America Makes

National Additive Manufacturing Innovation Institute

ANSI

American National Standards Institute

Standardization Roadmap for Additive Manufacturing

VERSION 1.0

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 standards and specifications consistent with stakeholder needs and thereby facilitate the growth of the additive manufacturing (AM) industry. The AMSC was not chartered to write standards.

America Makes is the National Additive Manufacturing Innovation Institute. Established in 2012 as the flagship Institute for Manufacturing USA, America Makes is the nation's leading and collaborative partner in additive manufacturing and three-dimensional (3D) printing technology research, discovery, creation, and innovation. It is driven by the National Center for Defense Manufacturing and Machining.

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 1.0* ("roadmap") represents the culmination of the AMSC's work over the past year to identify existing standards and standards in development, assess gaps, and make 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 89 gaps and corresponding recommendations across the topical areas of design, process and materials (precursor materials, process control, post-processing, and finished material properties), qualification and certification, nondestructive evaluation, and maintenance. Of that total, 19 gaps/recommendations have been identified as high priority, 51 as medium priority, and 19 as low priority. A "gap" means no *published* standard or specification exists that covers the particular issue in question. In 58 cases, additional research and development (R&D) is needed.

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 be widely promoted and subsequently updated over the course of the coming year, to assess progress on its implementation and to identify emerging issues that require further discussion.

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Summary Table of Gaps and Recommendations

	Section	Title	Gap	R&D Needed	Recommendation	Priority	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.).	Medium	ISO/ASTM, AWS, SAE
2.	2.1.2	Design Guides: General Guides for AM	**Gap D2: Decision Support: Additive Processes.** Currently 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. ASTM and ISO are developing a standard "WK38342 New Guide for Design for Additive Manufacturing" that is expected to be released in late 2016 or early 2017; however, additional standards may be needed to address trade-off criteria between processes.	Yes. R&D is needed to identify trade-off criteria.	Complete work on WK38342. There will still be a need to develop a standard for reporting process inputs and capabilities.	Medium	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 guideline for PBF is currently the sole process-specific design guideline under development by ASTM and ISO. 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.	Complete work on the ASTM/ISO JG57 design guideline for PBF. Develop guidelines for the six other AM processes defined in ISO/ASTM 52900.	Medium	ISO/ASTM, AWS
4.	2.1.2	Design Guides: Application-Specific Design Guides for AM	**Gap D4: Application-Specific Design Guidelines.** As industry fields mature in particular AM applications, best practices should be recorded.	TBD	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.	High	Various SDOs and/or industry consortia, ASTM
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.	As machines are benchmarked and calibrated, designers should have mechanisms available to them that will provide operation constraints on their available AM processes. Designers should understand what geometric and process liberties might be taken for their particular implementation.	Medium	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 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. The "WK54856	Yes. The identification of fundamental constructs should mirror key characteristics and decision criteria for designs, materials,	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.	Medium	ASTM, ISO, ASME, IEEE-ISTO PWG

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
			Principles of Design Rules in Additive Manufacturing" work item 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 of late 2017/early 2018.	and processes.			
7.	2.1.2	Design Guides: Design Guide for Surface Finish Post-processing	**Gap D7: New Surface Finish Capabilities.** There is a need for a design guide for new surface finish capabilities.	Yes	Develop a design guide for new surface finish capabilities.	Medium	ASME
8.	2.1.3	Design Tools: A Machine Input and Capability Report	**Gap D8: Machine Input and Capability Report.** A standard for reporting machine inputs and capabilities is needed to enable design tools to determine manufacturing feasibility.	No	Develop a standard for reporting machine inputs and capabilities that will clearly delineate the performance constraints of the machine, to include size, geometric complexity, material properties, tolerances, and other factors that would dictate the suitability of a particular machine to fabricate a particular implementation. See also Gap D20 on neutral build format.	Medium	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 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 verification and validation.	Low	NIST, America Makes, ASME V&V, ISO/ASTM
10.	2.1.4.1	Design for Assembly	**Gap D10: Design for Assembly.** Guidelines do not exist for AM design for 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 regards to parameters sets, factors of interest could include feed rate and diameters (for 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 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 assembly.	ISO/DIS 8887-1 and other DFMA standards can be reviewed and further developed to address AM related issues.	Low	R&D: Academia, industry, national laboratories. Standards: ISO, ASTM, AAMI, NEMA/MITA

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
11.	2.1.4.2	Design for Printed Electronics	**Gap D11: Design for Printed Electronics**. There is a need to develop standards on design for printed electronics.	No	Complete work on IPC-2292, Design Standard for Printed Electronics on Flexible Substrates.	Medium	IPC, ASTM
12.	2.1.4.3	Design for Medical: Input Data (CT, MRI, Ultrasound)	**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 will have to be developed specifically for that device. However, a set of consensus best practices for developing these plans could reduce the overhead in developing them and reduce the burden on imaging sites because individual plans would follow a single well-defined framework. This framework should rely on input from clinical experts to ensure that it accounts for and defers to clinical best practices where appropriate.	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.	Medium	NEMA/MITA, RSNA (Radiological Society of North America)
13.	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 separated by the process of segmentation. This segmentation process is not semi-automated and requires manual editing. Variabilities of output depend on factors such as grey scale resolution of the images which in turn depends on the x-ray dosage, operator capability, and low and high resolution on 2D to 3D conversion algorithms.	Yes. Develop standardized, physiologically relevant imaging phantoms that can be used to challenge all types of segmentation techniques (manual, semi-automated and automated techniques).	Develop a standard test method to use 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 facilitate size, orientation and color normalization in post-processing of data.	Medium	Methods: NEMA/MITA, ASME V&V 40, ASTM. Phantoms: NIST, FDA
14.	2.1.4.3	Design for Medical: Design of Complex Geometries	**Gap D14: Designing to be Cleaned.** Medical AM parts, like others must be cleaned of manufacturing residues. For patient contacting devices (especially implants) this cleaning must allow the device to pass tests for biological reactivity such as cytotoxicity and inflammation. Residues left on the parts may include, cooling fluids, or AM materials (powder or uncured monomer), among others that may be stuck within small geometric features or lattice structures. Under conditions in the body, it is often unclear if residuals will be removed or cause adverse reactions.	Yes, in terms of metrics to confirm how clean a part is and ways of determining 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.	High	AAMI, ASTM, ISO, FDA
15.	2.1.4.3	Design for Medical: Design of Complex Geometries	**Gap D15: Design of Test Coupons.** Medical devices have complex geometries and contours and in addition may have lattice structures. 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. No standards are available for the design of test coupons.	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.	Low	ASTM
16.	2.1.4.3	Design for Medical: Design of Complex Geometries	**Gap D16: Verifying Functionally Graded Materials.** Functionally graded materials are materials with variation in the composition or structure in order to vary the material properties (e.g., stiffness, density, thermal	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.	Low	ASTM F42, SAE AMS-AM, ASME

