.

Regarding precursor material handling, specifically terminology, [ISO/ASTM 52900:2015, Additive manufacturing – General principles – Terminology](#), contains the following terms and definitions:

Material supplier; Feedstock; Part cake; Powder batch; Powder blend; Powder lot; Used powder; and Virgin powder. [SAE AMS7003, Laser Powder Bed Fusion Process](#), contains requirements for feedstock powder handling and storage plans. No other published standards or standards in development have been identified.

Gap PC7: Recycle & Re-use of Materials. There are many practices in the materials industry of how to recycle, re-use, and revert materials in production. They are also highly material dependent. End users need to understand best practices for how to qualify their various precursor material streams.

R&D Needed: Yes. Research should be conducted to understand the effects of mixing ratios of reused to virgin material.

Recommendation: Develop guidance as to how reused materials may be quantified and how their history should be tracked (e.g., number of re-uses, number of exposure hours [for a laser system], or some other metric). Guidelines for sieving reused powder prior to mixing must be created.

Priority: High

Status of Progress: Green

Update: SAE is looking at it on the aerospace side. NIST has published one study on the subject on metals but more R&D is needed before you can build parts to be qualified.

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

Gap PC8: Stratification. Powders used in additive manufacturing are composed of a distribution of particle sizes. Stratification may take place during container filling, transportation, or handling before and after being received by a user of powder. Users must know what conditioning is appropriate to ensure that the powder's particle size distribution is consistent and acceptable for the specific process. There is currently a lack of guidance in this area.

R&D Needed: Yes. Research should be conducted to understand the effect of stratification on particle size distribution of as-received powder and mixed powder prior to being put into service. The results from this work can be used to guide the re-blending of powder before being put into service.

Recommendation: Develop guidelines on how to maintain OEM characteristics in new use and re-use powder scenarios. There is documented variability in the final part properties in various AM processes; the AM community must either rule out stratification of powder precursor material or provide guidelines for mixing of lots to achieve acceptable particle size distribution.

Priority: Medium

Status of Progress: Unknown

Update: None provided

Organization: NIST, trusted end user-group, ASTM

Gap PC9: Environmental Conditions: Effects on Materials. AM materials can be sensitive to changes in environmental conditions including temperature, humidity, and ultraviolet radiation. Therefore, general guidance must be provided to ensure the environmental conditions in which the material is used and stored remain within acceptable ranges for all material types. Specific material packaging requirements are addressed in Section 2.2.1.3.9. No standards or specifications have been identified regarding this topic.

R&D Needed: Yes

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

Priority: High

Status of Progress: Green

Update: [UL 3400, Outline of Investigation for Additive Manufacturing Facility Safety Management](#), is a document for the evaluation and certification of any additive manufacturing facility that uses powder as the initial form of feedstock material to print parts. It identifies the potential hazards within an AM facility, which includes environmental conditions. It does not provide specific reference to acceptable ranges for material storage within a facility. The effect of environmental conditions on AM materials can be dependent on a number of factors, which can vary by facility. UL 3400 provides guidance based on the requirements and conditions of the facility being evaluated. ASTM F42.06 is looking at environmental conditions for storage via work item [ASTM WK59813, New Guide for Hazard Risk Ranking and Safety Defense](#). [SAE AMS7003, Laser Powder Bed Fusion Process](#), contains requirements for feedstock powder handling and storage plans.

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

Gap PC10. Re-use of Material that Has Not Been Processed. There is a lack of industry guidance on the re-use of material that has not been processed.

R&D Needed: Yes

Recommendation: Develop a standard for the re-use of material that was not processed but is already within the system (e.g., for inkjet it can be in the plumbing, the reservoirs, the printing heads, etc.).

Priority: Medium

Status of Progress: Unknown

Update: None provided

Organization: ISO/ASTM

Gap PC11: Re-use of Material that Has Been Processed. There is a lack of industry guidance on the re-use of material that was already processed.

R&D Needed: Yes

Recommendation: Develop a standard for re-use of material that was already processed and cannot be reused as precursor material. For inkjet, there are two concerns: Material that was jetted but not polymerized and material that was polymerized to some extent (waste from each processed layer or the actual support material). Example: non-polymerized material that was jetted can be reused as material to fill bulky areas of the model (by filtering, re-jetting, and polymerizing).

Priority: Low

Status of Progress: Unknown

Update: None provided

Organization: ASTM

2.2.2.8 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](#), was published in October 2016 and 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

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: Medium

Status of Progress: Unknown

Update: None provided

Organization: NIST, ISO/ASTM

Inkjet (Material Jetting)

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

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: Low

Status of Progress: Unknown

Update: None provided

Organization: NIST, OEMs, ASTM, IEEE-ISTO PWG

2.2.2.9 Environmental Health and Safety: Protection of Machine Operators

Environmental, health and safety (EHS) is a key aspect of AM process control that includes protection of the operators from materials (hazardous and non-hazardous), protection of the materials from operator contamination, disposal of materials, and general operator safety in machine operation. The potentially significant weight of the materials, and accessory equipment to move materials, is also a consideration.

Research on indoor air quality, health, and human effects is underway between Underwriters Laboratories, Inc. (UL), Georgia Tech, and Emory University. Existing 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/ASSP¹³ Z9](#) series of standards that address industrial ventilation by scope and are specifically written to address dusts, vapors, and fumes
- [ANSI/ASSP Z10-2012 \(R2017\), Occupational Health and Safety Management Systems](#)
- [ANSI/ASSP Z244.1-2016, The Control of Hazardous Energy Lockout, Tagout and Alternative Methods](#), that addresses the issue of moving parts and accidental release of energy
- [ANSI/ASSP Z590.3:2011](#) that addresses prevention through design
- [Standards for risk management and risk assessment \(see below\)](#)
 - ANSI/ASSP/ISO Guide 73 (Z690.1-2011), *Vocabulary for Risk Management*
 - ANSI/ASSP/ISO 31000 (Z690.2-2011), *Risk Management – Principles and Guidelines*
 - ANSI/ASSP/ISO 31004, *Implementation for ISO 31000*
 - ANSI/ASSP/IEC/ISO 31010 (Z690.3-2011), *Risk Assessment Techniques*
- [ANSI B11](#) series of standards for machinery safety
- [ANSI Z136](#) series of standards for laser safety
- [ISO 11553-1:2005, Safety of machinery - Laser processing machines - Part 1: General 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.

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. Typical hazards to be addressed include: guarding from moving parts that are not protected from contact; chemical handling (liquids, powders, wires); 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). See Gaps P5 and P6 in section 2.2.3.6 related to health and safety, specifically to toxic gases/vapors from polymers.

R&D Needed: Yes

Recommendation: Recommend creating a standard addressing EHS issues relative to additive machines (power, laser, handling, air quality, etc.). Physical measurement of operator exposure to AM materials is one of the most critical needs and can be leveraged from existing industry standards. As noted in the text, research is underway.

Priority: High

¹³ On June 1, 2018, the American Society of Safety Engineers (ASSE) changed its name to the American Society of Safety Professionals (ASSP).

Status of Progress: Green

Update: UL has published [UL 3400, 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. [ASTM WK59813, New Guide for Hazard Risk Ranking and Safety Defense](#), is being developed to cover risks associated with different types of AM technologies and the recommended PPE and safety measures. [ISO/TC 261](#) has a Working Group on *Environment, health and safety* (ISO/TC 261/WG 6), and two Joint Groups with ASTM F42 on AM: *EH&S for 3D printers* (ISO/TC 261/JG 68) and *EH&S for use of metallic materials* (ISO/TC 261/JG 69).

Organization: ASTM F42/ISO TC 261, UL, ASSP, B11, LIA (Z136), ISO/TC 262

2.2.2.10 Configuration Management: Cybersecurity

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.

Existing standards and guidance include the following:

- [ABS Volume 1, Guidance Notes on the Application of Cybersecurity Principles to Marine and Offshore Operations \(revised and expanded\)](#)
- [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](#)
- [NIST Special Publication 800-82 Revision 2, Guide to Industrial Control Systems \(ICS\) Security, May 2015](#)
- [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](#)

Standards in development include:

- [UL 2900-2-2, Outline of Investigation for Software Cybersecurity for Network-Connectable Products, Part 2-2: Particular Requirements for Industrial Control Systems](#)
- [UL 2900-2-3, Outline of Investigation for Software Cybersecurity for Network-Connectable Products, Part 2-3: Particular Requirements for Security and Life Safety Signaling Systems](#)

The [NIST Cybersecurity for Smart Manufacturing Systems](#) project is also a resource on this topic.

Gap PC15. Configuration Management: Cybersecurity. Best practices for maintaining and controlling the programming environment for additive processes are needed to ensure repeatable product quality.

R&D Needed: Yes

Recommendation: Develop best practices to protect digital files used in the AM process. See also Gap M7 on cybersecurity for maintenance.

Priority: Medium

Status of Progress: Unknown

Update: None provided

Organization: America Makes, NIST, UL, IEEE-ISTO PWG

2.2.2.11 In-Process Monitoring

In-process monitoring is generally at a low technology readiness level (TRL) compared to more established NDE methods used to inspect parts after build (see gap NDE3). While systems are emerging and much research is being conducted, an analysis of in-process monitoring data will need to take into account the operator's level of knowledge of the process, maturity of the process, the design complexity of the component being manufactured, 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.

A related gap (Gap D22) is mentioned in 2.1 *Design* 2.1.5 *Design Documentation, In-Process Monitoring* section involving the use of physics-based models and simulation tools (analytics) to predict or optimize part properties by linking inputs (materials and processes) with final product outputs (microstructure and properties).

By comparison, the goal of Gap PC16 is to convert in-process monitoring data into an accurate layer-by-layer (3D) file or quality record that shows the part is defect-free or contains no critical flaws, or exhibits an in-family (nominal) response when interrogated. In this case, the data gathered is composed of real-time measurements of the part dimensions, surface finish, density, hot spots, or defect state.

Alternatively, when feedstock supply, process conditions, or process parameters are monitored during 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.

Gap PC16: In-Process Monitoring. No published standards have been identified that address 1) the conversion of in-process monitoring data into an accurate 3D file representing the part manufactured, or 2) the use of in-process monitoring data to self-monitor and self-calibrate processing equipment. 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. A standard guide is being developed in ASTM E07 (WK62181) that covers conversion of in-process monitoring data into an accurate 3D file representing the part manufactured, based on real-time measurement of part dimensions, surface finish, density, hot spots, or defect state during the build. Ideally, the information gathered during in-process monitoring is used to evaluate part acceptance, as a go/no-go before expensive post-processing operations are performed, and/or to guide NDE performed on the part after build.

R&D Needed: Yes. Seamless incorporation of sensor-based monitoring techniques into the build without interfering with the build is nontrivial. While commercial based systems have been developed (for example, visible-spectrum layer-wise imaging; co-axial melt pool monitoring (visible or near-infrared); infrared, off-axis thermography; single-point, and off-axis pyrometry and/or photodetectors), other techniques (for example, spectroscopic measurements of plume; high speed visible-spectrum imaging (stationary view); single-point surface profilometry; and in-situ laser ultrasonic or AE monitoring) are lower TRL and warrant additional R&D.

Recommendation: Issue standards on in-process monitoring of 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, density, hot spots, defect state). See also Gap D22 on the use of physics-based models and simulation tools (analytics).

Priority: Medium, given the relatively TRL state of the art

Status of Progress: Yellow

Update: ASTM E7.10 is developing a draft guide [WK62181](#) on in-process monitoring covering commercial based systems (visible-spectrum layer-wise imaging; co-axial melt pool monitoring (visible or near-infrared); infrared, off-axis thermography; single-point, off-axis pyrometry and/or photodetectors). Potentially, other techniques that show promise will be included (spectroscopic measurements of plume; high speed visible-spectrum imaging (stationary view); single-point surface profilometry; and in-situ laser ultrasonic or AE monitoring). The goal of WK62181 is to obtain a layer-by-layer (3D) file or quality record showing the as-built part is defect-free or contains no critical flaws, or exhibits an in-family (nominal) response when interrogated during the build. WK62181 does not address control of equipment functions such as feedstock supply, process conditions, or process parameters (no

known gap), or physics-based models or simulation tools used in prognostics or diagnostics (see Gap D22).

Organization: ASTM E07.10

2.2.2.12 Anti-Counterfeiting

Quality is compromised when a counterfeit substitutes for a genuine product. Cybersecurity, addressed in Section 2.2.2.10, 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 and New Gap NDE7 in section 2.4.7 NDE of Counterfeit AM Parts.

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 inspection, testing, and certification. These operations as a group are called post-processing. Post-processing differs depending upon the material and part being built; however, there are commonalities. These include removing excess material from the newly built part's external and internal surfaces, freeing the part from the build plate, heating operation(s) in the case of metal and some polymeric parts, machining or dissolving supports, machining of the part to final dimensional tolerances, and processing to attain the desired surface finish.

Post-processing procedures include post-build thermal heat treatments, hot isostatic pressing, sealing, chemical treatments, and surface 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.

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 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, which are currently under development. 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.

Gap P1. Post-processing Qualification and Production Builds. No known standards have been issued that require consistent post-processing to be applied for qualification and production builds.

R&D Needed: Yes

Recommendation: Guideline standards should be issued that require consistent post-processing for the various AM processes to be applied for qualification and production builds. These standards should be process and material specific and should seek to define minimum best practices for qualification and production builds, along with reporting requirements.

Priority: Medium

Status of Progress: Green

Update: For metals, AWS D20.1 is in development and SAE AMS7000 was published in June 2018. For polymers, ASTM F42/ISO TC 261 JG 55 is in development for material extrusion.

Organization: AWS D20, ASTM F42/ISO TC 261 JG 55, SAE

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 applied for additively-manufactured metal and non-metallic parts. 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. Additionally, depending on the alloy being heat treated, inert gas or other non-reactive atmospheres may be used 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) (e.g., ASTM Standard Specifications [F2924-14](#), [F3001-14](#), [F3055-14a](#) and [F3056-14e1](#)); however, more standards are needed for other materials and other processes. [SAE AMS4999A, Titanium Alloy Laser Deposited Products~6Al - 4V~Annealed](#), includes thermal processing information. Additional published heat treatment standards which may be applicable for heat treating additively manufactured parts include:

- [SAE AMS2750E, Pyrometry](#)
- [SAE AMS2759E, Heat Treatment of Steel Parts General Requirements](#)
- [SAE AMS2759/3F, Heat Treatment Precipitation-Hardening Corrosion-Resistant and Maraging Steel Parts](#)
- [SAE AMS2770N, Heat Treatment of Wrought Aluminum Alloy Parts](#)
- [SAE AMS2771F, Heat Treatment of Aluminum Alloy Castings \(applicable to AlSi10Mg, aka 359\)](#)
- [SAE AMS2774E, Heat Treatment, Wrought Nickel Alloy and Cobalt Alloy Parts](#)
- [SAE AMS2801B, Heat Treatment of Titanium Alloy Parts](#)
- [SAE AMS-H-6875B, Heat Treatment of Steel Raw Materials](#)
- [SAE AMS7000, 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](#)
- [ASTM A858/A858M-14, Standard Specification for Heat-Treated Carbon Steel Fittings for Low-Temperature and Corrosive Service](#)
- [ASTM F3301-18, Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion](#)

Another committee with relevant published standards is [ISO/TC 17/SC 4, Heat treatable and alloy steels](#).

In-Development Standards

There are several standards under development by ASTM that contain HT information for other materials produced by PBF ([ASTM WK51329](#), [ASTM WK53423](#)). SAE's Aerospace Metals Engineering Committee (AMEC) has opened a project to support OEMs and heat treaters that find benefit from creating unique heat treating specifications for items fabricated by additive manufacturing.