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
			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.		This is a broad topic however and depends on what is being evaluated.		
17.	2.1.5	Design Documentation: Technical Data Package (TDP)	**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. This highlights the need to develop specifications and standards that can be invoked within a TDP to ensure that the materials, process, and any post-processing are performed within an established framework that provides repeatable and high quality results.	Yes	Develop a standard (or revise Mil-STD-31000) 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)	High	ASME, ISO, ASTM, DoD
18.	2.1.5	Design Documentation: New Dimensioning and Tolerancing Requirements	**Gap D18: New Dimensioning and Tolerancing Requirements.** Although ASME Y14.41 does provide some capability in addressing some of the challenges in documenting AM designs, significant gaps still remain. ASME Y14.46 is a standard in development which will address these gaps. A first draft should be available as a guide in the next year.	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.	High	ASME
19.	2.1.5	Design Documentation: An Organization Schema Requirement	**Gap D19: Organization Schema Requirement.** A schema for organizing information in an AM digital product definition data set is required to define common practices and to deliver consistent data content and structure to consumers of the data.	No	ASME Y14.41.1 will address this gap and a standard should be available by the first quarter of 2018. ASME Y14.41.1 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 Y14.41.1. See also Gap D25, Configuration control of digital part design.	High	ASME
20.	2.1.5	Design Documentation: A Neutral Build Format	**Gap D20: Neutral Build Format.** No published or in development standards or specifications have been identified that incorporate laser path or powder 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, laser path, and power, 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.	Low	ISO/TC 184/SC4; ISO/TC 261/ASTM F42, consortium of industry, IEEE-ISTO PWG
21.	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 documentation. Terminology in a TDP needs to be clear.	No	ASME Y.14.46 has identified over 100 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	Medium	ASME, ISO/ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
		Design Documentation			inclusion in existing standards.		
22.	2.1.5	Design Documentation: In-Process Monitoring	**Gap D22: In-Process Monitoring.** 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.	Develop a new standard for the incorporation of process monitoring data into a single 3D file that represents a parent made through AM. This file will include all of the imperfections, porosities, and manufacturing errors that may have occurred and were captured through the monitoring during the AM process and would be constructed from data such as laser power, melt pool size and other applicable parameters which are now capable of being monitored during the AM process. See also Gap PC16 on process monitoring.	Medium	ASTM F42, ASME
23.	2.1.5	Design Documentation: Documentation of New Functional Surface Features	**Gap D23: Documentation of New Functional Surface Features.** There is a need for a specification on design documentation for new surface finishes.	Yes	ASME should continue its work to develop B46 to address design documentation for new surface finish capabilities.	Low	ASME
24.	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.	Medium	ISO/ASTM
25.	2.1.6	Design Verification and Validation	**Gap D25: Configuration control of digital part design.** AM parts are intrinsically tied to their digital definition. In the event of a design modification, proper methods of configuration and version control are needed for verification. This could include verification of the digital process parameter definitions, or software version, if applicable.	No	ASME Y14.41 and ISO/TC 10 could incorporate the digital configuration control into their developing standards if they have not already. See also Gap D19, Organization Schema Requirement.	Medium	ASME Y14.41, ISO/TC 10, ISO/TC 261/ASTM F42
26.	2.1.6	Design Verification and Validation	**Gap D26: 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. This will likely be relevant when measuring AM features such as helixes or other complex shapes, or internal features that are not compatible with common methods such as Go/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.	As GD&T standards continue to develop, perform parallel investigations of validation methods to ensure verification and validation is possible.	Medium	ISO/TC 261/ASTM F42, ASME Y14.46, ISO/TC 10
Process and Materials – Precursor Materials							
27.	2.2.1.3.2	Precursor Materials: 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. WK55610 (not specific to metal powders) addresses dynamic flow, aeration, permeability, consolidation and compressibility test procedures using for example a powder rheometer. Completion of	Medium	NIST, ISO/ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
					WK55610 is recommended in order to fill this gap. See also Gap PC12 on precursor material flow monitoring.		
28.	2.2.1.3.3	Precursor Materials: 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.	Medium	NIST, universities, ISO/ASTM
29.	2.2.1.3.5	Precursor Materials: 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, there are no known standards that link requirements for these attributes to the specific AM deposition process or fusion mechanism.	Yes. Pre-standardization research is needed to look at acceptable ranges of powder size and distribution for various AM processes.	See R&D needed.	Medium	ISO/ASTM
30.	2.2.1.3.6	Precursor Materials: 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 may be addressed indirectly by standards governing flow and spreadability requirements for a powder.	Low	NIST, ISO/ASTM
31.	2.2.1.3.7	Precursor Materials: Feedstock Sampling	**Gap PM5: 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.	No	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.	High	ISO/ASTM, SAE
32.	2.2.1.3.8	Precursor Materials: 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.	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.	Low	For R&D: NIST, ASTM, America Makes, Oak Ridge National Laboratory, universities. For standards: ISO/ASTM and SAE
33.	2.2.1.4	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	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	ASTM, SAE, AWS, industry OEMs

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
				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			
Process and Materials - Process Control							
34.	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.	Medium	NIST, ISO/ASTM, SAE, IEEE-ISTO PWG
35.	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. 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.	No	Complete work on AWS D20.1. 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.	High. There is an urgent need to develop guidelines on day-to-day machine calibration checks.	AWS, ASTM, OEMs, SAE, end users
36.	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 and ISO 13381-1. Additional information can be found in NISTIR 8012, Standards Related to Prognostics and Health Management (PHM) for Manufacturing. Further research/guidelines/specifications may be needed. For example, NIST may be able to identify critical indicators that need to be documented or controlled to assist end users with quality assurance.	Low	NIST, ISO, ASTM, AWS, IEEE-ISTO PWG, ASME
37.	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, 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.	Medium	NIST, AWS, SAE, ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
38.	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 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 process parameters produces an acceptable part, and for ensuring that those process parameters remain consistent from build to build.	No	Develop a standard that identifies key process parameters for AM machines. Complete work on AWS D20.1. See also Gap QC3 on harmonizing Q&C terminology for process parameters.	Medium	AWS, ASTM, OEMs, IEEE-ISTO PWG
39.	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.	Low	OEMs, DoD for military-specific operational environments, ASTM
40.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Powder	**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.	There must be 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.	High	ISO/ASTM, MPIF, SAE, NIST, trusted end user-group
41.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Powder	**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.	Medium	NIST, trusted end user-group, ASTM
42.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Powder	**Gap PC9: Environmental Conditions: Effects on Materials.** AM materials can be sensitive to changes in environmental conditions including temperature, humidity, and ultraviolet radiation. Therefore, guidance must be provided to ensure the environmental conditions in which the material is used and stored remain within acceptable ranges. No standards or specifications have been identified regarding this topic.	Yes	Guidance on storage of AM materials is needed so that AM materials are stored and used in environments with acceptable conditions. Research should be conducted to identify these ranges.	High	ISO/ASTM, Powder Manufacturers/Suppliers
43.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Powder	**Gap PC10. Re-use of Material that Has Not Been Printed.** There is a lack of industry guidance on the re-use of material that has <u>not</u> been printed.	Yes	A standard is needed for the re-use of material that was not printed but is already within the system (for inkjet it can be in the plumbing, the reservoirs, the printing heads, etc.).	Medium	ISO/ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
44.	2.2.2.7	Process Control: Precursor Material Handling: Use, Re-use, Mixing, and Recycling Powder	**Gap PC11: Re-use of Material that Has Been Printed.** There is a lack of industry guidance on the re-use of material that was already printed.	Yes	A standard is needed for re-use of material that was already printed 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 printed 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).	Low	ASTM
45.	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: • Method of DED process powder flow monitoring • Location of monitoring • Accuracy of flow monitoring • Standardized calibration process of flow	Yes	A standard is needed 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.	Medium	NIST, ISO/ASTM
46.	2.2.2.8	Process Control: Precursor Material Flow Monitoring: Inkjet (Material Jetting)	**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.	Yes	A standard is needed 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. • Expending 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.	Low	NIST, OEMs, ASTM, IEEE-ISTO PWG
47.	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 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	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.	High	UL, ISO/ASTM, OSHA

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
			UV light (may require eye and skin protection based on design).				
48.	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.	Medium	America Makes, NIST, UL, IEEE-ISTO PWG
49.	2.2.2.11	Process Control: Process Monitoring	**Gap PC16: Process Monitoring.** No published standards or standards in development have been identified to address process monitoring. More than likely, there will be no "one size fits all" standard for any given additive process or material. It would be highly dependent on end user analytics of OEM or internally developed sensing systems.	Yes	Issue standard practices to qualify in-process sensed data to physical measurements of finished components. See also Gap D22 on in-process monitoring.	Medium, given the relatively low technology readiness level (TRL) state of the art	ASTM
50.	2.2.2.11	Process Control: Process Monitoring	**Gap PC17: Motion Control.** AM machines have many mechanical components that are similar to conventional subtractive machinery. The motion control components are blindly trusted to provide accurate positioning. This is important during machine qualification and could be addressed in a standard.	Yes, with respect to Galvanometer-driven mirrors	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.	Low	OEMs, Experts in machine metrology
Process and Materials – Post-processing							
51.	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	A standard should be issued that requires consistent post-processing to be applied for qualification and production builds. Complete AWS D20.1.	Medium	AWS D20, ISO/ASTM
52.	2.2.3.2	Post-processing: Heat Treatment (Metals)	**Gap P2: Heat Treatment (HT).** 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 HIP processing is used to consolidate AM material, the process may be modified to meet HT requirements as well, negating the need for additional HT standards.	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.	Medium	R&D: universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE. (Additional text in 2.2.3.2)

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
53.	2.2.3.3	Post-processing: Hot Isostatic Pressing (HIP) (Metals)	**Gap P3: Hot Isostatic Pressing (HIP).** 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. 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: • Effect of max thermal exposure on microstructure evolution (XXX temperature for more than XXX hours) • Effect of cooling rate • Discontinuities extended to the surface • Incipient melting with and without voids • Discontinuities larger than XXX 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 (Example: In 718 laves phase, delta phase morphology, etc.) • Number of discontinuities larger than XXX in per certain view area (Example: within 1 sq. inch) • Number of discontinuities in subsurface area (XXX microns from the surface) larger than XXX inch • Linear formation of discontinuities (other than interconnected porosity) and minimum distance of XXX inches between adjacent discontinuities	Medium	R&D: various entities. Standards: ASTM F42, SAE AMS-AM
54.	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, are more easily manufactured using AM versus subtractive machining. However, the applicability of current measurement methods to these features is not clear or captured in standards. For example, features such as helixes or lattices may produce wire-like structures that are not as easily measured using stylus instruments as flat surfaces. • Also, the suitability of current specification methods must be investigated for AM. ASME Y14.6 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	Yes	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.	Medium	ISO/ASTM; ASME (B46 new project team 53 on surface finish), IEEE-ISTO PWG