Gap P2: Heat Treatment (HT)-Metals. The existing and in-development ASTM 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. In this example, both processes are considered to be the same regarding HT requirements, when in reality PBF-EB is performed at much higher temperature and may not require residual stress relief and produce a more uniform microstructure. Heat treatment requirements for metals made with non-powder processes such as directed energy deposition using wire feedstock, sheet lamination, etc., are currently not addressed in any standards except for titanium-6Al-4V via DED. There are currently no standards on heat treatments designed to reduce anisotropy in properties. 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. 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 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: Medium

Status of Progress: Green

Update: [SAE AMS7000, 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](#), states that several thermal processing steps (stress relief and solution annealing) need to be performed in accordance with [SAE AMS2774E, Heat Treatment, Wrought Nickel Alloy and Cobalt Alloy Parts](#). [ASTM F3301-18, Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion](#) (formerly WK58233) addresses this.

Organization: R&D: universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE AMS-AM.

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 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.

NEW 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. There are currently no 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.

R&D Needed: Yes. 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: Low

Organization: R&D: NIST, universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE AMS-AM.

2.2.3.3 Hot Isostatic Pressing (HIP) (metals)

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.

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 parameters¹⁴ for specific metals include:

¹⁴ 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.

- [ASTM B998-17, Standard Guide for Hot Isostatic Pressing \(HIP\) of Aluminum Alloy Castings](#) (previously WK47205)
- [ASTM F2924-14, Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion](#)
- [ASTM F3001-14, Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI \(Extra Low Interstitial\) with Powder Bed Fusion](#)
- [ASTM F3049-14, Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes](#)
- [ASTM F3055-14a, Standard Specification for Additive Manufacturing Nickel Alloy \(UNS N07718\) with Powder Bed Fusion](#)
- [ASTM F3056-14e1, Standard Specification for Additive Manufacturing Nickel Alloy \(UNS N06625\) with Powder Bed Fusion](#)
- [ASTM A1080-15, Standard Practice for Hot Isostatic Pressing of Steel, Stainless Steel, and Related Alloy Castings](#)
- [ASTM A988/A988M-17, Standard Specification for Hot Isostatically-Pressed Stainless Steel Flanges, Fittings, Valves, and Parts for High Temperature Service](#)
- [ASTM F3301-18, Standard for Additive Manufacturing – Post Processing Methods – Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion](#)
- SAE AMS-AM standards that contain specific HIP process parameters for specific metals include:
 - [SAE AMS4999A, Titanium Alloy Laser Deposited Products~6Al - 4V~Annealed](#)
 - [SAE AMS7000, 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](#)

In Development Standards

- ASTM work items that contain, or will contain, specific HIP process parameters for specific metals:
 - [ASTM WK51329, New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy \(UNS R30075\) with Powder Bed Fusion1](#)
 - [ASTM WK53423, New Specification for Additive Manufacturing-Finished Part Properties-Standard Specification for AlSi10Mg via Powder Bed Fusion](#)
- [SAE AMS AMEC, Hot Isostatic Pressing](#)

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. 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

Recommendation: Develop material specific standards based on R&D defined HIP parameters for AM with acceptance criteria for internal discontinuities. Some examples include the following:

- 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: Medium

Status of Progress: Green

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 AMS7000 was published in June 2018 and SAE AMS AMEC is working on a [HIP spec](#).

Organization: R&D: various entities. Standards: ASTM F42, SAE AMS-AM, possibly SAE AMEC

2.2.3.4 Surface Finish (Surface Texture) (metals, polymers)

Introduction

Parts built using AM processes display different surface textures that may require post-build finishing. 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. In addition, a mismatch between core and surface (e.g., contour, upskin, downskin) beam scanning patterns, or non-optimized surface parameters, 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. 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 asperities, surface breaking porosity, or poorly fused particle boundaries may entrap post-processing solvents and etchants and therefore complicate rinsing, and/or entrap fluid and gas during service and promote corrosion. Complex internal passages may inhibit the finishing and coating of internal surfaces while surface texture may entrain chemical, abrasive, or polishing media. 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.

The selection of plastics, including compounded plastics, affects the surface texture of printed parts. For example, ABS typically prints in a dull finish, while PLA is semi-transparent, often resulting in a glossy and smooth finish.

Standards for Surface Finish of AM Parts

There are many challenges to the standardization of surface finishing techniques. Uniform material removal around complex and internal structures is one. For 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. The internal surface polishing of surface asperities and subsurface porosity, without deteriorating material integrity, such as intergranular attack (IGA)/Intergranular Oxidation (IGO) can be a challenge. Other important considerations include edge retention, surface roughness variation throughout the length of internal passages, extent of bell mouching in internal passages, and achieving the required final surface roughness values.

Complex curved surfaces, re-entrant features, or lattice structures, easily designed and deposited, can challenge common finishing methods. DED processes using wire feedstock display a surface typical of weld-clad surfaces often requiring 100% machining to achieve a finished component.

Standards for reliable NDT methods, such as CT scan with high resolution for evaluation of internal passages surface roughness, are needed.

Due to its influence on final material performance, this gap analysis will address the applicability of current surface finish definitions, measurements, and application standards to AM materials.

Published Standards

Surface texture, is currently characterized via waviness, roughness, and profile (i.e., lay). Definitions and interpretations of surface finish specifications are included in the standards listed below.

The following table lists standards that guide the definition of surface texture on product specifications.

Standard	Title
ISO 4287/ Amd1:2009	<i>Geometrical Product Specifications (GPS) - Surface Texture: Profile Method - Terms, definitions and surface texture parameters – Amendment 1: Peak count number</i>
ISO 25178-1:2016(E)	<i>Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 1: Indication of surface texture</i>
ISO 25178-2:2012(E)	<i>Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 2: Terms, definitions and surface texture parameters</i>
ASME B46.1-2009*	<i>Surface Texture (Surface Roughness, Waviness, and Lay)</i>
ISO 1302:2002	<i>Geometrical Product Specifications (GPS) - Indication of surface texture in technical product documentation</i>
ISO 12085:1996	<i>Geometrical Product Specifications (GPS) - Surface texture: Profile method - Motif parameters</i>
SAE AS291F	<i>Surface Texture, Roughness, Waviness and Lay (Stabilized: Sep 2014)</i>
ANSI/ASME Y14.36M-1996 (R2008)	<i>Surface Texture Symbols</i>

*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 B46.1-2009	<i>Surface Texture (Surface Roughness, Waviness, and Lay)</i>
ASTM D7127-17	<i>Standard Test Method for Measurement of Surface Roughness of Abrasive Blast Cleaned Metal Surfaces Using a Portable Stylus Instrument</i>
ASTM D4417-14	<i>Standard Test Methods for Field Measurement of Surface Profile of Blast Cleaned Steel</i>
ISO 4288:1996	<i>Geometrical Product Specifications (GPS) - Surface texture: Profile method - Rules and procedures for the assessment of surface texture</i>
ISO 8503-2:2012	<i>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</i>
ISO 25178-3:2012(E)	<i>Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 3: Specification operators</i>
ISO 25718-6:2010(E)	<i>Geometrical Product Specifications (GPS) – Surface Texture: Areal – Part 6: Classification of methods for measuring surface texture</i>

Standard	Title
NACE SP0287-2016	<i>Field Measurement of Surface Profile of Abrasive Blast-Cleaned Steel Surfaces Using a Replica Tape</i>
MPIF Standard Test Method 58	<i>Method for Determination of Surface Finish of Powder Metallurgy (PM) Products</i>
SAE AMS 03-2A-2017	<i>Cleaning and Preparation of Metal Surfaces</i>
SAE J911	<i>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</i>

- Additionally, ISO 25178-601, -602, -603, -604, -605, and -606 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\(2014\)](#) and [F1330-91\(2012\)](#), respectively and [SAE AMS2430T, 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 plating or electro-chemical finishing, 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](#), [F3001-14](#), [F3055-14a](#), and [F3056-14e1](#)) leave surface finish to agreement between the component supplier and purchaser and lack specific recommendations.

In Development Standards: None

Gap P4: 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.

- [ANSI/ASME Y14.36M-1996 \(R2008\), *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 micro-machining 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

- 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)
- Investigation of mechanical techniques such as shot peening or media blasting and their effect on fatigue life for AM materials

Recommendation: Verify if there are certain measurement methods more appropriate to AM-unique features than a stylus approach such as laser or white light 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.

Priority: Medium

Status of Progress: Green for R&D (metals). Unknown for Standards (metals and polymers).

Update: In terms of R&D for metals, NIST is currently investigating several research topics related to surface texture of parts produced via laser powder bed fusion. Current research is focused on process-structure relationships and the identification of complex structures that result from the AM process in anticipation that better identification and definition of as-built surfaces will lead to stronger functional correlations for AM parts. To this end, current topic areas include: investigation of surface texture parameters beyond Ra (including both areal and profile parameters) to better define AM parts, variability of as-built surface texture (i.e., methods for describing changes in the as-built surface texture

as position and orientation within the build chamber change), and use of XCT for determining surface texture.

Organization: ISO/ASTM; ASME (B46 new project team 53 on surface finish), IEEE-ISTO PWG, NIST

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.

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 (T_g), 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

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 E37.01	ASTM E2602-09(2015)	<i>Standard Test Methods for the Assignment of the Glass Transition Temperature by Modulated Temperature Differential Scanning Calorimetry</i>
ASTM E37.10	ASTM E1356-08(2014)	<i>Standard Test Method for Assignment of the Glass Transition Temperatures by Differential Scanning Calorimetry</i>
ASTM D20.10	ASTM D4473-08(2016)	<i>Standard Test Method for Plastics: Dynamic Mechanical Properties: Cure Behavior</i>
ASTM D20.70	ASTM D4526-12	<i>Standard Practice for Determination of Volatiles in Polymers by Static Headspace Gas Chromatography</i>
ASTM D30.04	ASTM D7028-07(2015)	<i>Standard Test Method for Glass Transition Temperature (DMA Tg) of Polymer Matrix Composites by Dynamic Mechanical Analysis (DMA)</i>
ASTM E37.10	ASTM E1640-13	<i>Standard Test Method for Assignment of the Glass Transition Temperature By Dynamic Mechanical Analysis</i>
ASTM E37.10	ASTM E1824-13	<i>Standard Test Method for Assignment of a Glass Transition Temperature Using Thermomechanical Analysis: Tension Method</i>
ASTM E37.10	ASTM E1545-11(2016)	<i>Standard Test Method for Assignment of the Glass Transition Temperature by Thermomechanical Analysis</i>
ASTM E37.01	ASTM E2550-17	<i>Standard Test Method for Thermal Stability by Thermogravimetry</i>
ASTM E37.01	ASTM E2160-04(2012)	<i>Standard Test Method for Heat of Reaction of Thermally Reactive Materials by Differential Scanning Calorimetry</i>
ASTM D20.30	ASTM D3795-00a(2012)	<i>Standard Test Method for Thermal Flow, Cure, and Behavior Properties of Pourable Thermosetting Materials by Torque Rheometer</i>
ASTM D01.55	ASTM D3732-82(2017)	<i>Standard Practice for Reporting Cure Times of Ultraviolet-Cured Coatings</i>
ASTM	ASTM MNL45	<i>Radiation Curing of Coatings (Koleske JV)</i>
ASTM F04.11	ASTM F2042-00(2011)	<i>Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II – Crosslinking and Fabrication</i>

Committee	Standard	Title
ASTM D09.12	ASTM D150-11	<i>Standard Test Methods for AC Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulation</i>
ASTM D01.55	ASTM D5403-93(2013)	<i>Standard Test Methods for Volatile Content of Radiation Curable Materials</i>
ASTM D01.24	ASTM D4144-94(2014)	<i>Standard Test Method for Estimating Package Stability of Coatings for Ultraviolet Curing</i>
ASTM D09.12	ASTM D257-14	<i>Standard Test Methods for DC Resistance or Conductance of Insulating Materials</i>
ASTM D20.10	ASTM D638-14	<i>Standard Test Method for Tensile Properties of Plastics</i>
ASTM F42.05	ASTM F3091/F3091M-14	<i>Standard Specification for Powder Bed Fusion of Plastic Materials</i>
ISO/TC 51/SC 12	ISO 14322:2012	<i>Plastics - Epoxy resins - Determination of degree of crosslinking of crosslinked epoxy resins by differential scanning calorimetry</i>
ISO TC138/SC 5	ISO 10147:2011	<i>Pipes and fittings made of crosslinked polyethylene (PE-X) - Estimation of the degree of crosslinking by determination of the gel content</i>
ASTM E21.05	ASTM E1559-09(2016)	<i>Standard Test Method for Contamination Outgassing Characteristics of Spacecraft Materials</i>
ASTM E21.05	ASTM E595-15	<i>Standard Test Method for Total Mass Loss and Collected Volatile Condensable Materials from Outgassing in a Vacuum Environment</i>

In Development Standards

[ASTM WK53878, New Specification for Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 1: Feedstock materials](#), is being developed within F42.

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: No

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: Low

Status of Progress: Not Started, or Unknown

Update: None provided

Organization: ASTM D20, ISO/TC 261/ASTM F42

Gap P6: Guidelines for Post-curing AM Plastics to Address Outgassing and Offgassing. Guidelines for evaluating the outgassing and offgassing properties and the effects of post-polymerization treatments have not been evaluated, specifically for AM materials. The voids and entrapments that can form in this case warrant some method of evaluating AM plastics over traditional methods.

R&D Needed: Yes, R&D may be needed to look at environmental conditions and health and safety aspects. Outgassing (thermal vacuum stability) and offgassing (toxicity) 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: Low

Status of Progress: Not Started, or Unknown

Update: None provided

Organization: ASTM E21.05, ASTM D20, ISO/TC 138, ISO/TC 261/ASTM F42

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: material properties (mechanical and thermal), component testing, biocompatibility and cleanliness of medical devices, chemistry, design allowables, and microstructure.

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 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 structure and defects (percentage, distribution, and morphology) in AM metal deposits defies the typical conceptualization of bulk material. The material chemistry and AM processing conditions (including post-processing) drives the structure and defect levels, and the structure 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, 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 design allowables 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, such as thermal conductivity and specific heat capacity, of additively manufactured materials are often required for thermal 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.

Minimum Mechanical Properties or Test Methods for Mechanical Properties of AM Parts

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, and the geometry, 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. Currently, the only standards that contain minimum properties for AM parts are those from [ASTM Committee F42](#) for specific metals produced by laser powder bed fusion. 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 design allowables.

There are currently no standards on mechanical property test methods that are specific for AM parts; the existing mechanical test methods for traditionally-manufactured parts are used as needed instead, and are acceptable for many purposes. Unique tests that take into consideration characteristics that are unique to AM parts such as property inhomogeneity and anisotropy do not currently exist.

Published Standards

There are several specifications for metal AM materials that cover the manufacturing process and state minimum properties of specific materials produced by powder bed fusion. Typically, the properties of these specifications are based on consensus and currently derived from metal casting properties. The published standards are listed below.

Existing Standards with Minimum Mechanical Properties for AM Parts

Committee	Standard	Title
ASTM F42	F2924-14	<i>Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion</i>
	F3001-14	<i>Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion</i>
	F3055-14a	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion</i>
	F3056-14e1	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion</i>
SAE AMS-AM	AMS4999A	<i>Titanium Alloy Laser Deposited Products~6Al - 4V~Annealed</i>

Committee	Standard	Title
	AMS7000	<i>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</i>

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](#)), a standard on how to report data ([ASTM F2971-13](#)), and many standards within ASTM and other organizations that describe how to conduct tensile, fracture, fatigue, and other types of mechanical tests that can be used for AM applications.