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
			time how to accommodate this in AM product specifications in a standard form. • 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.				
55.	2.2.3.6	Post-processing: Post-curing Methods (Polymers)	**Gap P5**: **Use of Post-cure to Reduce Toxicity of UV Polymers.** An evaluation of the toxicity 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.	Low	ASTM D20, ISO/ TC 261/ASTM F42
56.	2.2.3.6	Post-processing: Post-curing Methods (Polymers)	**Gap P6: Guidelines for Post-curing AM Plastics to Address Outgassing.** Guidelines for evaluating the outgassing 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.	Extend existing methods with AM-specific recommendations.	Low	ASTM E21.05, ASTM D20, ISO/ TC 138, ISO/TC 261/ASTM F42
Process and Materials - Finished Material Properties							
57.	2.2.4.2	Finished Material Properties: Mechanical Properties	**Gap FMP1: Mechanical Properties.** Many machine manufacturers offer general values for parts made from select powders in their machines. However, these values are not statistically validated and do not have the pedigree required for material design. Standards for 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 made by a given AM system using a given set of AM parameters for a given AM build design, and for non-metals made by various processes. 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.	Medium (Metals, Polymers); Low (Ceramics)	AWS, ISO/ASTM, SAE (Additional text in 2.2.4.2)
58.	2.2.4.3	Finished Material Properties: Component Testing: Additive Part Qualification: Medical Device Perspective	**Gap FMP2: Coupon Testing.** For any given application there is not a clear method or best practice document to help determine the applicability and validity of coupon testing to a specific type of component or feature.	Yes. It is currently unknown how well a coupon will represent a final part due to uncertainty around reproducibility with a printer. Additionally, computational models of the heating and cooling of a part during a build based on surrounding parts and material properties would facilitate creation of guidelines in the recommendation.	Within the medical space, SDOs that publish topic-specific or device-specific standards should analyze existing manufacturing systems and good manufacturing practices to determine the alterations or modifications from existing practices that should be made to accommodate the way finished materials are created in a printer. There is FDA Guidance on the use of coupons to test implant porous coatings made with traditional manufacturing using standard test methods and scientifically determined acceptance criteria. Two outstanding issues are: 1) there is no specific guidance on how to determine what effect the coupon will have on other parts in a build when added to the build platform of a powder bed printer, and 2) there is no guidance on how to verify or validate that a minimalistic coupon accurately represents the intended feature of the part when built with an additive manufacturing process. Guidelines or standards should be developed to address these issues.	Medium	ASTM (design/specification of coupons for specific applications), ASME V&V 50 (computational modeling Verification and Validation). ASTM F42.01 may have interest.

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
59.	2.2.4.4	Finished Material Properties: Biocompatibility & Cleanliness of Medical Devices: Cleanliness of Medical AM Parts	**Gap FMP3: Cleanliness of Medical AM Parts.** 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 on the application of 3D measurement techniques to discern clean from uncleaned parts; specifically, to reliably distinguish unsintered, unmelted, and uncured material from the intended part.	Develop standard test methods for measuring complex 3D geometries that are based on existing standards but focus on AM-specific considerations. ASTM F04 already has work in progress.	High	ASTM F04, AAMI, ISO
60.	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 additive 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. Other organizations (CMH-17) are beginning to look at the development of design allowables, with several projects in the initial research planning stages.	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 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.	Multiple developments must take place prior to generation and acceptance of design allowables for additive materials. 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 additive materials. ASTM F42.05 may also have interest. 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 guidance on minimum data requirements and statistical processes. Test methods: Test standards organizations, such as ASTM, should provide recommendations on established test methods with special considerations for AM materials. If necessary, new coupon or component test methods should be developed.	Material specifications: High. Data requirements and statistical analyses: Medium. Test Methods: Medium.	SAE, ASTM, MMPDS, CMH-17

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
61.	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).	Medium	NIST, ASTM
Qualification & Certification (not covered elsewhere)							
62.	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.	High	ISO/ASTM, SAE, ASME
63.	2.3.3.1	Qualification & Certification: Aerospace Industry: Parts/Products	**Gap QC2: Qualification Standards by Part Categories.** A standard classification of parts is needed, such as those described in the Lockheed Martin AM supplier quality checklist (2.3.2.2) and the NASA Engineering and Quality Standard for Additively Manufactured Spaceflight Hardware (2.3.2.6). This is a gap for the aerospace and defense industries.	No	A classification of parts should be defined as well as a minimum set of qualification requirements and related technology readiness level (TRL) and manufacturing readiness level (MRL) metrics for each part category that takes into consideration the intended part usage/environment. It is suggested that mission critical parts be looked at first.	High	NASA, SAE, ISO/ASTM
64.	2.3.3.2	Qualification & Certification: Defense Industry: Technical Data Package (TDP)	**Gap QC3: 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 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. See also Gap PC5 on parameter control.	Medium	ISO/ASTM, IEEE-ISTO PWG
65.	2.3.3.2	Qualification & Certification: Defense Industry: Source (i.e., Vendor) Approval	**Gap QC4: DoD Source (i.e., Vendor) Approval Process for AM Produced 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. Today, 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, develop standards to assess required checks for levels of criticality and safety as part of the source approval process.	High	Service SYSCOMS, Industry, ASME, ISO/ASTM, SAE
66.	2.3.3.2	Qualification & Certification: Defense Industry:	**Gap QC5: Machine Operator Training and Qualification.** Currently, there are no published standards or guidelines outlining AM training requirements, though AM machine manufacturers typically are available to provide training to	No	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.	Low	AWS, UL, AAMI, OEMs, ISO/ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
		Machine Operator Training and Qualification	new operators. The AWS D20.1 standard in development includes requirements for AM machine operator performance qualification based on training, written and practical examinations, and the demonstration of successful AM builds. In addition to training programs offered by OEMs, Underwriters Laboratories (UL), in cooperation with the University of Louisville, is offering a comprehensive AM training program initially focused on metals.		Develop additional standards for artisanal levels of competency and experience, delineating an individual's expertise in the field or subsets of the AM field.		
67.	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.	Medium	DICOM, IEEE, ISO, ASTM
68.	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.	Medium	DICOM, IEEE, ASME, ISO, ASTM, RSNA (Radiological Society of North America)
69.	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.	Medium	Biomedical Engineering Society, NEMA/MITA, ISO, ASTM
70.	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.	High	SME, RSNA, ASTM
71.	2.3.3.3	Qualification & Certification: Medical Industry: Quality, Verification and Validation of Final 3D Models for Device Design	**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.	High	ASTM, NEMA/MITA, AAMI, ASME, ISO
72.	2.3.3.3	Qualification & Certification: Medical Industry: Qualification & Certification of Materials	**Gap QC11: Process Validation for Pigments and Processing Aid Materials.** There is a gap in terms of qualification guidance for pigments (colorants) and processing aid materials. While ISO 13485, *Medical devices - Quality management systems - Requirements for regulatory purposes*, and 21CFR820 apply, process validation for these AM materials is not completely understood. Colorants add additional regulatory	Yes	Develop qualification guidance for pigments and processing aid materials. Consider process validation.	Low	ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
			requirements.				
73.	2.3.3.3	Qualification & Certification: Medical Industry: Resorbable Materials	**Gap QC12: Resorbable Materials.** There are few available standards for testing of degradation of the resorbable polymers in living tissues and therefore a standard needs to be developed.	Yes	Develop guidance on how to test the degradation of resorbable polymers to support material selection for AM.	Medium	ASTM
74.	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 reporting template and data set for material pedigree, recommended testing, and handling procedures would simplify evaluation of material suitability.	Low	Material providers, ASTM
75.	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.	Medium	RSNA, DICOM, ASTM
76.	2.3.3.3	Qualification & Certification: Medical Industry: Validation of Sterilization Processes and Anatomical Models	**Gap QC15: Anatomical Models: Sterilization.** Anatomical models may require sterilization if they are to come into contact with compromised tissue of patients. There may be a need for guidance in this area.	Maybe. Some has been done but more may be needed on whether/how traditional sterilization models work with AM.	Development of guidance for additive manufacturers on the application of existing standards may be the most feasible and productive goal in this area.	Low	R&D: OEMs. Guidance: AAMI, AOAC International, ASTM, ISO, USP
Nondestructive Evaluation							
77.	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.	High	ISO/ASTM
78.	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.). 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	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 ASTM WK56649, *Standard Practice/Guide for Intentionally Seeding Flaws in AM Parts*, now proceeding as ISO/TC 261/ASTM F42 JG60, to establish flaw types and conditions/parameters to recreate flaws using AM processes.	Medium	ISO/ASTM

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
			standards or AM representative artifacts or phantoms.				
79.	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 in ASTM E07. A future need will be a precision and bias statement to generate standard test methods to use to accept/reject AM parts and in procurement of AM parts.	Complete work on ASTM WK47031 and ISO/ASTM JG59.	High	ISO/ASTM
80.	2.4.4	Nondestructive Evaluation: Dimensional Metrology of Internal Features	**Gap NDE4: Dimensional Metrology of Internal Features.** Standards are needed for the dimensional measurement of internal features of AM objects.	Yes	ASTM F42 and E07 should identify and address additive manufacturing related areas for alignment with current computed tomography dimensional measurement capabilities.	Medium	ASTM
81.	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: • Specific industry standards are needed for data fusion in AM NDT techniques • Expert education, training, and certification for AM data fusion in NDT	Medium	ASTM
Maintenance							
82.	2.5.2	Maintenance: Standard Repair Procedures: Maintenance and Sustainment of Machines	**Gap M1: AM Analyses in RCM and CBM.** Standards for AM analyses in Reliability Centered Maintenance (RCM) and Conditioned Based Maintenance (CBM+) are needed.	No	Update SAE JA1012 RCM, a guide to provide analytics for AM trade-offs in RCM and CBM+.	Medium	SAE, ISO, ASTM
83.	2.5.2	Maintenance: Standard Repair Procedures: Maintenance and Sustainment of Parts	**Gap M2: Using AM to Print Tools.** Current standards may not consider the variety of materials that can be used to create tools using additive manufacturing.	No	Amend the ASME B107 series of standards to require specific strength/loads for hand tools to ensure that AM printed tools function like machined tools. Examples include: • ASME B107.100-2010, *Flat Wrenches* • ASME B107.110-2012, *Socket Wrenches, Handles, and Attachments* • ASME B107.300-2016, *Torque Instruments* • ASME B107.400-2008, *Striking Tools* • ASME B107.410-2008, *Struck Tools* • ASME B107.500-2010, *Pliers* • ASME B107.600-2008, *Screwdrivers* Also update SAE AS1390:2014, *Level of Repair Analysis (LORA)*, to include trade space of repairs including on AM. Trade space would address reduction of time and	Medium	ASME, SAE

	Section	Title	Gap	R&D Needed	Recommendation	Priority	Organization
					increase in skill set (e.g., for qualified printer operators).		
84.	2.5.2	Maintenance: Standard Repair Procedures: Maintenance and Sustainment of Parts	**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.	No	Update SAE AS1390:2014 to address AM LORA.	Medium	SAE with input from DoD, ISO, ASTM
85.	2.5.3	Maintenance: Standard Technical Inspection Processes	**Gap M4: Physical Inspection of AM Parts and Tools for Defects.** 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.	Medium	SAE, ISO/ASTM
86.	2.5.4	Maintenance: Model-Based Inspection	**Gap M5: Model-Based Inspection.** Standard practices for model-based inspection methods using AM are needed for maintenance assessments and scheduling.	No	Develop standard practices for assessing level of damage for end-use parts and AM machine "health" using model-based inspection. See also Gap PC3 on machine health monitoring.	Medium	ASME, ISO/ASTM, Dimensional Metrology Standards Consortium
87.	2.5.5	Maintenance: Standards for Tracking Maintenance Operations	**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. • Develop a standard to address emergency repair/limited life parts for urgent cases in the field.	Medium	AWS, ASTM
88.	2.5.6	Maintenance: 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.	Medium	NIST, NEMA/ MITA, NDIA JWG, ASTM, IEEE-ISTO PWG
89.	2.5.7	Maintenance: Finishing and Assembly, Welding, Grinding, Coating, Plating	**Gap M8. Finishing and Assembly, Welding, Grinding, Coating, Plating.** 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.	Medium	ASTM, SAE, ISO

1. Introduction

Additive Manufacturing (AM), sometimes referred to as three-dimensional (3D) printing, 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.

Around ten years ago, 3D printing 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, the National Additive Manufacturing Innovation Institute (America Makes). With these developments, 3D printing 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 and collaborative partner in AM and 3DP technology research, discovery, creation, and innovation. It is a program of 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, the market for additive manufacturing "grew at a compound annual growth rate (CAGR) of 35.2 percent to $4.1 billion in 2014. The industry expanded by more than $1 billion in 2014, with 49 manufacturers producing and selling industrial-grade additive machines." This growth "occurred in all segments of the additive manufacturing industry, including the low-cost "desktop" 3D printer segment. The use of industrial metal additive systems for demanding production applications in the aerospace and medical markets also grew strongly."[1] Industry analyst reports of recent acquisition announcements signal that AM is here to stay.[2]

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, something that ANSI's charter expressly prohibits it from doing.