Existing Standards for Testing Mechanical Properties which can be Applied to AM Parts

Committee	Standard	Title
ASTM B07	B557-15	<i>Standard Test Methods for Tension Testing Wrought and Cast Aluminum- and Magnesium-Alloy Products</i>
	B645-10(2015)	<i>Standard Practice for Linear-Elastic Plan-Strain Fracture Toughness Testing of Aluminum Alloys</i>
	B646-17	<i>Standard Practice for Fracture Toughness Testing of Aluminum Alloys</i>
ASTM E04	E384-17	<i>Standard Test Method for Microindentation Hardness of Materials</i>
ASTM E08	E399-17	<i>Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness K_{Ic} of Metallic Materials</i>
	E466-15	<i>Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials</i>
	E561-15a	<i>Standard Test Method for KR Curve Determination</i>
ASTM E28	E8/E8M-16a	<i>Standard Test Methods for Tension Testing of Metallic Materials</i>
	E9-09(2018)	<i>Standard Test Methods of Compression Testing of Metallic Materials at Room Temperature</i>
	E10-17	<i>Standard Test Method for Brinell Hardness of Metallic Materials</i>
	E18-17e1	<i>Standard Test Methods for Rockwell Hardness of Metallic Materials</i>
ASTM F42	F3122-14	<i>Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes</i>
	F3184-16	<i>Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion</i>

In Development Standards

There are several new standards under development that discuss minimum properties for metal AM parts of specific materials produced by powder bed fusion, as listed below, although they do not state exactly how to determine these properties.

Standards in Development with Minimum Mechanical Properties for AM Parts

Committee	Work Item Number	Title
ASTM F42	WK51329	<i>New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion1</i>
	WK53423	<i>New Specification for Additive Manufacturing-Finished Part Properties-Standard Specification for AlSi10Mg via Powder Bed Fusion</i>
ASTM F42/ISO TC261 JG 61	WK49229 (ISO/ASTM PWI 52909)	<i>New Guide for Orientation and Location Dependence Mechanical Properties for Metal Additive Manufacturing</i>
SAE AMS-AM	AMS7004	<i>Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate- Ti6Al4V-Stress Relieved</i>
	AMS7009	<i>Additive Manufacturing of Titanium 6Al4V with Laser-Wire Deposition - Annealed and Aged</i>
	AMS7011	<i>Additive Manufacture of Aerospace Parts from T-6Al-4V using the Electron Beam Powder Bed Fusion (EB-PBF) Process</i>
	AMS7100/1	<i>Fused Filament Fabrication - Stratasys Fortus 900mc Plus with Type 1, Class 1, Grade 1, Natural Material</i>
AWS D20	AWS D20.1	<i>Standard for Fabrication of Metal Components using Additive Manufacturing</i>

The AWS D20.1 standard has been approved by the D20 committee and will next undergo review by the AWS Technical Activities Committee. The AWS D20.1 standard establishes qualification requirements for fabricating metal components using AM. The qualification requirements are designed to demonstrate that the minimum mechanical properties established by the engineer for a given component can be met.

[ASTM Committee F42](#) has produced the majority of the standards to-date and is actively developing others. The lack of an established “qualification procedure” in existing ASTM F42 standards could be filled by the aforementioned AWS standard. Similarly, the medical community may need to have standards written by the ASTM committee F04 on medical devices, which would then reference Committee F42 standards. Most ASTM F42 standards are now being developed jointly with [ISO TC 261](#) and will be usable in Europe where regulations favor ISO standards.

The SAE AMS-AM Committee is actively working on development of finished material specifications that will include minimum specification values for tension at room temperature and elevated temperature for several materials as listed in the table above, including metal and polymer AM materials. These values will be lot acceptance minimums, not design allowable numbers.

Gap FMP1: Material Properties. Many machine manufacturers offer general values for parts made from select materials in their machines. However, these values are not statistically validated and do not have the pedigree required for material design. Standards for thermal properties and minimum mechanical

properties that also contain qualification procedures cannot currently be produced for AM materials, given the current state of knowledge, for the reasons stated above. Testing standards modified for use with AM parts that are designed/built to be inhomogeneous are also not available at this time.

R&D Needed: Yes

Recommendation: Develop standards that identify the means to establish minimum mechanical properties (i.e., AM procedure qualification requirements) for metals and polymers made by a given AM system using a given set of AM parameters for a given AM build design. Developing these standards will require generating data that currently doesn't exist or is not in the public arena. Qualification requirements to establish minimum mechanical properties for AM parts, both homogeneous and deliberately inhomogeneous, need to be developed.

Priority: High (Metals, Polymers); Low (Ceramics)

Status of Progress: Green

Update: Work in progress is noted in the text.

Organization: ASTM F42/ISO TC 261, SAE AMS-AM, AWS D20, CMH-17, MMPDS, NIST

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, 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 F3127-16](#), [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 & Cleanliness of Medical Devices

Biocompatibility

It is generally thought that biocompatibility standards such as ANSI/AAMI/ISO 10993-1:2009 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.

Published standards and guidance include:

- [ANSI/AAMI/ISO 10993-1:2009 \(R2013\), 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 \(June 16, 2016\)](#)

No gaps have been identified with respect to biocompatibility.

Cleanliness of Medical AM Parts

It can be very difficult to clean parts of remaining raw 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 include:

- [ASTM F3127-16, Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices](#)
- [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](#)
- [ASTM F3208-17, Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices](#) (previously WK50782)

Standards in development include:

- [ASTM WK53082, Characterizing the Cleaning Performance of Brushes Designed to Clean the Internal Channel of a Medical Device](#)
- [ASTM WK60265, Assessing the Removal of Additive Manufacturing Residues in Medical Devices Fabricated by Powder-bed Fusion](#)
- [United States Pharmacopeia-National Formulary \(USP-NF\), General Chapter 788 Revision, Particulate Matter in Injections](#)

Gap FMP3: Cleanliness of 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. For patient-contacting (both direct and indirect) devices this cleaning must allow the device to pass tests for biological reactivity such as cytotoxicity and inflammation as described in ISO 10993. They should also ensure that AM materials such as powder are removed before use. Residues left on the parts may

include but are not limited to cooling fluids or AM materials (powder or uncured monomer), that may be stuck within small geometric features or lattice structures. There are no standardized protocols or acceptance criteria to reproducibly measure and evaluate the cleanliness of a part with relevant, risk-based acceptance criteria.

R&D Needed: Yes. R&D is needed to establish standards which discern clean from uncleaned parts; 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 F04](#) already has work in progress.

Priority: High

Status of Progress: Green

Update: As noted, ASTM F04.15 is working on WK53082 and WK60265.

Organization: AAMI, ASTM F04, ASTM F42/ISO TC 261, ISO, ISO/TC 150, ISO/TC 194

2.2.4.5 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	<i>Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion</i>
	F3001-14	<i>Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion</i>
	F3055-14a	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion</i>
	F3056-14e1	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion</i>
	F3184-16	<i>Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion</i>
SAE AMS-AM	AMS7000	<i>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</i>

In Development Standards

Specifications in Development Including Chemical Composition Requirements for AM Parts

Committee	Work Item Number	Title
ASTM F42	WK51329	<i>Standard Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion1</i>
	WK53423	<i>New Specification for Additive Manufacturing-Finished Part Properties-Standard Specification for AlSi10Mg via Powder Bed Fusion</i>
SAE AMS-AM	AMS7004	<i>Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate-Ti6Al4V-Stress Relieved</i>
	AMS7009	<i>Additive Manufacturing of Titanium 6Al4V with Laser-Wire Deposition - Annealed and Aged</i>
	AMS7011	<i>Additive Manufacture of Aerospace Parts from T-6Al-4V using the Electron Beam Powder Bed Fusion (EB-PBF) Process</i>

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.

2.2.4.6 Design Allowables

Design allowables are statistically derived material properties based on a defined set of data and analysis methods. The allowables are used as design values that are accepted by government procuring and/or certification agencies for the development and manufacture of aerospace products. For the widespread adoption of AM for the aerospace industry, these design allowables must be developed and accepted by the various procuring and certification agencies.

Test Methods or Best Practice Guides for Design Allowables of AM Parts

The development of standard test methods, specifications, and best practice guides will allow for the standardization of additively manufactured materials design data that is acceptable to government procuring and certification agencies. The data obtained through these standards and specifications can be used for statistical analysis of design allowables (typically A-Basis or B-Basis values). Currently, there is no accepted or approved statistical analysis procedure for additively manufactured materials. Once these design allowables are established, the application of AM components can be accelerated.

The following test standards and specifications are published for use with additively manufactured materials:

Material Type	Committee	Standard	Title
Any	ASTM F42	ISO/ASTM 52900:2015	<i>Additive Manufacturing - General principles – Terminology</i>
Any	ASTM F42	ISO/ASTM 52901	Additive manufacturing - General Principles - Requirements for Purchased AM Parts
Metal	ASTM F42	F2924-14	<i>Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion</i>
Metal	ASTM F42	F3055-14a	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion</i>
Metal	ASTM F42	F3056-14e1	<i>Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion</i>
Any	ASTM F42	F2971-13	<i>Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing</i>
Metal	ASTM F42	F3122-14	<i>Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes</i>
Metal	ASTM F42	F3184-16	<i>Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion</i>
Metal	ASTM F42	F3187-16	<i>Standard Guide for Directed Energy Deposition of Metals</i>
Any	ASTM F42	ISO/ASTM 52921:2013	<i>Standard terminology for additive manufacturing - Coordinate systems and test methodologies</i>
Metal	NASA	MSFC-STD-3716	<i>EM20, MSFC Technical Standard, Standard For Additively Manufactured Spaceflight Hardware By Laser Powder Bed Fusion In Metals</i>

Material Type	Committee	Standard	Title
Metal	NASA	MSFC-SPEC-3717	<i>EM20, MSFC Technical Standard, Specification For Control And Qualification Of Laser Powder Bed Fusion Metallurgical Processes</i>
Metal	SAE AMS-AM	AMS7000	<i>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</i>
Metal	SAE AMS-AM	AMS7001	<i>Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, 62Ni - 21.5Cr - 9.0Mo - 3.65 Nb</i>
Metal	SAE AMS-AM	AMS7002	<i>Process Requirements for Production of Powder Feedstock for use in Laser Powder Bed Additive Manufacturing of Aerospace parts</i>
Metal	SAE AMS-AM	AMS7003	<i>Laser Powder Bed Fusion Process</i>

Although the material standards above have been published for use with AM materials, they are not sufficient enough in detail to support the development of design allowables. The minimum mechanical properties values are not statistically derived and, therefore, cannot be used to develop S-, A-, and B-basis values. Typically, these properties are based on consensus and 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 standards ([MSFC-STD-3716](#) and [MSFC-SPEC-3717](#)) listed above. In these documents, rather than a one-time development of comprehensive allowables, the method required employs an increased level of scrutiny on the build-to-build material quality accompanied by periodic review and confirmation of the material 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.

The following test standards, specifications, and guides are in development for use with additively manufactured materials:

Material Type	Committee	Standard	Title
Metal	SAE AMS-AM	AMS7004	<i>Titanium Alloy Preforms from Plasma Arc Directed Energy Deposition Additive Manufacturing on Substrate-Ti6Al4V-Stress Relieved</i>
Metal	SAE AMS-AM	AMS7005	<i>Plasma Arc Directed Energy Deposition Additive Manufacturing Process</i>

Material Type	Committee	Standard	Title
Metal	SAE AMS-AM	AMS7006	<i>Alloy 718 Powder</i>
Metal	SAE AMS-AM	AMS7007	<i>Electron Beam Powder Bed Fusion Process</i>
Metal	SAE AMS-AM	AMS7008	<i>Nickel Alloy, Corrosion and Heat-Resistant, Powder for Additive Manufacturing, Ni-Cr22-Fe18-Mo9-Co</i>
Metal	SAE AMS-AM	AMS7009	<i>Additive Manufacturing of Titanium 6Al4V with Laser-Wire Deposition - Annealed and Aged</i>
Metal	SAE AMS-AM	AMS7010	<i>Laser-Wire Directed Energy Deposition Additive Manufacturing Process</i>
Metal	SAE AMS-AM	AMS7011	<i>Additive Manufacture of Aerospace Parts from T-6Al-4V using the Electron Beam Powder Bed Fusion (EB-PBF) Process</i>
Metal	SAE AMS-AM	AMS7012	<i>17-4PH Powder for Additive Manufacturing</i>
Metal	SAE AMS-AM	GA AM17-B	<i>SAE AMS AM Metals Data Submission Guidelines (for Additive Manufactured Metals)</i>
Polymer	SAE AMS-AM	AMS7100	<i>Fused Filament Fabrication Process</i>
Polymer	SAE AMS-AM	AMS7101	<i>Material for Fused Filament Fabrication</i>
Metal	ASTM F42	WK49229	<i>New Guide for Orientation and Location Dependence Mechanical Properties for Metal Additive Manufacturing</i>
Any	ASTM F42	WK55297	<i>New Guide for Additive Manufacturing – General Principles – Standard Test Artefacts for Additive Manufacturing</i>
Metal	ASTM F42	WK51329	<i>New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion1</i>
Metal	ASTM F42	WK53423	<i>New Specification for Additive Manufacturing-Finished Part Properties-Standard Specification for AlSi10Mg via Powder Bed Fusion</i>
Polymer	ASTM F42	WK53878	<i>New Specification for Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 1: Feedstock materials</i>
Polymer	ASTM F42	WK53879	<i>Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 2: Process-equipment</i>
Polymer	ASTM F42	WK53880	<i>Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials: Final Part Specification</i>
Any	ASTM F42	WK56649	<i>New Guide for Standard Practice/ Guide for Intentionally Seeding Flaws in Additively Manufactured (AM) Parts</i>
Metal	AWS D20	D20.1	<i>Standard for Fabrication of Metal Components using Additive Manufacturing</i>

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 design 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: Design Allowables. Current standards and underlying infrastructure/technology are not mature enough to support the development of design allowables. For metallic additively manufactured material, a guideline was published by the MMPDS Coordination Committee describing an exploratory study for developing a metallic design allowable entitled “11-40. Guidelines for Emerging Materials and Technologies.” This guideline includes potential procedures to publish design allowables in a handbook and illuminates the gaps that would need to be addressed before AM could be included. For polymer based additively manufactured materials, an FAA sponsored research program is currently developing statistical procedures for allowables that will eventually be submitted to CMH-17 for consideration to be published in a new volume.

R&D Needed: Yes. Recommended R&D required to fill this gap includes the generation of a set of initial seed data and subsequent statistical analyses. The initial data may be developed via round robin testing and procedures to capture the multiple sources of variability inherent in AM materials and processes. These data should result from programs through public-private partnerships or government laboratories to ensure the sharing of information. Separate test programs must be developed for different material types as the distributions may not be the same across all materials (i.e., metallic, polymer, etc.). The generation of data and subsequent analyses will help define the minimum requirements and statistical methods necessary for additive materials.

Recommendation: Multiple developments must take place prior to generation and acceptance of design allowables for additive materials.

1. Material Specifications: SDOs involved in developing and publishing material specifications should continue their efforts to adequately capture the relevant material parameters and minimum mechanical properties required for a specification. These specifications can be used in the future to support testing that will lead to the level of data needed to support design allowable basis values. Currently, the SAE AMS-AM Committee is actively developing specifications for lot acceptance of metallic and polymer additive materials. [ASTM F42.05](#) may also have interest.

2. Data Requirements and Statistical Analyses: Established organizations, such as MMPDS and CMH-17, should be involved in establishing the methodology required for deriving the allowables through a statistical process that takes into account the variability and parameters associated with additively manufactured materials. The MMPDS General Coordinating Committee, CMH-17 Executive Group, and/or other steering groups of organizations familiar with curating design allowable databases should develop guidelines on minimum data requirements and statistical processes. Although the key

material/process parameters affecting allowables and in some cases the required test methods will differ, it is recommended to start with the currently available statistical analysis methods for metals and polymer composites as a baseline.

3. Test methods: Test standards organizations, such as ASTM/ISO, should provide recommendations on established test methods with special considerations for AM materials. If necessary, new coupon or component test methods should be developed.

Priority: High (Material Specifications); Medium (Data Requirements and Statistical Analyses); Medium (Test Methods)

Status of Progress: Green

Update: At this time, no publicly available methodology for design allowables of additively manufactured materials has been identified. However, the three sections listed above (Material Specifications, Data Requirements and Statistical Analyses, and Test Methods) are all being addressed throughout multiple SDOs and other programs.