The establishment of the AMSC complemented America Makes' formulation of a standards strategy for AM. America Makes recognized the need 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

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[1] Cole, Jedd (Ed.), "Additive Manufacturing Report Details Industry Growth," *Modern Machine Shop*, dated 5/20/2015, http://www.mmsonline.com/news/additive-manufacturing-report-details-industry-growth

[2] Petch, Michael, "3D Printing Industry Insiders comment on $1.4 billion GE takeover bid," *3D Printing Industry*, dated 9/6/2016, https://3dprintingindustry.com/news/3d-printing-industry-insiders-comment-1-4-billion-ge-takeover-bid-95366/

qualification of AM materials, processes, and systems, and by regulatory bodies during certification of AM parts.

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

This resulting document, the *Standardization Roadmap for Additive Manufacturing, Version 1.0*, represents the culmination of the AMSC's work over the past year.

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 draft roadmap for public comment, ANSI was contacted by the American Petroleum Institute (API), an ANSI accredited SDO, who has expressed interest in the topic and has 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 formed five primary working groups covering Design, Process and Materials, Qualification and Certification, Nondestructive Evaluation, and Maintenance. The Process and Materials group was further divided into four subgroups covering Precursor Materials, Process Control, Post-processing, and Finished Materials Properties.

Following an initial 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, the AMSC held its second face-to-face meeting 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 served as a steering committee for the project.

1.4 Roadmap Structure

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 research and development (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.

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

Low Priority (a score of 4-6)

Medium Priority (a score of 7-9)

High Priority (a score of 10-12)

Figure 1: AMSC Prioritization Matrix

A table summarizing the gaps, recommendations, and priorities by issue as described in the text appears after the Executive Summary to this document. Chapter 3 briefly describes next steps.

This roadmap is supplemented by the *AMSC Standards Landscape*, a list 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 Y14.46-201x Product Definition Practices for Additive Manufacturing

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 on engineering drawings, in Model-Based Definition (MBD) models, 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 Y14.41.1-201x Model Organization Schema Practices

This standard establishes a schema for organizing information in a 3D model within a digital product definition data set when conveying the product definition in 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 xx on Direction and Load Indicator Requirements

This standard 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.

At the time this roadmap section was written, a subcommittee was to have been formed in October 2016 and a draft was 60% complete.

ASME B46 Project Team on Additive Manufacturing

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 verification and validation 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 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 X-ray computed tomography (CT) systems for point-to-point length measurements of homogeneous materials. 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 B5 Technical Committee 65 Micro Machining

Committee Webpage:
https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=100757853

Charter: Standardization of manufacturing methods, technologies, equipment, terminology, organizational strategy, and systems for the manufacture of products and/or features concerning dimensions and/or accuracies of less than 100 micrometers.

Document: This committee has been formed and is working to complete a draft document scope by February 2017. It may cover some of the post-processing related to additive.

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 uniform practices for stating and interpreting dimensioning, tolerancing, and related requirements for use on engineering drawings 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 400+ individuals and organizations representing 20 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 13 standards at the time of writing this roadmap section, with an additional 15 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 3 joint ISO/ASTM standards (below), with approximately 15 additional joint standards projects under development.

ISO/ASTM52900-15, *Standard Terminology for Additive Manufacturing – General Principles – Terminology*

ISO/ASTM52915-16, *Standard Specification for Additive Manufacturing File Format (AMF) Version 1.2*

ISO/ASTM52921-13, *Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies*

The ISO TC261 work program contains the 3 joint standards (above), 3 additional standards, and 7 other work items in various stages of development. (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.