Material specifications are being generated by multiple SDOs at this time. SAE has a Data Management Sub-Committee currently defining guidelines to generate specifications minimum values for both metals and polymers. In addition to the work in progress noted in the text and gap statement, ASME's BPVC committee is looking at this. Regarding characterization methods for metals, the MMPDS coordinating committee has concerns that existing data requirements and statistical analysis methods are not sufficient. Their primary concern is the level of maturity of standards and specifications needed to ensure consistent properties. Polymer AM material test methods have similar issues; methods can either be adopted from plastic or polymer matrix composites methods, both of which may need modification.

Organization: ASTM F42/ISO TC 261, SAE AMS-AM, AWS, NASA, ASME BPVC, MMPDS, CMH-17, NIST

2.2.4.7 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.

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 A247-17	<i>Standard Test Method for Evaluating the Microstructure of Graphite in Iron Castings</i>	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)	<i>Standard Guide for Preparation of Metallographic Specimens</i>	

Committee	Test Standard Number	Title	Notes
ASTM Subcommittee: E04.01	ASTM E407-07(2015)e1	<i>Standard Practice for Microetching Metals and Alloys</i>	The procedures in this standard can be followed for inspecting AM metals
ASTM - Subcommittee: E04.08	ASTM E112-13	<i>Standard Test Methods for Determining Average Grain Size</i>	Does not account for heterogeneous microstructure
ASTM - Subcommittee: E04.08	ASTM E930-99(2015)	<i>Standard Test Methods for Estimating the Largest Grain Observed in a Metallographic Section (ALA Grain Size)</i>	Does not account for spatial location of ALA grain and the alignment relative to the build direction
ASTM - Subcommittee: E04.08	ASTM E1181-02(2015)	<i>Standard Test Methods for Characterizing Duplex Grain Sizes</i>	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	<i>Standard Practice for Determining Average Grain Size Using Electron Backscatter Diffraction (EBSD) in Fully Recrystallized Polycrystalline Materials</i>	Not suitable for AM grain structure
ASTM - Subcommittee: E04.14	ASTM E562-11	<i>Standard Test Method for Determining Volume Fraction by Systematic Manual Point Count</i>	Partial use in AM because volume fraction is not enough
ASTM - Subcommittee: E04.14	ASTM E1382-97(2015)	<i>Standard Test Methods for Determining Average Grain Size Using Semiautomatic and Automatic Image Analysis</i>	An average is not suitable for AM
ASTM Subcommittee: E04.14	ASTM E1268-01(2016)	<i>Standard Practice for Assessing the Degree of Banding or Orientation of Microstructures</i>	Not suitable for AM. While banding is a sort of heterogeneity, in AM there is size heterogeneity in addition to orientation banding
ISO/TC 202	ISO 13067:2011	<i>Microbeam analysis - Electron backscatter diffraction - Measurement of average grain size</i>	It does not address the size of EBSD scan to have reliable statistics of grains in AM material

In Development Standards

There are no current standards being developed for quantification of microstructure in metallic AM.

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. NIST should help develop Calphad databases suitable for non-equilibrium solidification.

Recommendation: ASTM should develop a standard for characterization and acceptance criteria of AM microstructures (both identification and quantification).

Priority: Medium

Status of Progress: Not Started, or Unknown

Update: Nothing started in terms of ASTM work.

Organization: NIST, ASTM

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. This section discusses some of these issues – and applicable qualification and certification (Q&C) procedures – in more detail. Please note that some gaps related to Q&C also appear elsewhere in this roadmap.¹⁵

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 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.¹⁶

The first part of this section focuses on industry documents and related activities that provide guidance on suggested or necessary components of an acceptable qualification procedure. The next part discusses primary qualification issues within the aerospace, defense, and medical sectors, noting areas where there is a need for further guidance on the topic of qualification.

Q&C Terminology

One of the major issues clouding 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 competence 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.

¹⁵ See Gaps D12, D20, PC4, P1, FMP1, and NDE5.

¹⁶ Prepared by Energetics Incorporated for the National Institute of Standards and Technology, *Measurement Science Roadmap for Metal-Based Additive Manufacturing*, May 2013, https://www.nist.gov/sites/default/files/documents/el/isd/NISTAdd_Mfg_Report_FINAL-2.pdf

Competence: Ability to apply knowledge and skills to achieve intended results

- Note 1 to entry: Demonstrated competence is sometimes referred to as qualification [emphasis added].
- Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

For purposes of this roadmap, qualification is defined as ensuring suitability to meet functional requirements in a repeatable manner, or assuring the desired outcome of a defined process. Such validation is a shared responsibility of both the supplier and the end user.

Certification has a similar formal definition to verification (qualification):

Certification: Third-party attestation related to products, processes, or persons *that conveys assurance that specified requirements have been demonstrated*.¹⁷

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.

Validation is defined in ISO 9000:2015 as: confirmation, through the provision of *objective evidence*, that the *requirements* for a specific intended use or application have been fulfilled.

Verification and validation are also defined in the [International Vocabulary of Metrology – Basic and General Concepts and Associated Terms \(VIM\), 3rd edition, 2008 version with minor corrections \(JCGM 200:2012\)](#).¹⁸

Verification: provision of objective evidence that a given item fulfils specified requirements

Validation: verification, where the specified requirements are adequate for an intended use

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

¹⁷ *The United States Conformity Assessment Principles (USCAP)* www.ansi.org/uscap. Italics in the USCAP definition indicate a term has a specific meaning in the United States. The USCAP definition is based on the ISO/IEC 17000:2004 definition:

Certification - Third-party attestation related to products, processes, systems or persons

NOTE 1- Certification of a management system is sometimes also called registration.

NOTE 2 - Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable.

¹⁸ http://www.bipm.org/utis/common/documents/jcgm/JCGM_200_2012.pdf

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.”¹⁹ Terminology within the medical community is defined in law or regulation.

Though not specific to Q&C aspects, AM terminology documents include:

- [ISO/ASTM 52900:2015, Additive manufacturing - General principles - Terminology](#)
- [ISO/ASTM 52921:2013, Standard terminology for additive manufacturing - Coordinate systems and test methodologies](#)

[ASTM E2161-15, Standard Terminology Relating to Performance Validation in Thermal Analysis and Rheology](#), is another possible reference document.

In addition to the source documents already mentioned, the [ISO Online Browsing Platform](#)²⁰ 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: No

Recommendation: Compare how the terms qualification, certification, verification and validation are used by industry sector. Update as needed existing quality management system standards and other terminology standards to harmonize definitions and encourage consistent use of terms across industry sectors with respect to AM.

Priority: High

Status of Progress: Green

Update: In discussions between the AMSC advisory group and the SDOs, there was a general sense that relevant AM terminology could be captured in the ISO/ASTM 52900 document to the extent possible. However, that document does not currently address the disparities on Q&C terminology discussed here. As a general matter, ASME has been coordinating AM terminology activity with ASTM. SAE has noted the challenges of coming to consensus on terminology and has been using the ASTM definitions when they exist but coming up with new terms for aerospace applications when a term is not defined. ASTM has offered to convene a virtual meeting with the SDOs and technical experts to discuss terminology.

¹⁹ In a recent update to the Undersecretary of the Navy, Q&C are defined as follows: Qualification of a component is the verification of materials, processes, procedures, and personnel used in the production of the component that show repeatability and reliability of properties to prescribed acceptable levels. Certification of a component is the verification that qualified materials, processes, personnel and procedures will provide the intended form, fit, and function of the design and meet naval requirements.

²⁰ <https://www.iso.org/obp/ui/#home>

America Makes could help to promote such collaboration. This would be a step forward though it may not solve the issue of getting different sectors to adopt the same terminology.

Organization: ASTM F42/ISO TC 261, AAMI, ASME, SAE

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. In 2012, 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 80 AM-fabricated devices by the end of 2014.

In this initial period, AM was used primarily for two specific purposes that were facilitated by the AM process: 1) creating porous, lattice-like structures on the surface or throughout the body of an orthopaedic implant, and 2) creating medical implants and surgical instruments (e.g., cutting guides) that match the anatomy of a specific patient, so-called patient-matched medical devices.

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.²¹ 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 2018, RSNA and FDA will publish a white paper summarizing the meeting and highlighting discussions on the benefits and risks of anatomic models, technical considerations that inject uncertainty and variability, and best practices for safe and effective production of anatomic models.

Interaction between FDA and clinical societies will be key to ensuring both groups are aligned and have transparent practices. This will help facilitate 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 Advice²² and the FDA 3D Printing²³ 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 regulations²⁴ and clarified in process or device-specific guidance documents. The Agency

²¹ FDA/RSNA Meeting Info:

<https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm569452.htm>

²² CDRH Device Advice: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>

²³ FDA 3D Printing Website: www.fda.gov/3dprinting/

²⁴ CFR for med devices (21 CFR 800-1099)

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=800&CFRPartTo=1099>

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 is especially 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, hobbyists).

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.

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 special process accreditations throughout the aerospace and defense industries.²⁵

In October 2013, the Welding Task Group was assigned responsibility to assess the industry needs and develop an audit criteria capable of assessing suppliers utilizing additive manufacturing technology. Analysis demonstrated that the Task Group would be best suited developing an 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 checklists via trial audits. This culminated in the approval of the checklist AC7110/14, *Nadcap Audit Criteria for Laser and Electron Beam Metallic Powder Bed Additive Manufacturing*, which was released for use in early 2017.

²⁵ More information on the Nadcap program can be found at <https://p-r-i.org/nadcap/about-nadcap/>

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 checklist. Audits already have been performed and suppliers accredited to the checklist.

The Task Group has received several comments on the existing checklist and begun the process of revising it to incorporate changes. Once industry standards become available, the Task Group will again review the checklist to ensure that it adequately meets industry requirements.

The AC7110/14 checklist is available for downloading at no charge to any person registered in eAuditNet (www.eauditnet.com). Once registered, the checklist 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 checklists.

2.3.2.3 Aerospace Mission Assurance Information Workshop (MAIW)

The Aerospace Corporation sponsors a yearly workshop involving subject matter experts (SMEs) from the U.S. space community that come together and evaluate specific mission assurance issues important to the space enterprise. Examples of previous topics include counterfeit parts prevention strategies, root cause investigation best practices guide, and supplier risk evaluation and control. For each topic of interest, a team is created that is composed of SMEs from various industry, academic, and government institutions. The team is charged with addressing the particular question of interest culminating in an out brief to the community and a final report.

In August 2015, a team was stood up for a 3-month term to examine mission assurance considerations relative to additive manufacturing. Because of the short timeframe, the team realized that this would need to be an initial study that could feed into a more comprehensive evaluation during future MAIW workshops. For a starting point, the members of the team polled their SMEs to come up with a group of questions specific to potential risks of utilizing AM technologies. The goal was to help mission assurance professionals, who are not necessarily subject matter experts, to begin to understand AM-specific issues that need to be addressed when evaluating the insertion of AM parts into flight systems. To that end, every question was supported with a background statement, a short discussion of the issue, and an assessment of the criticality of the issue. More than 50 questions were captured in a chart deck that at the time of this writing was currently in the final clearance process but will eventually be available to the community.

2.3.2.4 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 design allowables.

As additively manufactured materials are expanding into regulated areas, these handbook organizations are considering the inclusion of design allowables and qualification and certification guidance. 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) design 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 adhesive bonding guidance and data, and new materials data linked to publically-available material and process specifications.

Additive Polymers: As part of a Federal Aviation Administration (FAA) led effort, qualification data of a polymer AM material is being generated and will be submitted to CMH-17 for consideration. Submission to the handbook will likely occur in 2018 and will require substantial review prior to publication. A separate group under CMH-17 will drive the development effort of this new Volume to include statistically reduced data and guidelines for both filled and unfilled polymer AM materials. Note: CMH-17 is mainly devoted to composite materials. Composites, as additively manufactured polymers, are

considered as being 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 38 companies from 12 countries. The Government Steering Group (GSG) includes representatives of the FAA, U.S. Air Force, U.S. Navy, 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 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.

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 assuming that the data fit an approved probability distribution function. 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 coordination 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 a couple of additive manufacturing materials, analyzing data beginning with SAE AMS4999. However, at the time, the data submitted did not meet the existing data requirements which would allow publication of data in the Handbook. At present, no additively manufactured alloys are contained in the Handbook. The unique nature of additive manufacturing materials requires a different approach for deriving supportable material allowables than

those applied to more traditional metal alloys. To that end, approaches more applicable for AM materials are being discussed in a working group devoted to process intensive materials. The Emerging Technology Working Group (ETWG), composed of interested ISG and GSG organizations, is seeking to develop an approach for driving supportable material allowables for AM materials. Initial efforts have been made on presentation of the data, equivalency determination methods, and other general guidance. *Guidelines for Emerging Materials and Technologies*, which closed Agenda Item 11-40, summarizes proposed data presentation, equivalency determination, and other general guidance. The proposal was not adopted by MMPDS as it was determined that defining generic guidelines for additive metals was premature due to significant gaps in both technology and infrastructure. For example, inclusion in MMPDS is predicated upon the existence of public specifications. In the case for AM, both the feedstock material and processing standards were not generally available. Few specifications exist and data sets submitted to Battelle have been judged under current MMPDS procedures to be inadequate for deriving publishable allowables. In general, there are no approved MMPDS guidelines currently by which the MMPDS organization can generate an allowable warranting the government approved “A- or B-Basis” values. Currently, the MMPDS organization is assessing if AM materials could be published in a separate volume or document with special guidance more suited to AM materials than those currently applied to more traditional materials. Battelle continues to solicit input from industry and government entities on suitable guidelines and data to validate those guidelines in this proposed new volume.

2.3.2.5 AWS D20

The American Welding Society (AWS) assigned a task group to study whether or not AM fell within its charter and whether there was a need for standards developed by AWS. It was emphasized that there should not be duplication of effort and the AWS committee would develop broader application codes/standards that would integrate requirements for AM of metals, including requirements for design, qualification, fabrication, and inspection. It was decided that a standalone committee was needed for the creation of an AM standard and the [D20 committee](#) was formed at the end of 2013.

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 draft AWS D20.1 standard was approved by the committee following three rounds of balloting. The standard will now be sent to the AWS Technical Activities Committee (TAC) for vote.

2.3.2.6 NASA Marshall Space Flight Center (MSFC) Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals

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 Space Launch System, Orion Spacecraft, and 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. Select pieces of flight hardware have already been produced and continued production of AM flight hardware is imminent.

As is common across industry, the objectives and schedules of programs have been leading the development of AM requirements and have been embracing an AM adoption agenda that challenges the pace of AM process understanding itself. This creates a significant pull on engineering organizations to establish a framework for AM requirements while process understanding evolves. From the perspective of a certifying agency, the absence of requirements creates significant issues including a lack of adequate review products and ambiguity in the evaluation of available products, lack of consistency across programs and even internal to programs, poorly integrated flight rationale for certification logic, and contractual uncertainty including loss of contractual leverage.

NASA has endeavored to engage the efforts of industry standards development organizations (SDOs) as each has become involved in AM, and NASA continues to actively support these efforts. It has been clear that standards from SDOs will eventually play a key role in governing the AM process for NASA spaceflight hardware, just as they do for most all other processes. However, none have yet become sufficiently mature to adopt independently and there remains a significant need to frame the overall AM process in the context of NASA's overarching standards for materials, structures, and fracture control.

Objectives and Content

The primary objective of the NASA document, developed by the NASA Marshall Space Flight Center (MSFC), is to provide an overarching framework of methodologies to meet the intent of existing requirements in materials, structures, and fracture control for AM parts produced with the laser powder bed fusion process. The document has been publicly available in draft form since mid-2015. It was published in October 2017 as two documents: a standard [MSFC-STD-3716, Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals](#), and an associated specification [MSFC-SPEC-3717, Specification for Control and Qualification of Laser Powder Bed Fusion Metallurgical Processes](#).

The following principles guided the development and philosophy of the document:

- 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 processes, instead define methodologies for qualifying 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 document provides a framework of requirements for design evaluation, metallurgical process control, part process control, equipment control, and the implementation of a quality management system. Examples of the controls defined in the document are as follows:

- Design Evaluation
 - Part classification system for evaluating risk based on consequence of failure, structural margins, and risks associated with the physics of the AM build process
 - Adaptable framework to handle material design values for AM products given the evolving and process sensitive nature of the technology
 - The document rejects the assumption underlying the standard “once-and-done” development of material design values—a finalized and fully stable process. Instead, it requires ongoing statistical process control of material quality. Until substantive feedback from AM machines is feasible, each AM machine is required to demonstrate the ability to produce material that is in-family with that used to establish the suite of AM material design values.
- Metallurgical Process Control
 - Requirement to qualify the AM metallurgical process (not unlike that used for weld processes)
 - A Qualified Metallurgical Process (QMP) is established (or shown equivalent to existing) for each individual AM machine.
- Part Process Control
 - Requirement for a Part Development Plan (PDP) 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
 - Requirements for formal First Article Inspection (FAIs) and Manufacturing Readiness Review (MRR) leading to a locked and qualified part process – a Qualified Part Process (QPP)
- Equipment Process Controls and Quality Management Systems
 - Requirement for AM Equipment Control Plan (ECP) to formalize AM equipment process controls

- Requirement for the integration of an AS9100 (or equivalent) Quality Management System (QMS) throughout the AM process

The resulting products of these controls (QMP, PDP, QPP, ECP, etc.) provide a consistent and quantifiable set of deliverables for the Agency to reliably evaluate the implementation of AM parts.

2.3.2.7 ASME Y14.46

ASME Y14.46, Product Definition for AM, is a subcommittee formed by the ASME Y14 Engineering Product Definitions and Related Documentation 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 project teams (PT): 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 the ASME B46 Dimensional Metrology Standards Committee.

The Y14.46 standard was published on November 17, 2017. This draft standard for trial use will be available for one year for comments.²⁶ Following the one year period, all comments received will be submitted to the Y14.46 Committee. The committee plans to revise the standard based on the comments received.

2.3.2.8 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. 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

²⁶ See <https://www.asme.org/career-education/media/training/y1446-recommended-use-additive-manufacturing> for a recorded webinar on “Why Y14.46 is recommended for use in AM.”

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

2.3.3 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 four sectors (aerospace, defense, medical, and electronic and electrical products) are discussed and gaps are identified.

2.3.3.1 Aerospace Industry

The aerospace industry is different from other industries in that space based parts typically cannot be recalled and parts must withstand space environments. Human space flight poses unique safety concerns and therefore requires more stringent flight qualification than other industries. The intended use of the product dictates the rigor of the material and part qualification categories.

Most flight components will be metal structural/flight components such as titanium or aluminum, so this should be a priority for standards development. ULTEM™ 9085 is also being used for non-structural flight parts. Many aerospace industry components will include integration of mixed materials.

Materials

Typical industry practice is that precursor materials are “certified” (qualified) and/or verified, though FAA only certifies final products. Material certification standards in existence can be used as is, with modifications, or as a point of departure for new standards for AM materials. Normally, material suppliers certify their materials to these standards and the buyers verify the certification. These certifications are to be included in the data package required for qualification and certification of the AM processed part. AM material properties are highly dependent on process/machine variables as well as post-processing.

Parts/Products

Parts/products are qualified and verified. The part qualification process achieves a product certification, which ensures the product meets all technical requirements. Part qualification is typically governed by program/customer technical requirements and standards.

Product verification requirements define activities to minimize risk and certify that the delivered system or product satisfies hardware, software, and system requirements, as qualified. Each product goes through verification, also known as product acceptance, to ensure requirements are met during or after the build process by performing an inspection, demonstration, analysis, or test. These verification activities are often performed to standards (e.g., ASTM, etc.). Product verification may include 1st article inspection to demonstrate the suitability of 1st time use by performing additional inspection, test, and demonstration activities.

Gap QC2: AM Part 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. A common classification system for AM parts by industry sector is needed to provide consistent evaluation criteria for AM part risk. This should include a definition of criticality levels. Consistent risk criteria provide the basis for consistent expectations and levels of qualification rigor. Examples of classification systems can be found in NASA's [MSFC-STD-3716, Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals](#), and the draft AWS D20.1 standard, which utilizes the part classification system identified in [AWS D17.1/D17.1M:2017-AMD1, Specification for Fusion Welding of Aerospace Applications](#). Any industry requiring rigorous AM part qualification and system certification would benefit from a common part classification system.

R&D Needed: No

Recommendation: A technical report describing existing classification systems for AM parts would be useful. It could include the recommended minimum process and part qualification requirements commensurate with part risk for each classification level.

Priority: High

Status of Progress: Green

Update: ASTM F42.01 will explore developing this technical report. This will require coordination between the SDOs and relevant federal agencies. It may also be application-specific (e.g., spaceflight, military, etc.). This is more a harmonization issue. Procurement and level of testing required need to be addressed. The primary beneficiaries will be industry.

Organization: ASTM F42/ISO TC 261, AWS, DoD, FAA, NASA, SAE

Processes or Procedures

Each implementation of an AM process requires qualification prior to use in most aerospace applications. An implementation of an AM process may be referred to as an AM procedure, such as the case of the AWS D20 standard, which inherits its terminology from AWS D17.1 regarding welding procedure qualification. Process or procedure qualification is essential to ensure the fundamental integrity of material produced by any given AM machine under a fully defined and fixed process. There is currently no consensus definition for the qualification of additive processes. This lack of standard definition presents a risk to the additive user community in aerospace by introducing significant variation in the evaluations included in the qualification methodology. This renders process qualification largely vendor-specific, and requires a case-by-case evaluation of the qualification methodology for any given set of requirements. A vendor's assertion of qualified additive processes does not, in and of itself, provide meaning if not presented with the specifics of the qualification methodology. A few common examples of variations in the additive process/procedure qualification methodology include the degree of internal material quality assessment (microstructure, porosity, lack of fusion, etc.), the degree of

mechanical property evaluation (tensile, fatigue, fracture toughness, etc.), degree of evaluation in the quality of surfaces and rendered details, and the extent of build quality evaluation throughout the available build area/volume.

The definition of the actual process or procedure being qualified often lacks consistency. For example, feedstock controls and thermal processes may, or may not, be included in the definition. Such precursor and successor steps to the base AM process are critical if the process qualification is intended to guarantee fundamental material performance.

Different approaches also exist in the aerospace industry regarding the distinction between the qualification of additive parts and the foundational processes/procedures. A few examples are listed below:

NASA: The NASA document, [MSFC-STD-3716, Standard for Additively Manufactured Spaceflight Hardware by Laser Powder Bed Fusion in Metals](#) (see section 2.3.2.7), separates the qualification of the foundational PBF-L process (as described by [MSFC-SPEC-3717, Specification for Control and Qualification of Laser Powder Bed Fusion Metallurgical Processes](#)) from the qualification of an additive part, which is considered a geometry-specific implementation of the qualified process. The part then requires its own part-specific qualifications to demonstrate successful implementation of the process.

AWS: By contrast, the developing AWS D20 standard requires the qualification of the AM procedure used to produce a component, where the qualified procedure must contain all variables required to fabricate the component, such as the build model, feedstock and build platform characteristics, AM machine variables, build environment requirements, build parameters, and component post-processing. In this scenario, the AM procedure is part-specific and is qualified through the fabrication and evaluation of test articles.

SAE: The SAE AMS AM-M (metallic) specifications under development are hierarchical and define the requirements and establish controls for a material process combination. They are based on a material specification, including material requirements. Each material specification is linked to a separate process and feedstock specifications, as well as a feedstock process specification. The SAE AMS AM-P (polymer) specifications are similar with a base material specification that is linked to a process specification. In addition, there are separate detailed material specifications that include the specification minimum values for specific material/process combinations. For further information on the SAE specification approach, see Section 1.5.11 of this Roadmap.

Personnel

Personnel are “certified.” Currently, operator certification is through on the job training coupled with OEM-provided training (classroom and hands on experience) specific to particular machines/equipment. Procedures may be written to document how personnel certifications are accomplished. Some certifications include levels of certification that determine the specific activities/operations that an operator can perform, such as product acceptance, equipment maintenance, or certification of other operators. Future needs may call for formal personnel certification by process, or process and material,

as well as for specific machines. AWS D20 has a section on qualification of AM machine operators and operator certifications are described in the NASA MSFC standard for laser powder bed fusion for AM. ASTM offers a general AM certification and may also be looking at other certifications. The aerospace and defense industries are aligned in their approach to personnel certification, so the gap identified in the Defense Industry section below is applicable.

AM Equipment

AM equipment is calibrated and/or certified by the OEM or aerospace industry company that purchases the equipment per certification and/or calibration procedures. Some companies refer to calibration as certification.

Adverse machine environmental condition standards are needed so the build environment can be compared to the as specified parameters for environmental control through methods such as chamber gas, temperature, and pressure monitoring. Gaps for adverse machine environmental condition standards are addressed in the Process Control section of this roadmap.

The aerospace industry needs additively manufactured physical calibration standards for NDE. Those standards are covered in the NDE section of this roadmap.

AM Drawing and Model Standards

It is anticipated that the aerospace industry will adopt industry standards for drawings and for DSR4 and DSR6 (no drawing) models. It is anticipated that only models will be needed in the future and the models will cover all aspects currently in the drawings and will include things like x,y,z orientation, growth direction, etc. Drawing and model standards are needed so the as-built models can be compared to the as-designed models for product acceptance through inspection methods such as 3D scanning and CT scanning. Gaps for drawing and model standards are addressed in the Design section of this roadmap.

2.3.3.2 Defense Industry

As part of Defense Acquisition, 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. 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. There are additional Q&C burdens for AM developed or manufactured parts arising from the lack of specifications and standards for the various AM processes, the precursor materials used in AM processes, the finishing and post-processing of AM parts, and nondestructive evaluation criteria. These gaps are being addressed within this document. There are also no established design allowables for AM processes,

which results in much higher requirements for Q&C to have the baseline understanding of the material properties of a given part and whether or not that part will meet the established performance criteria.

The Secretary of the Navy (SECNAV) has formed an AM Executive Committee (EXCOMM) comprised of leadership that includes the System Commands, Fleet Units, and the R&D community with the intent of ultimately integrating AM into Defense Acquisition. One of the stated goals of the EXCOMM is to “Develop the ability to qualify and certify AM parts.” This encompasses several focus areas, including broadening the library of materials, processing, material properties, nondestructive evaluation, standards/specifications development, manufacturing process control, and expeditionary and afloat environmental effects. These goals and their associated efforts are captured in the Department of the Navy (DON) AM Implementation Plan.

In addition, the Defense Logistics Agency 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 usually found as 2D blueprints, thus requiring a conversion to 3D models. In addition to the added cost of this process, current methods of converting to 3D data introduces errors that increase the complexity of the certification process.

Technical Data Package (TDP)

A TDP is defined by the Defense Acquisition University as: “A technical description of an item adequate for supporting an acquisition strategy, production, engineering, and logistics support (LS). The description defines the required design configuration and procedures to ensure adequacy of item performance. It consists of all applicable TD such as drawings, associated lists, specifications, standards, performance requirements, quality assurance provisions, and packaging details.” A TDP is used to contract out for the procurement of parts and components for DoD assets.

There are several ongoing efforts throughout the Navy that are geared towards the development of a common TDP. The goal of developing this 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 a common TDP will not be possible without specifications and standards that can be invoked to guide the manufacturing process.

In order to achieve the goal of producing accurate parts repeatedly, a certified TDP format must be developed and proven. This certified TDP format will increase certainty of acquiring repeatedly accurate components as well as providing the logistics communities the ability to successfully order additively manufactured components in the future. Current Navy efforts include 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 the Design Documentation section of this roadmap for Gap D17 on TDPs.

Neutral build files are the desired end state for build files that can be ported between different types of machines/processes. See also Gap D20 on neutral build file.

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.

In terms of standards in development, the draft AWS D20.1 standard has been approved by the D20 committee. As noted earlier, AWS D20.1 includes process parameters for PBF and DED processes. The SAE AMS7000 series includes references to ISO/ASTM 52900 and ARP1917 Rev A. Specifically, in AMS7003 *Laser Powder Bed Fusion Process*, Section 8.1 lists several additional definitions that are not included in ISO/ASTM 52900 or ARP1917. ASTM F42 also has a dedicated terminology subcommittee F42.91 working with ISO/TC 261 on JG 51. Additional terms are being developed by SDOs to meet industry requirements.

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: No

Recommendation: Develop standardized terminology for process parameters for use across all AM equipment. Potentially, incorporate these into [ISO/ASTM 52900:2015, Additive manufacturing - General principles - Terminology](#). See also Gap PC5 on parameter control.

Priority: Medium

Status of Progress: Green

Update: As noted in the text.

Organization: ASTM F42/ISO TC 261 JG 51, AWS D20, SAE AMS-AM, IEEE-ISTO PWG

Process Approval for DoD-procured Parts

For Navy platforms, before a vendor can supply a component, that vendor must be qualified to manufacture that part. 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. The government 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 for the government 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 and [ASTM E384-17, Standard Test Method for Microindentation Hardness of Materials](#). Standards in development include: [ASTM WK51329, New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy \(UNS R30075\) with Powder Bed Fusion1](#), and other ASTM standards.

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

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: Medium

Status of Progress: Yellow

Update: DoD is holding AM business model workshops, the agenda for which includes developing an AM contracting guide for the Navy/DoD. None provided vis a vis work by the SDOs.

Organization: ASME, ASTM F42/ISO TC 261, DoD, Industry, SAE, Service SYSCOMS

Machine Operator 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. Operator training has also been identified as a need for the medical devices industry which may have different requirements (e.g., for point of care providers).

In terms of existing standards and specifications, the [NASA MSFC-SPEC-3717](#) addresses training and certification of personnel for PBF-L operations. There is also [SAE ARP 1962A, Training and Approval of Heat-Treating Personnel](#) though it is not AM specific.

The draft AWS D20.1 standard includes requirements for AM machine operator performance qualification based on training, written and practical examinations, and the demonstration of successful AM builds. The SAE 7000 series also addresses training.

AM training programs include but are not limited to those offered by OEMs and other third party organizations. 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.

R&D Needed: No

Recommendation: Develop AM operator training and qualification standards or guidelines. Training should cover the various AM materials and processes available in the market and be 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: Low

Status of Progress: Green

Update: As noted in the text.

In the specific case of DoD, consideration should be given to establishing a sub-specialty code for AM. 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

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

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 design 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.

2.3.3.3 Medical Industry²⁷

The medical industry has begun to adopt AM, using the ability to make patient-specific devices that are matched to a single patient's anatomy as well as to integrate lattice structures.²⁸ Patient-specific devices are becoming more prevalent in certain areas such as 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 methods of design and manufacturing may not encompass all of the capabilities, important 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 and evaluation and approval of AM devices. FDA Guidance documents provide recommendations for device production and testing as well as regulatory submission requirements. 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.²⁹ Class I is the lowest risk device; Class II is higher risk than Class I; and Class III is the highest risk device. This document does not directly reference FDA classification. Rather, for purposes of this document, devices will be categorized as having short term or long term contact with an internal body system, and based on whether or not they are load bearing.

There are many reasons to use AM for medical devices. Among the most popular to date are porous surfaces, lattice features, and patient-specific devices and accessories. Porous and lattice features are generated through computational methods, whereas patient-specific devices often start from patient imaging. The AM workflow and quality systems remain the same for patient-specific devices fit to patient images with the addition of image acquisition and quality, image processing, clinical design

²⁷ Readers of this section are also encouraged to review other relevant parts of this document that are general in nature but that may have application to the medical industry. These would include, for example, file format, process monitoring, and NDE, among others.

²⁸ While the discussion herein focuses on AM of medical devices, the FDA has approved at least one AM pharmaceutical.

²⁹ See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/>

iteration, and final clinical sign-off. Especially important are aspects of version control to ensure the appropriate design iteration is provided to the clinician. Some of the requirements, such as data acquisition, are common to all types of devices.