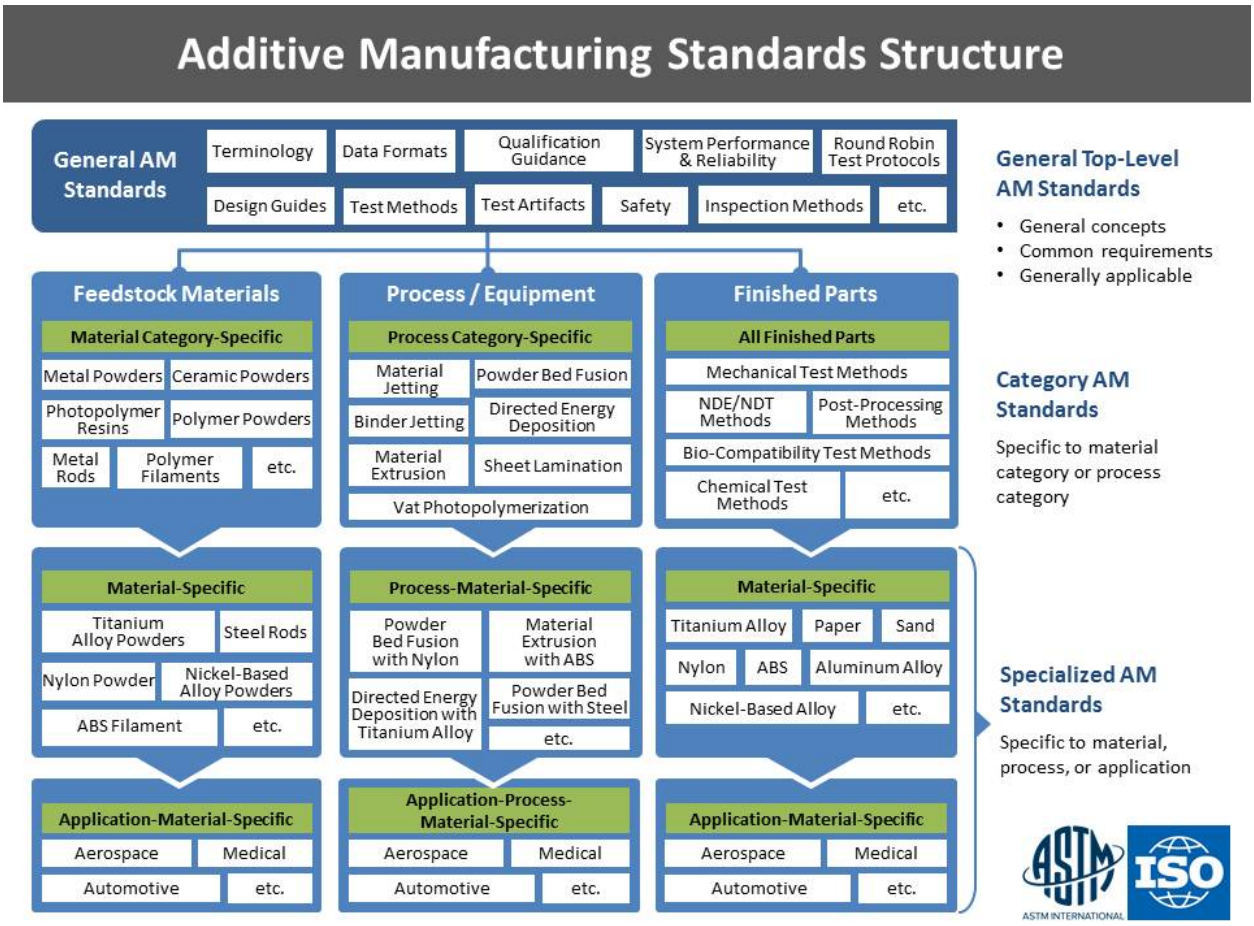

Figure 2: Standards structure approved by ASTM F42 and ISO TC261. Used with permission of NIST.

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, is in the process of completing a draft of the AWS D20.1 standard, *Specification for Fabrication of Metal Components using Additive Manufacturing*. AWS D20.1 will be a comprehensive document that identifies requirements related to AM component design, 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 AWS D20 committee currently has three active task groups: Qualification, Fabrication, and Inspection. The Qualification Task Group is working on finalizing the AWS D20.1 clauses on AM procedure qualification and machine operator performance qualification. The AM procedure qualification clause contains requirements to demonstrate the capability of an AM procedure to produce a component that meets acceptance requirements, including qualification test piece design,

testing, and acceptance; procedure qualification variables for each AM process covered by AWS D20.1; and requalification requirements based on changes to procedure 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 will include 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 is working on the clause that will contain requirements designed to ensure the successful fabrication of AM components. Examples of topics covered by this clause include requirements related to feedstock storage, cleanliness, equipment calibration and testing, use of qualified procedures and personnel, witness specimens, interpass temperature control, build interruptions, part identification, post-build processing, and repair.

The Inspection Task Group is working to draft inspection requirements for AM components based on component classification. Due to the limitations of volumetric inspection techniques to measure discontinuities for typical AM component geometries, this task group is considering multiple potential options for inspection of AM components. These options may include the demonstration that acceptable discontinuity size requirements are met through volumetric inspection of the component (similar to the inspection requirements of AWS D17.1, *Specification for Fusion Welding for Aerospace Applications*), characterization of discontinuities in AM procedure qualification mechanical test specimens and verification that the discontinuities in a prototypic component build are no worse, and the use of proof tests based on individual component functional requirements.

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, *Specification for Welding Procedure and Performance Qualification*; AWS D17.1, *Specification for Fusion Welding for Aerospace Applications;* 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)

Below are IEEE projects that are relevant to additive manufacturing. The first 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: 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: 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 Std 1500) 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.

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: IPP 3D Printing Extensions
Scope: This specification defines an extension to the Internet Printing Protocol [PWG 5100.12] 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 – the 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.

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.

Printed Electronics Base Materials/Substrates Subcommittee (D-62)
This subcommittee is responsible for generating standards for printed electronics base materials.

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.

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.

Printed Electronics Terms and Definitions Task Group (D-64a)
This task group will define terminologies used for the base materials, design and production of printed electronics. It will cover printed electronics on flexible substrates, rigid substrates, 3D substrates, and rigid or flexible printed circuit boards.

Printed Electronics Test Method Development and Validation (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 TM-650.

Printed Electronics Processes Subcommittee (D-66)
This subcommittee is responsible for developing standards on processes for the manufacture of printed electronics.

Published Standards

IPC-2291, *Design Guideline for Printed Electronics (2013)*
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-4591, *Requirements for Printed Electronics Functional Conductive Materials (2012)*
This document provides comprehensive data to help users more easily determine material performance, capabilities, and compatibility of functional conductive materials for the manufacture of printed electronics. It includes

- classification schemes based on composition, conductor type, and post-processing structure;

- functional conductive material specification sheets to present properties for the different conductive material types; and
- the most current classification system, qualification and quality conformance requirements, including those raw material properties of particular interest to the printed electronics designer, fabricator, or other user.

IPC-4921, *Requirements for Printed Electronics Base Materials (2012)*
This document provides comprehensive data to help users more easily determine both material capability and compatibility for flexible and rigid base dielectric materials for the manufacture of printed electronics. It includes base material specification sheets that have been updated with the newest properties for the specification material types. It establishes the most current classification system, qualification and quality conformance requirements, including those raw material properties of particular interest to the printed electronics designer, fabricator, or user.

IPC-6901, *Application Categories for Printed Electronics (2015)*
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.

IPC-6903, *Terms and Definitions for the Design and Manufacture of Printed Electronics (2015)*
This standard provides industry-approved terms and definitions to create a common language for users and suppliers to develop electronics products that utilize printed electronics alone or as additive processes combined with traditional rigid, flexible and rigid-flex printed wire board assemblies.

Draft Standards (NEW)

IPC-2292, *Design Standard for Printed Electronics on Flexible Substrates*
D-61
This standard 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.

IPC/SGIA-5222, *Process Guideline for Screen Printing for Printed Electronics (Additive Manufacturing)*
D-66
This will be a joint industry guideline for best practices related to screen printing specifically for printed electronics (additive manufacturing). This guideline covers printing equipment, presses, substrate requirements, printing materials, 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. IPC is the lead developer of this guideline, which will have involvement of Specialty Graphic Imaging Association (SGIA) members.