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 ultrasound output data varies depending on the manufacturer. DICOM WG17 on 3D manufacturing deals with this issue.

Gap QC6: Importing Ultrasound Data. The DICOM standard needs to be more widely promoted and may need to be revised to enable data to be imported from any ultrasound equipment similar to the CT scan or MRI data. There is a concern that the data coming from the ultrasound may not be providing adequately detailed images but this cannot be assessed until the interoperability concerns are eliminated.

R&D Needed: Yes

Recommendation: Promote and potentially revise the DICOM standard for importing data from ultrasound equipment. Use cases are obstetrics and pre-natal diagnosis. CP 1071 correction proposals should be approved. This relates to codes for cardiac ultrasound data target sites.

Priority: Medium

Status of Progress: Green

Update: [ISO/ASTM NP 52916, Additive manufacturing -- Data formats -- Standard specification for optimized medical image data](#), is being developed by ASTM F42 and ISO/TC 261 as JG 70.

Organization: DICOM, IEEE, ASTM F42/ISO TC 261 JG 70

Data Acquisition for 3D Modeling: Protocols for Image Accuracy

The issue here is multifold:

- Diagnostic CT and MRI image data is routinely acquired but 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.

Gap QC7: Protocols for Image Accuracy. 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.

R&D Needed: Yes. More R&D is needed on data for image accuracy before a standard can be developed.

Recommendation: Develop standard protocols for acquiring data for 3D modeling to ensure image accuracy. 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.

Priority: Medium

Status of Progress: Green

Update: [ISO/ASTM NP 52916, Additive manufacturing -- Data formats -- Standard specification for optimized medical image data](#), is being developed by ASTM F42 and ISO/TC 261 as JG 70.

Organization: DICOM, IEEE, ASME, ASTM F42/ISO TC 261, RSNA (Radiological Society of North America)

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.³⁰ 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

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.

³⁰ 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: Medium

Status of Progress: Green

Update: The RSNA 3DP Special Interest Group (SIG) is developing best practices for phantoms.

Organization: Biomedical Engineering Society, NEMA/MITA, ISO, ASTM, RSNA

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: No

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

Status of Progress: Green

Update: The SME AM3DP medical WG has developed competency models and is working on a detailed body of knowledge (BOK) to help recruit skilled workers to the profession, along with training, curriculum development, and a certification program.³¹ The FDA is involved with SME and RSNA. There is no separate interest at the federal level; certifications happen at the state level.

Organization: SME, RSNA, ASTM F42/ISO TC 261

Quality, Verification, and Validation of Medical Product 3D Models

3D models are typically created for an 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.

³¹ <http://sme.org/am3dpjobmodel/>

Gap QC10: Verification of 3D Model. There are currently no standards for the final verification of a 3D model before it is approved for AM for the intended purpose (e.g., surgical planning vs. implantation; cranial replacement piece; cutting guides which have a low tolerance for anatomical discrepancy).

R&D Needed: Yes, in terms of tolerances

Recommendation: Develop standards for verification of the 3D model against the initial data. Ideally, they should identify efficient, automatable methods for identifying discrepancies.

Priority: High

Status of Progress: Green

Update: ASTM F42/ISO 261 are looking at image quality as part of the model verification. ASME V&V 40 addresses verification and validation in computational modeling of medical devices. This issue requires cooperation between clinical societies, the FDA and industry. It may also be a general, not only medical, concern.

Organization: ASTM F42/ISO TC 261, NEMA/MITA, AAMI, ASME, NIST, ACR

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 7:

Examples of Some Materials for Medical Applications

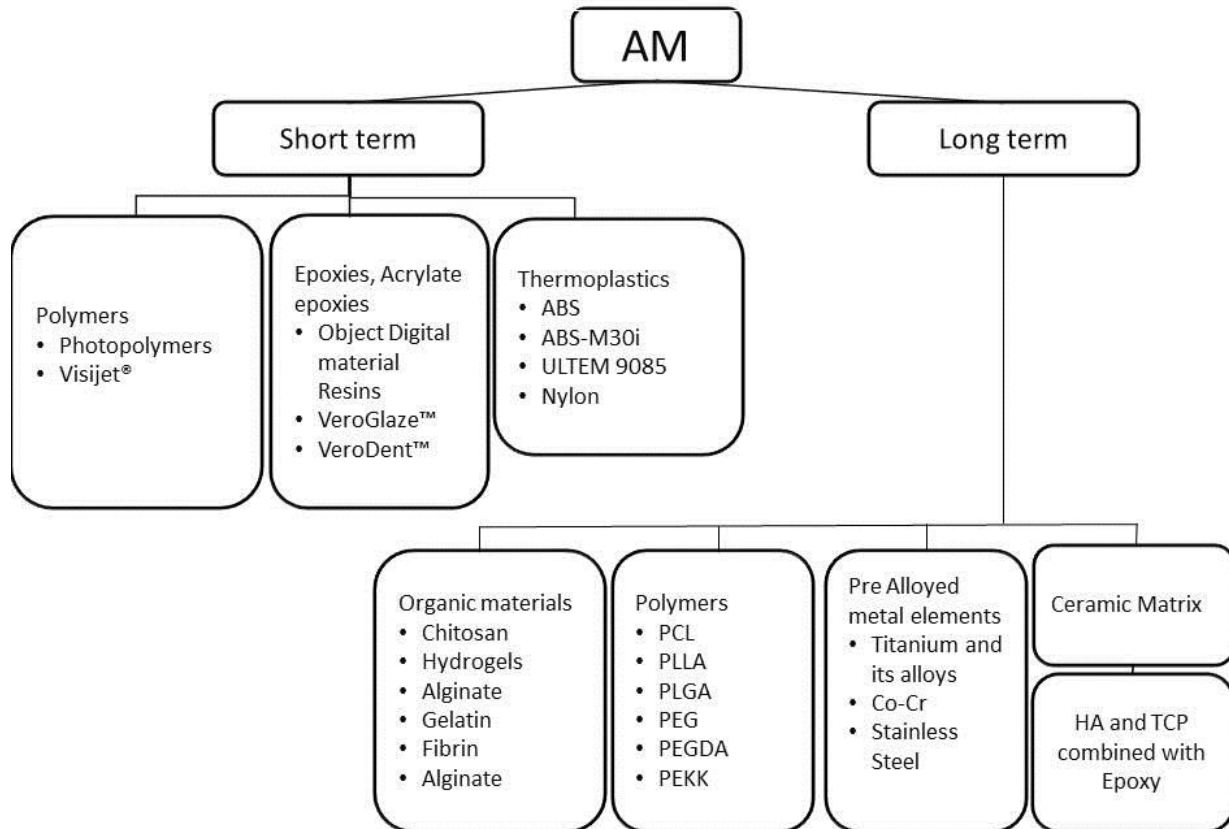


Figure 7: Examples of some AM materials for medical applications. Figure courtesy of Dr. Jayanthi Parthasarathy and Lauralyn McDaniel

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, Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion](#)
- [ASTM F3001-14, Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI \(Extra Low Interstitial\) with Powder Bed Fusion](#)

- [FDA 21 CFR 820.70, Production and process controls](#)
- [ISO 13485:2016, Medical devices - Quality management systems - Requirements for regulatory purposes](#)

Standards in development include:

- [ASTM WK51329, New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy \(UNS R30075\) with Powder Bed Fusion1](#)
- [ASTM WK53878, New Specification for Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 1: Feedstock materials](#)

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.

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 include:

- [ASTM F1635-16, Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants](#)
- [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](#)
- [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](#)
- [ISO/TR 37137:2014, Cardiovascular biological evaluation of medical devices -- Guidance for absorbable implants](#)

Standards in development include:

- [ISO/AWI TS 20721, Implants for surgery -- Standard guide to assessment of absorbable metallic implants](#)
- [ASTM WK52640, New Guide for In-Vitro Degradation Testing of Absorbable Metals](#)
- [ISO/DTR 37137-2, Cardiovascular biological evaluation of medical devices -- Guidance for absorbable implants -- Part 2: Standard guide for absorbable metals](#)
- [ASTM WK61103, New Guide for Corrosion Fatigue Evaluation of Absorbable Metals](#)

Gap QC12: Resorbable Materials. Testing of degradation of the new resorbable metals/polymers in living tissues cannot be adequately achieved using existing standards.

R&D Needed: Yes, in terms of rate and amount of degradation for new polymers and resorbable metals.

Recommendation: Develop guidance on how to test the degradation of new resorbable metals/polymers to support material selection for AM.

Priority: Medium

Status of Progress: Green

Update: None provided

Organization: ASTM F4, ISO, ISO/TC 150, ISO/TC 194

Biocompatibility Testing Standards Available for Resorbable and Non-resorbable Materials

Existing standards include [ANSI/AAMI/ISO 10993-1:2009 \(R2013\), *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.

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.

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

Recommendation: A standard or specification describing a data set for material pedigree, recommended testing, and handling procedures would simplify evaluation of material suitability.

Priority: Low

Status of Progress: Unknown

Update: None provided

Organization: Material providers, ASTM

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 (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/>)
- Use of International Standard [ANSI/AAMI/ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*](#)
- Guidance for Industry and Food and Drug Administration Staff (June 16, 2016) <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf>

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 include:

HL7 Standard for CDA Release 2: Imaging Integration. 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. Site: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=13

DICOM, Digital Imaging and Communications in Medicine. DICOM is the international standard for medical images and related information ([ISO 12052:2017](#)). It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use. DICOM is implemented in almost every radiology, cardiology imaging, and radiotherapy device (X-ray, CT, MRI, ultrasound, etc.), and increasingly in devices in other medical domains such as ophthalmology and dentistry. With tens of thousands of imaging devices in use, DICOM is one of the most widely deployed healthcare messaging standards in the world. Note: The specification is the current standard for all medical images captured in an institutional setting.

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.

Standards in development include:

DICOM. DICOM has activated a WG to integrate the needs of AM/3DP into the DICOM standard. Incorporation of 3D segmentations/reconstructions into the DICOM specification will address many clinical concerns such as

- patient confidential information,
- HIPAA compliance,
- data maintenance/preservation, and
- semi-automatic query.

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. There is no group or entity that oversees segmentation within a clinical setting. RSNA has a special interest group that may set standards for segmentation and/or 3D printing. DICOM WG 17 also is looking at this.

R&D Needed: No

Recommendation: There is a need to create an augmented file specification for 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.

Priority: Medium

Status of Progress: Green

Update: DICOM is addressing most of this. They will have public comment by the end of 2018, with a target for the first update being made by the second quarter of 2019.

Organization: RSNA, DICOM, ASTM

Validation of Sterilization Processes

The issues of concern are: sterile barrier packaging; validation of the ability to clean, disinfect, and sterilize products intended for subsequent processing; impact on final mechanical properties; and final 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.³² 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 \(CGTP\)](#)

³² 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 141 standards with further information available by clicking on the title.

[and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products \(HCT/Ps\).](#)

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 ST67:2011 \(R2017\)](#) provides a risk management framework for justifying alternative SALs. For medical devices produced via aseptic processing, the [ANSI/AAMI/ISO 13408](#) series provides guidance.

Sterile barrier packaging: ANSI/AAMI/ISO [11607-1:2006 \(R2010\)](#) and [11607-2:2006 \(R2010\)](#) provide requirements for packaging intended to maintain sterility, and ASTM standards provide packaging test methods ([D3078-02\(2013\)](#), [D4169-16](#), [F1140/F1140M-13](#), [F1608-16](#), [F17-17](#), [F1886/F1886M-16](#), [F1929-15](#), [F1980-16](#), [F2054/F2054M-13](#), [F2095-07\(2013\)](#), [F2096-11](#), [F2097-16](#), [F2203-13](#), [F2217/F2217M-13](#), [F2228-13](#), [F2250-13](#), [F2251-13](#), [F2252/F2252M-13e1](#), [F2338-09\(2013\)](#), [F2391-05\(2016\)](#), [F2475-11](#), [F2638-12e1](#), [F2825-10\(2015\)](#), [F88/F88M-15](#)).

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 TIR12:2010, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers](#) provides guidance on designing, testing and labeling devices intended to be sterilized by healthcare facilities or other device users.

Impact of sterilization on mechanical properties of devices and geometric fidelity of devices: 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 17:2008](#) provides information on materials compatibility with sterilization processes.

Gap QC15: Sterilization of Anatomical Models. Anatomical models are frequently made in a healthcare setting and their final use may differ from the initial intended use. For instance, a surgeon may determine that a model patient education may be useful for reference in the operating room during the surgical procedure. If the models enter the sterile field they would require sterilization and the effects of sterilization on the geometric fidelity of the model should be assessed. If they are to come into contact with the patient the effects of sterilization on the materials are especially important. While many standards and industry best practices exist, the healthcare facilities may not have relevant experience.

R&D Needed: No. Procedures and protocols for determining appropriate materials, sterilization cycles, and validation tests are already available but may not be implemented in healthcare settings.

Recommendation: Develop guides and best practices to help identify critical parameters and apply existing standards in a clinical setting.

Priority: Low

Status of Progress: Unknown

Update: The SME medical group is working on a biocompatibility worksheet for use with both models and surgical guides. This will not be a standard, but a guide of considerations.

Organization: R&D: OEMs. Guidance: AAMI, AOAC International, ASTM, ISO, PDA, USP, RSNA 3DP SIG.

Sterilization of Tissue Engineered Products

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.

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 (e.g., [ANSI/AAMI/ISO 13022:2012, Medical products containing viable human cells - Application of risk management and requirements for processing practices](#)), that have not been recognized by the FDA. Another international standard which was not recognized by the FDA or adopted by the U.S. is [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.

The FDA list of recognized standards provides known information about revisions of some of these standards. An international technical specification, [ISO/PRF TS 19330, Guidance on aspects of a risk-based approach to assuring sterility of terminally-sterilized, single-use health care products](#), is being developed to provide a framework for evaluating alternatives for medical devices that cannot be adequately sterilized via standard protocols.

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 D14.

NEW Gap QC16: Sterilization of Tissue Engineered Products. 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 can help decrease the risks of contamination with best practices but not provide defined measures to ensure the sterility or assess contamination in a tissue engineered product.

R&D Needed: Maybe. 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 tissue engineered products.

Recommendation: Develop and validate standard methods of sterilizing and verifying the sterility of tissue engineered products, especially those that can be applied in healthcare settings.

Priority: Medium

Organization: R&D: OEMs, FDA, BioFabUSA. Standards: AAMI, ISO, ASTM, AATB.

2.3.3.4 Electronic 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.

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 product manufacturing purposes.

More recently, there has been an industry shift toward an interest in using AM to produce parts of end-products. The Department of Energy has realized the advantages of AM for production of electronic and electrical products. Multiple trade organizations and academic research institutions have begun to examine the advantages of AM and are promoting its adoption for these applications.

Qualification and Certifications

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.

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 matures as a method 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.

2.4 Nondestructive Evaluation (NDE)

2.4.1 Introduction (metals)³³

Nondestructive evaluation (NDE), also known as nondestructive testing (NDT) or nondestructive inspection (NDI), is one of the engineering disciplines used to verify the integrity of high value components.³⁴ Task-specific NDE methods have been developed over many years. The most common methods recognized and controlled by industrial standards are: X-ray, digital radiography, dye penetrant, eddy current, magnetic particle, and ultrasonic testing. Adaptations of these methods are also used in the medical industry for patient diagnoses. While both the industrial and medical industries use these methods, the application of each is specifically designed for an intended purpose, material, and characterization goal.

The U.S. military first controlled many of these standards used for the inspection of products provided by the aerospace industry. During the military acquisition reform of the 1990s, changes shifted from the military as owners to industry as owners. Two primary receiving organizations were ASTM International and SAE International. These organizations continue to create, revise, and release NDE standards used by U.S. industry to this day.

NDE methods to detect discontinuities and flaws are often cataloged by the character of the flaw and the location within the part for which the inspection method is best suited. These flaw locations are often referred to as: embedded, subsurface, surface, or surface breaking. Embedded flaw methods include: X-ray, ultrasonic, eddy current, thermal imaging, and acoustic emission. Surface flaw detecting methods include: dye penetrant, eddy current, acoustic emission, and ultrasonic.

NDE methods have differing outputs to display or record the testing results. For example, an X-ray is viewed by an inspector who interprets what is recorded by the film or digital image. 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. To the X-ray inspector, a pore or void indication may appear the same in a number of manufacturing processes with a lower density than the surrounding material. In ultrasonic inspection using the ultrasonic pulse echo, 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).

³³ The scope of this NDE section is generally focused on additive manufacturing of metal components. Other materials are discussed in section 2.4.6.

³⁴ In this section, the term “component” is used to refer to the finished AM part or component being inspected. The term “phantom” refers to a calibration standard or other test specimen specifically designed and manufactured to demonstrate the capability of an inspection process (i.e., physical reference standard). When referring to both a component and a phantom, the term “object” is used.

There are currently five categories used to create 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:

- PBF-L, Laser powder bed fusion
- PBF-EB, Electron beam powder bed fusion
- DED-L, Laser directed energy deposition
- DED-EB, Electron beam directed energy deposition
- DED-GMA, DED-PA, Gas metal arc and plasma arc directed energy deposition processes

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 medical sectors' NDE standardization needs or gaps have been evaluated and are summarized in the discussion that follows. Figure 8 shows an evolving sequence of these gaps that are relevant to both sectors.

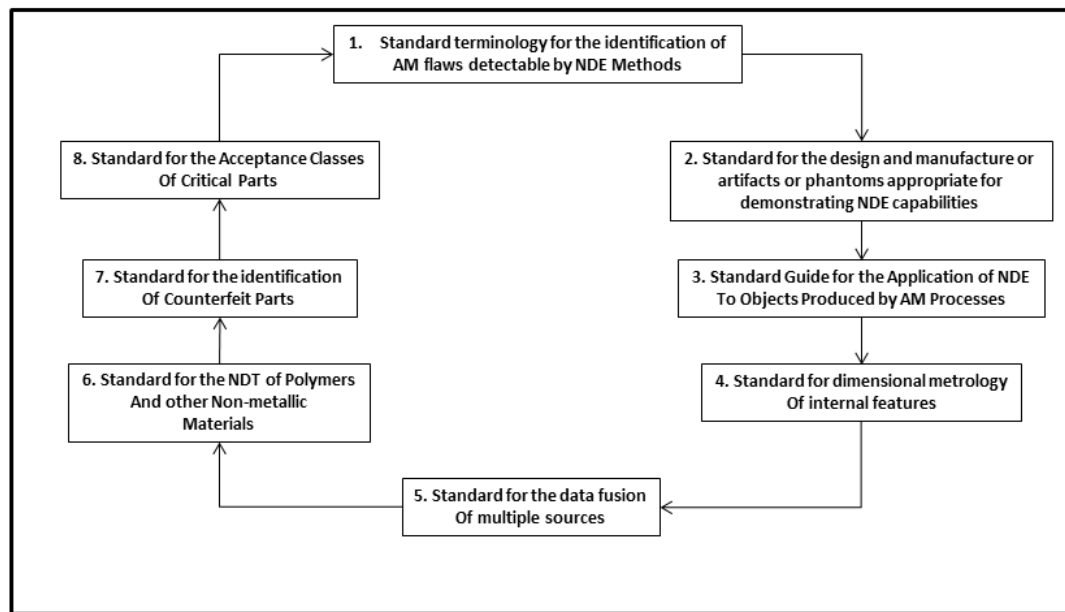


Figure 8: Evolving sequence of AM NDE gaps

2.4.2 Common Defects Catalog Using a Common Language for AM Fabricated Parts

Terminology

Historically, flaw types, names, or classifications are associated with the generating process, e.g., castings may contain “shrinkage” and welds may contain “incomplete penetration.” There are also overlapping flaw types, for example, porosity. Additive manufacturing is another form of part manufacturing with unique flaw types and classifications associated with the process. The need to establish consensus flaw descriptions based on consensus terminology to accurately identify flaw types and classifications is a gap that needs to be addressed.

Individual engineers and companies have discovered and termed additively manufactured flaws stemming from their work in the AM process; however, there has been no industry-based standard with the specific intent to address flaw types and names. Currently, flaw types, while described in literature reports, have been restricted in definition to the content of the report.

As a new technology operating on principles many of which are foreign to conventional machining, additive manufacturing is in need of 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.

Published standards addressing terminology but not the individual flaw types or classifications needed to accept or reject AM parts by nondestructive testing include:

- [ISO/ASTM 52900:2015, Additive Manufacturing - General Principles Terminology](#), developed by ISO/TC 261 and ASTM F42 under their PSDO cooperation agreement
- [ISO/ASTM 52921:2013, Standard terminology for additive manufacturing - Coordinate systems and test methodologies](#), developed by ASTM F42.01 and adopted via a fast-track procedure by ISO/TC 261 under the PSDO cooperation agreement with ASTM F42
- [ASTM E1316-18a, Standard Terminology for Nondestructive Examinations](#), developed by ASTM E07.92

Standards in development include:

- [ISO/ASTM DIS 52902, Additive manufacturing -- Test artefacts -- Standard guideline for geometric capability assessment of additive manufacturing systems](#), addressing flaw types, being developed jointly by ASTM F42 and ISO/TC 261 as JG 52
- [ISO/ASTM CD 52905, Additive Manufacturing — Non-Destructive Testing and Evaluation — Standard Guideline for Defect Detection in Metallic Parts](#), being developed jointly by ISO/TC 261

and ASTM F42 as JG59, with the unique approach of reviewing existing standards and an a la carte approach.

- [WK56649, New Guide for Standard Practice/Guide for Intentionally Seeding Flaws in Additively Manufactured \(AM\) Parts](#) being developed as JG 60 by ASTM F42 and ISO/TC 261
- [ASTM WK47031, New Guide for Nondestructive Testing of Additive Manufactured Metal Parts Used in Aerospace Applications](#), which includes terminology, being developed in ASTM E07.10. SAE AMS K, Non Destructive Methods and Processes Committee, coordinates with ASTM E07.
- ASME's Boiler & Pressure Vessel Code group will be looking at NDE of a pressure vessel. They are also looking at working with ASTM.
- [AWS D20.1, Standard for Fabrication of Metal Components using Additive Manufacturing](#), which includes nondestructive and destructive examination requirements and acceptance criteria for metal AM parts.

Gap NDE1: Terminology for the Identification of AM Flaws Detectable by NDE Methods. An industry driven standard needs to be developed, with input from experts in metallurgy, NDE, and additive manufacturing fabrication, to identify flaws or flaw concentrations with the potential to jeopardize an AM object's intended use. Many flaws have been identified but more effort is needed to agree on flaws terminology, providing appropriate names and descriptions.

R&D Needed: No

Recommendation: Develop standardized terminology to identify and describe flaws, and typical locations in a build.

Priority: High

Status of Progress: Green

Update: As noted in the text.

Organization: ASTM E07, ASTM F42/ISO TC 261, SAE AMS K, ASME BPVC, AWS D20, NIST

Defect Catalog and Equipment Standardization

Additively manufactured metal parts are made by sintering or melting powder, wire, or other feedstock 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-2001, Electron-Beam Welding for Fatigue Critical Applications](#).

The ASTM work item [WK47031](#) (under the [ASTM E07](#) committee on NDT) will house, at a minimum, a table with defects. Another work item (proceeding jointly as JG 60 under the ISO/TC 261 and ASTM F42 committees on Additive Manufacturing) is [WK56649, New Guide for Standard Practice/Guide for Intentionally Seeding Flaws in Additively Manufactured \(AM\) Parts](#), previously known as ASTM WK49798. This work item is addressing “how to create defects” 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.

Nondestructive testing uses physical standards – specimens or phantoms – to ensure the equipment is functioning at a specified level. These are in place for the inspection of well-established product forms. The complexities of emerging 3D printed parts require new approaches and standards to set and demonstrate equipment functionality. These new approaches and standards must have industry acceptance as the basis for inspection techniques.

Gap NDE2: Standard for the Design and Manufacture of Artifacts or Phantoms Appropriate for Demonstrating NDE Capability. No published standards exist for the design or manufacture of artifacts or phantoms applicable to calibrating NDE equipment or demonstrating detection of naturally occurring flaws (lack of fusion, porosity, etc.), or intentionally added features (watermarks, embedded geometrical features, etc.). Current standards under development, ISO/ASTM CD 52905 JG59 and ASTM WK47031, are partially addressing this with seeded defects and demonstration of NDT detectability. This standard should identify the naturally occurring flaws and intentional features. This standard should also include recommendations regarding the use of existing subtractive machined calibration standards or AM representative artifacts or phantoms.

R&D Needed: No. This may not need R&D but it will require obtaining the knowledge necessary to state requirements and present supporting evidence, much like a round robin activity.

Recommendation: Complete work on JG59, JG60 and ASTM WK47031.

Priority: Medium

Status of Progress: Green

Update: As noted in the text.

Organization: ASTM F42/ISO TC 261

2.4.3 Test Methods or Best Practice Guides for NDE of AM Parts

Additive manufacturing technologies for the development, prototyping, and production of three-dimensional 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 category can produce and the appropriate NDE processes for discovering those flaws.

Although there are some commonalities in the types of defects in AM compared to other more matured processes such as casting, forging and welding, AM has additional unique defects. In addition, AM typically provides an increased level of geometric complexity, all of which require additional standards. 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., castings, forgings, billet). 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 E127-15](#) and [ASTM E428-08\(2013\)](#) and implemented as acceptance classes in [SAE AMSSTD2154C](#) and [ASTM E2375-16](#). Similarly, X-ray inspection of titanium castings uses reference radiographs to measure severity as defined in [ASTM E1320-15](#). Acceptance standards may be imbedded in the process standard or in a stand-alone standard such as [MIL-STD-1907\(4\) NOT 3](#) for the penetrant inspection of castings. 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.

In terms of standards in development, ASTM E07.10 is working on [ASTM WK47031, New Guide for Nondestructive Testing of Additive Manufactured Metal Parts Used in Aerospace Applications](#). ISO/TC 261/JG 59 is creating a similar standard, [ISO/ASTM CD 52905, Additive Manufacturing — Non-Destructive Testing and Evaluation — Standard Guideline for Defect Detection in Metallic Parts](#). This is a joint project between ISO/TC 261 and ASTM Committee F42. Guidance documents such as these will provide the NDE industry a starting point for designing inspection processes for additively manufactured objects. The knowledge generated with the creation of these documents will establish 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 non-complex objects can be inspected using existing standards. Post-processing of the objects is generally required and can be performed to currently released standards.

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 provide an introduction to nondestructive testing and inspection requirements.

R&D Needed: Yes. Round robin testing is underway on ASTM WK47031 and ISO/ASTM CD 52905. A future need will be a precision and bias statement to generate standard test methods to accept/reject AM parts and in procurement of AM parts.

Recommendation: Complete work on [ASTM WK47031, New Guide for Nondestructive Testing of Additive Manufactured Metal Parts Used in Aerospace Applications](#) and [ISO/ASTM CD 52905, Additive Manufacturing — Non-Destructive Testing and Evaluation — Standard Guideline for Defect Detection in Metallic Parts](#), proceeding as ISO/TC 261/JG 59.

Priority: High

Status of Progress: Green

Update: ASTM WK47031 and ISO/TC 261/JG 59 are in development. ASME is also looking at NDE vis a vis its boiler and pressure vessel code.

Organization: ASTM E07, ASTM F42/ISO TC 261, ASME, NIST

2.4.4 Dimensional Metrology of Internal Features

The additive manufacturing process presents unique challenges in dimensional metrology. There are many aspects when determining the quality and form, especially internal features, of the parts produced via the AM process. Destructive measurement methods produce results that differ from those generated by nondestructive methods. Therefore, dimensional control is a challenge when measuring internal features of certain parts created in the AM process. Internal structures, tolerances and their limits, and material characterization of complex 3D structures cannot be measured with the standard metrological methods available today.

Among the leading NDT technologies in the AM world are X-ray computed tomography (CT), which can measure internal features of a part after fabrication, and structured light, which can measure external features either during or after fabrication. CT technology provides important measurements such as wall thickness, porosity analysis, material structural analysis, and, most importantly, complex internal hollow structures that are otherwise impossible to measure.

Another important aspect is determination of the type of NDT process to be applied, knowing the surface roughness measurement. Surface roughness may meet the print specifications but there can be abnormalities (uneven surface, etc.) from the build. Further, the type of AM process to be used, and what parts need to be manufactured, are key design aspects. All these factors must be kept in mind when applying measurement techniques to AM parts.

Published CT or related standards include:

- [ASTM E1570-11, Standard Practice for Computed Tomographic \(CT\) Examination](#)

- [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](#)
- A German standard [VDI/VDE 2630 Blatt 1.4, Computed tomography in dimensional metrology: measurement procedure and comparability](#)

AM-related standards in development outside of ASTM Subcommittee E07.01 on Radiology (X and Gamma) Method include:

- [ASTM WK47031, New Guide for Nondestructive Testing of Metal Aerospace Additive Manufactured Parts After Build](#), by ASTM E07.10 on Specialized NDT Methods

ASTM E07.01 has started work on two draft practices on:

- CT metrology based on German VDI standards ([WK61974, New Practice for Standard Practice for characterization of computed tomography systems for dimensional measurement](#)), and
- Qualification of CT for inspection for volumetric flaws, cracks and defects using cone beam CT ([WK61161, New Practice for Volumetric Computed Tomographic \(CT\) Examination Using Digital Detector Arrays](#)).

In addition, a current E07.01 standard for evaluating CT system performance is undergoing revision ([WK61162, Revision of E1695 - 95\(2013\) Standard Test Method for Measurement of Computed Tomography \(CT\) System Performance](#)).

It should be noted that, while the above CT standards address internal metrology directly (WK61161 and WK61974) or indirectly (E1570 and E1695), providing a basis for dimensional metrology of internal features in AM parts, none are written specifically for AM parts.

Research on the topic of dimensional metrology of internal features of AM parts has been undertaken by, among others, NASA, the Army, Air Force, and Navy. A significant study is “Nondestructive Evaluation of Additive Manufacturing” by NASA. Other texts include:

- Higginbotham, K. Additive Manufacturing & NDE Tasks Applicable to SLS. MSFC/Advanced Development Office, April 3, 2014.
- Kjelgaard, C. The new meaning of additive value. Aerospace America, 20-22, November 2013.
- Ghidini, T. European Space Agency Perspective on Additive Manufacturing (AM). 3D Printing & Additive Manufacturing – Industrial Applications, Global Summit, London, UK, November 2011.

Research has also been undertaken on the topic of CT measurement of porosity distribution in AM fatigue samples:

- Brandão, Gumpinger, Gschweilb, Seyfert, Hofbauer, Ghidini, Fatigue Properties of Additively Manufactured AISi10Mg – Surface Treatment Effect, Procedia Structural Integrity, 7, 58-66 (2017).

Gap NDE4: Dimensional Metrology of Internal Features. The utility of existing and draft CT standards are needed for the dimensional measurement of AM internal features.

R&D Needed: Yes

Recommendation: ASTM E07 should address the applicability of current and draft CT standards (E1570, E1695, WK61161, and WK61974) for measurement of internal features 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 D26, Measurement of AM Features/Verifying the designs of features such as lattices, etc.

Priority: Medium

Status of Progress: Green

Update: As noted in the text.

Organization: ASTM

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 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.

No published standards or standards in development have been identified.

Gap NDE5: Data Fusion. 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.

R&D Needed: No

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: Medium

Status of Progress: Unknown

Update: None provided

Organization: ASTM

2.4.6 NDE of Polymers and Other Non-Metallic Materials

For polymers, the most common NDE methods recognized and controlled by industrial standards are surface and embedded: acoustic emission, computed tomography, leak testing, radiography, shearography, spectroscopy, strain measurement, thermography, ultrasonic testing, and visual testing. [ASTM E2533-17e1, 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 (ABS, PLA, nylon, PEKK, Ultem). That said, AM plastic parts are expected to have similar characteristics to PMCs; therefore, the same or similar NDE techniques might be applicable.

There are currently five categories used to create AM polymer parts. The categories are:

- Powder bed fusion
- Material extrusion
- Vat polymerization
- Material jetting
- Sheet lamination

NEW Gap NDE6: NDE of Polymers and Other Non-Metallic Materials. No published or in development standards or specifications have been identified for NDE of polymers and other non-metallic materials.

R&D Needed: Yes. Research who uses AM Fused Filaments or pellets with PAI/Torlon and/or carbon fiber reinforced filaments with a high degree of fiber loading to see what they are anticipating for testing requirements for NDE for strength or structural qualities.

Recommendation: 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 provide an introduction to nondestructive testing and inspection requirements for structural or load bearing polymers and other non-metallic materials. Use ASTM E2533-17e1 as a guideline when applicable.

Priority: Low

Organization: ASTM F42/ISO TC 261, ASTM E07, ASTM D20

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.³⁵ An Aerospace Industries Association (AIA) report covering counterfeiting recommended that standards in the area of mechanical parts and materials be established.³⁶

³⁵ See for example [Best Practices in the Fight Against Global Counterfeiting](#), published by ANSI in 2011.

³⁶ See [A Special Report Counterfeit Parts; Increasing Awareness and Developing Countermeasures](#), published by AIA in March 2011.

Potentially relevant published standards for general industry include:

- [SAE AS 5553B-2016, Counterfeit Electrical, Electronic, and Electromechanical \(EEE\) Parts; Avoidance, Detection, Mitigation, and Disposition](#)
- [SAE AS 6174A-2014 \(SAE AS6174A-2014\), Counterfeit Materiel; Assuring Acquisition of Authentic and Conforming Materiel](#)

Potentially relevant standards in development for general industry include:

- [ISO/DIS 22380, Security and resilience -- Authenticity, integrity and trust for products and documents -- General principles for product fraud risk and countermeasures](#)

NEW 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: Not at this time. 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.

Priority: Low

Organization: ASTM F42/ISO TC 261, ASTM E07, SAE AMS-AM

2.4.8 NDE Acceptance Criteria for Fracture Critical AM Parts

In general, fracture critical AM hardware requires comprehensive volumetric and surface NDE to ensure the hardware is acceptable for use. To quantify the risks associated with parts that must demonstrate damage tolerance, it is incumbent upon the structural assessment community 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 the application of NDE, the types of defects that are relevant to the AM process must be considered. There are longstanding NDE standard defect classes for welds and castings. 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-2001, 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-L, DED. 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.

NEW Gap NDE8: NDE Acceptance Criteria for Fracture Critical AM Parts. There is a need for an industry standard that establishes NDE acceptance classes for fracture critical AM parts.

R&D Needed: Yes. Well-characterized samples should be fabricated with controlled loadings of technologically important AM defects in order to conduct effect-of-defect studies.

Recommendation: Develop an industry standard that establishes different degrees of flaw concentrations for quality acceptance. Fabricate effect-of-defect samples with the appropriate level of fidelity, i.e., sufficient similarity between the defect state in sacrificial samples (for example, ASTM E8 compliant dogbones) with natural flaws in actual production parts

Priority: Medium

Organization: ASTM F42 / ISO TC 261 JG 59, ASTM E07, ASTM E08 on Fracture and Fatigue

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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)³⁷ as it relates to the use of metal and polymer AM processes and equipment; level of repair analysis (LORA)³⁸ and reliability centered maintenance (RCM)³⁹ 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.

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

³⁷ 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*

³⁸ 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/non-economic constraints and operational readiness requirements. Source: AS1390, *Level of Repair Analysis (LORA)*

³⁹ 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*

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 industrial or aerospace 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

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.

R&D Needed: No

Recommendation: Update [SAE JA 1012-2011](#), a guide to provide analytics for AM trade-offs in RCM and CBM⁺.

Priority: Medium

Status of Progress: Not Started

Update: SAE G-11M, Maintainability, Supportability and Logistics Committee, will consider inclusion of analytics for AM trade-offs in the next update of JA1012_201108.

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)⁴⁰ Analysis, LORA, and RCM⁴¹
- 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.

Existing standards that relate to this topic include:

- DoD: [MIL-STD-3049\(1\)](#) on DED metal remanufacture/restoration

⁴⁰ 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)*

⁴¹ "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.

- ISO/TC 44 (welding): [ISO 15609-1:2004, Specification and qualification of welding procedures for metallic materials - Welding procedure specification - Part 1: Arc welding](#)
- American Welding Society (AWS) [D17.1/D17.1M:2010-AMD1, Specification for Fusion Welding for Aerospace Applications - AMD](#)
- [AWS B2.1/B2.1M:2014, Specification for Welding Procedure and Performance Qualification](#)
- SAE AMS-B, Finishes, Processes and Fluids: [SAE AMS2680C-2001, Electron-Beam Welding for Fatigue Critical Applications](#) (Reaffirmed: March 2010) which is currently under revision
- ASME B107 series of standards
- Metallic Materials Properties Development and Standardization (MMPDS), April 2011
- DoD: [MIL-STD-3021\(2\), Materials Deposition, Cold Spray](#)

Standards in development include: [AWS D20.1, Specification for Fabrication of Metal Components using Additive Manufacturing](#).

NEW 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.

R&D Needed: No

Recommendation: Ensure that laser based additive repair processes are included in AWS D20.1

Priority: Low

Organization: AWS, SAE AMS-AM

Gap M3: AM Level of Repair Analysis. Standards for AM LORA are needed. In performing a repair versus discard analysis, the use of AM can change the LORA decision due to shifts in factors relating to logistics delay time, spares availability, cost of spares, etc. Trade space would address reduction of time and increase in skill set (e.g., for qualified printer operators).

R&D Needed: No

Recommendation: Update [SAE AS1390, Level of Repair Analysis \(LORA\)](#), to include impact of AM on trade space of repairs.

Priority: Medium

Status of Progress: Green

Update: SAE's LCLS (Life Cycle Logistics Supportability) Committee plans to include AM in the upcoming revision of AS1390. Although the LCLS Committee has not opened a Work in Progress for AS1390, a team is working on revisions and has agreed to include AM. The SAE G-11M Committee is in the process of reorganizing but the chair has the AMSC requests on his radar. In addition, AMS2680C is currently under revision.

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

Existing standards that relate to this topic include:

- [SAE JA1011, Evaluation Criteria for Reliability-Centered Maintenance \(RCM\) Processes](#)
- [SAE JA1012, A Guide to the Reliability-Centered Maintenance \(RCM\) Standard](#)
- [ASTM E1742/E1742M-12, Standard Practice for Radiographic Examination](#)
- [ASTM E1444/E1444M-16e1, Standard Practice for Magnetic Particle Testing](#)
- [SAE AS1390, Level of Repair Analysis \(LORA\)](#)

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: No

Recommendation: Update SAE JA1011/1012 to include an inspection process for additive manufacturing repairs.

Priority: Medium

Status of Progress: Not Started

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_200908 and JA1012_201108.

Organization: SAE, ISO/ASTM

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.

Identified published standards related to this topic include: [ASME Y14.41-2012](#), [ISO 16792:2015](#), and [ANSI QIF 2.1:2016](#). No standards in development have been identified.

Gap M5: Model-Based Inspection. Standard practices for model-based inspection methods using AM are needed for repair assessments and scheduling.

R&D Needed: No

Recommendation: Develop standard practices for assessing level of damage for end-use parts.

Priority: Medium

Status of Progress: Not Started, or Unknown

Update: No updated provided.

Organization: ASME, ISO/ASTM, Dimensional Metrology Standards Consortium

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 include:

- [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.

No standards in development have been identified.

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: No

Recommendation:

- Develop a standard for tracking maintenance operations to ensure a printer is ready when needed. See also Gap PC3 on machine health monitoring.
- Develop a standard to address emergency repair/limited life parts for urgent cases in the field.

Priority: Medium

Status of Progress: Unknown

Update: None provided

Organization: AWS, ASTM

2.5.7 Cybersecurity for Maintenance

Issues related to cybersecurity (digital thread) for AM technology and maintenance relate to both AM parts and AM machines. Examples of maintenance 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 guidance documents include:

- [NIST Special Publication 800-53, Revision 4, Security and Privacy Controls for Federal Information Systems and Organizations](#). This NIST special publication is relevant to on-site printing of repair parts in the field and security and privacy controls for federal information systems and organizations. This includes a process for selecting controls to protect organizational operations (including mission, functions, image, and reputation); organizational assets; individuals; other organizations; and the nation from a diverse set of threats including hostile cyber-attacks, natural disasters, structural failures, and human errors.
- [NIST Special Publication 800-82 Revision 2, Guide to Industrial Control Systems \(ICS\) Security](#), May 2015
- [NISTIR 8183, Cybersecurity Framework Manufacturing Profile](#)⁴²
- [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](#)

Published rules for DoD contractors and subcontractors include:

⁴² 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>.

- [Defense Federal Acquisition Regulation Supplement \(DFARS\) Publication Notice 20160802, Detection and Avoidance of Counterfeit Electronic Parts – Further Implementation \(DFARS Case 2014-D005\)](#). Amends the DFARS to implement a requirement of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2012, as modified by a section of the National Defense Authorization Act for Fiscal Year 2015, which addresses required sources of electronic parts for defense contractors and subcontractors. This final rule, effective August 2, 2016, requires DoD contractors and subcontractors, except in limited circumstances, to acquire electronic parts from trusted suppliers in order to further address the avoidance of counterfeit electronic parts. Affected parts/subparts/sections include: 202.101; 212.301; 242.302; 246.870, 246.870-0, 246.870-1, 246.870-2, 246.870-3; 252.246-7007, and 252.246-7008.

Other notable activities include:

- [The Cybersecurity for Smart Manufacturing Systems project](#) within the [NIST Smart Manufacturing Operations Planning and Control Program](#)
- [NISTIR 8041, Proceedings of the Cybersecurity for Direct Digital Manufacturing \(DDM\) Symposium](#) (April 2015)
- [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 M7: Cybersecurity for Maintenance. In support of on-site repairs, guidance is needed that addresses cybersecurity considerations for maintenance and repair of parts that have 3D models ready to print. Secure storage in a database should ensure that only authorized personnel can download files and print parts.

R&D Needed: Yes

Recommendation: Guidance is needed to ensure the integrity and safe storage of AM files as maintenance and repair operations may take place in an uncontrolled environment. See also gap PC15 on configuration management: cybersecurity.

Priority: Medium

Status of Progress: Not Started, or Unknown

Update: None provided

Organization: NIST, NEMA/MITA, NDIA JWG, ASTM, IEEE-ISTO PWG

2.5.8 Surface Preparation for 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, 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

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: Medium

Status of Progress: Not Started, or Unknown

Update: None provided

Organization: ASTM, SAE, ISO

3. Next Steps

It is essential that this roadmap continue to be widely promoted at industry events 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, additional meetings with the SDO community may be useful to continue to discuss coordination, forward planning, and implementation of the roadmap's recommendations.

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, this roadmap may be updated in the future to report on the progress of its implementation and to identify emerging issues that require further discussion.

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

3D – three-dimensional	CFAM – Cybersecurity for Advanced Manufacturing
3DP – three-dimensional printing	CMH-17 – Composite Materials Handbook
3MF – 3D Manufacturing Format	CMM – coordinate measuring machine
AAMI – Association for the Advancement of Medical Instrumentation	CMMS – computerized maintenance management software
AATB – American Association of Tissue Banks	CSG – Constructive Solid Geometry
ABS – acrylonitrile butadiene styrene	CT – computed tomography
ACR – American College of Radiology	DED – directed energy deposition
AM – additive manufacturing	DFAM – Design for Additive Manufacturing
AMAM – Association for Metal Additive Manufacturing	DFMA – Design for Manufacture and Assembly
AMF – additive manufacturing file format	DICOM – Digital Imaging and Communications in Medicine
AMS – Aerospace Material Specification	DLP – Digital Light Processing
AMSC – America Makes & ANSI Additive Manufacturing Standardization Collaborative	DMA – dynamic mechanical analysis
ANSI – American National Standards Institute	DoD – U.S. Department of Defense
API – American Petroleum Institute	DSC – differential scanning calorimetry
ASME – American Society of Mechanical Engineers	EB – electron beam
ASTM – ASTM International	EBSD – electron backscatter diffraction
AWS – American Welding Society	EHS – environmental health and safety
BPVC – Boiler and Pressure Vessel Code	ELI – extra low interstitial
CAD – computer-aided design	EPA – U.S. Environmental Protection Agency
CAGR – compound annual growth rate	FAA – Federal Aviation Administration
CAM – computer-aided manufacturing	FDA – U.S. Food and Drug Administration
CBM – condition based maintenance	FDM – Fused Deposition Modeling
CDRH – Center for Devices and Radiological Health	FGM – functionally graded materials
	FR – flame retardant

FTIR – fourier transform infrared	MPIF – Metal Powder Industries Federation
GD&T – Geometric Dimensioning and Tolerancing	MRI – magnetic resonance imaging
HIP – hot isostatic pressing	NACE – NACE International
HT – heat treatment	NASA – National Aeronautics and Space Administration
IACC – International AntiCounterfeiting Coalition	NCAMP – National Center for Advanced Materials Performance
IEC – International Electrotechnical Commission	NCDMM – National Center for Defense Manufacturing and Machining
IEEE – Institute for Electrical and Electronics Engineers	NDE – nondestructive evaluation
IEEE-ISTO PWG - IEEE Industry Standards and Technology Organization (ISTO) Printer Working Group (PWG)	NDI – nondestructive inspection
IGA – intergranular attack	NDIA – National Defense Industrial Association
IGO – intergranular oxidation	NDT – nondestructive testing
IPC – IPC – Association Connecting Electronics Industries	NEMA – National Electrical Manufacturers Association
IPP – Internet Printing Protocol	NFPA – National Fire Protection Association
ISO – International Organization for Standardization	NIST – National Institute of Standards and Technology
ISTO – IEEE Industry Standards and Technology Organization	OEMs – original equipment manufacturer
JG – Joint Group	OSHA – U.S. Department of Labor Occupational Safety and Health Administration
LCCA – life cycle cost analysis	PA – polyamide
LDW – Laser Direct Writing	PBF – powder bed fusion
LORA – Level of Repair Analysis	PBF-EB – powder bed fusion – electron beam
MBE – Model-Based Enterprise	PBF-L – powder bed fusion – laser
MIMA – Metal Injection Molding Association	PC – polycarbonate
MITA – Medical Imaging & Technology Alliance	PDA – Parenteral Drug Association
MMPDS – Metallic Materials Properties Development and Standardization Handbook	PEEK – polyether ether ketone
	PJP – Plastics Jet Printing
	PLA – polylactic acid

PM – powder metallurgy	SDO – standards developing organization
PMC – polymer matrix composites	SLA or STL – Stereolithography
PMPA – Powder Metallurgy Equipment Association	SLS – Selective Laser Sintering
PPE – personal protective equipment	SME – subject matter expert
PSD – particle size distribution	STEP – Standard for the Exchange of Product
PSDO – partner standards developing organization	TAG – Technical Advisory Group
PVA – polyvinyl alcohol	TDP – Technical Data Package
PWG – Printer Working Group	Tg – glass transition temperature
Q&C – qualification and certification	TiAl – titanium aluminide
R&D – research and development	TGA – thermogravimetric analysis
Ra – arithmetic average of the roughness profile	TMA – thermomechanical analysis
RCM – reliability centered maintenance	TRL – technology readiness level
RFI – ready-for-issue	TSV – through-silicon via
RMA – Refractory Metals Association	UL – Underwriters Laboratories, Inc.
ROI – region of interest	USAF – United States Air Force
RSNA – The Radiological Society of North America	UV – ultraviolet
SAE – SAE International	V&V – verification and validation
	VOC – volatile organic chemical

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