IPC-9204, *Guideline on Flexibility and Stretchability Test Methods for Printed Electronics*
D-65
This document provides an overview of proposed test methods that may be suitable for use to evaluate the flexibility and stretchability of printed electronics for flexible, stretchable and wearable applications.

Draft Standards (REVISIONS – scopes included in published information)

IPC-4921A (D-62) and IPC-4591A (D-63) are both in revision to account for additional testing and reporting requirements.

IPC-6903A (D-64a) will add terms and definitions not included in the original publication.

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 53 "Joint ISO/TC 261-ASTM F 42 Group, Requirements for purchased AM parts"

ISO/TC 261/JG 54 "Joint ISO/TC 261-ASTM F 42 Group, Design guidelines"

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 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, Specification for AMF support for solid modeling, voxel information, constructive solid geometry representations ..."

ISO/TC 261/JG 65 "Joint ISO/TC 261-ASTM F 42 Group, Specification for additive manufacturing stainless steel alloy with powder bed fusion"

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"

Below is a list of the current work items of ISO/TC 261 (and finished projects) as of September 2016:

Reference	Document title	Committee
ISO/ASTM DIS 52901	Additive manufacturing -- General principles -- Requirements for purchased AM parts	ISO/TC 261/JG 53
ISO/ASTM 52921:2013	Standard terminology for additive manufacturing -- Coordinate systems and test methodologies	ISO/TC 261
ISO/ASTM NP 52902	Additive manufacturing -- General principles -- Standard test artifacts	ISO/TC 261/JG 52
ISO/ASTM CD 52903-2	Additive manufacturing -- Standard specification for material extrusion based additive manufacturing of plastic materials -- Part 2: Process -- Equipment	ISO/TC 261/JG 55
ISO/ASTM DIS 52910	Standard Practice -- Guide for Design for Additive Manufacturing	ISO/TC 261/JG 54
ISO/ASTM DIS 52903-1	Additive Manufacturing -- Standard Specification for Material Extrusion Based Additive Manufacturing of Plastic Materials -- Part 1: Feedstock materials	ISO/TC 261/WG 2
ISO/ASTM NP 52905	Additive manufacturing -- General principles -- Nondestructive testing of additive manufactured products	ISO/TC 261/JG 59

ISO/NP TR 52912	Design of functionally graded additive manufactured parts	ISO/TC 261/JG 67
ISO 17296-4:2014	Additive manufacturing -- General principles -- Part 4: Overview of data processing	ISO/TC 261/WG 4
ISO 17296-3:2014	Additive manufacturing -- General principles -- Part 3: Main characteristics and corresponding test methods	ISO/TC 261/WG 3
ISO/ASTM 52915:2016	Specification for Additive Manufacturing File Format (AMF) Version 1.2	ISO/TC 261
ISO/ASTM PWI 52904	Additive manufacturing -- General principles -- Standard Practice for Metal Powder Bed Fusion to Meet Rigid Quality Requirements	ISO/TC 261/JG 56
ISO/ASTM 52900:2015	Additive manufacturing -- General principles -- Terminology	ISO/TC 261/WG 1
ISO 17296-2:2015	Additive manufacturing -- General principles -- Part 2: Overview of process categories and feedstock	ISO/TC 261/WG 2
ISO/PWI 52913	Additive manufacturing -- Cloud platform and model specification	ISO/TC 261/WG 4

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 September 2016):

ISO/TC 44	Welding and allied processes
ISO/TC 44/SC 14	Welding and brazing in aerospace
ISO/TC 61	Plastics
ISO/TC 61/SC 9	Thermoplastic materials
ISO/TC 106	Dentistry
ISO/TC 106/SC 9	Dental CAD/CAM systems
ISO/TC 119	Powder metallurgy
ISO/TC 184	Automation systems and integration
ISO/TC 213	Dimensional and geometrical product specifications and verification
ISO/TC 292	Security and resilience
IEC/TC 76	Optical radiation safety and laser equipment
ISO/IEC JTC 1	Information technology

Apart from the work of ISO/TC 261, a separate recent development occurred at the November 2016 plenary meeting of ISO/IEC JTC1 on information technology. At that meeting, JTC1 established a study group on 3D printing and scanning to understand the current state of standardization and to explore a possible role for JTC1 in this area.

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.

Digital Imaging and Communications in Medicine (DICOM) is *the* international standard for medical images and related information (ISO 12052). 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. 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. DICOM will develop any standards related to formats for images, quality and data necessary to enable additive manufacturing in the medical field.

The DICOM Standard is a product of the DICOM Standards Committee and its many international working groups. Day-to-day operations are managed by MITA, which holds the copyright to the Standard. MITA is the secretariat of DICOM.

1.5.9 Metal Powder Industries Federation (MPIF)

The Metal Powder Industries Federation (MPIF)[3] 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 Isostatic Pressing Association (IPA). It also includes other corporate members that may be end users or designers of PM parts and related products/material.

MPIF standards cover five categories:

1. PM Terminology
2. Testing Procedures/Methods for Powder
3. Testing Procedure/Methods for Parts

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

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)
- MIMA Standards Committee (MIM parts makers and powder producers)
- MPPA Standards Committee (conventional PM powder producers) – Coordinates PM equipment needs and concerns through liaison with PMEA
- ANSI B11.16/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, *Practice for Conducting an Interlaboratory Test Program to Determine the Precision of Test Methods.*

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 an 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*

1.5.10 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 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, 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 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.

Over 250 global participants representing aircraft, spacecraft, and engine OEMs, material suppliers, operators, equipment/system suppliers, regulatory authorities, and defense agencies are active in the committee. There are currently six subcommittees: Materials, Processes, Nondestructive Inspection, General, Data Management, and Regulatory Coordination.

Four initial material and process specifications are under development that encompass the additive manufacture of aerospace parts from Ni-base Superalloy 625 via the laser powder bed fusion process. It is anticipated that these specifications will be ready for publication in 2017. Once the 625 PBF-L specs are balloted, the committee will identify select additional metallic and non-metallic materials and processes to initiate specification development.

SAE AMS-AM Specification Framework/Hierarchy

The AMS-AM Committee has adopted a framework for creating aerospace additive manufacturing 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, specification minimums, and design allowables.

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 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.

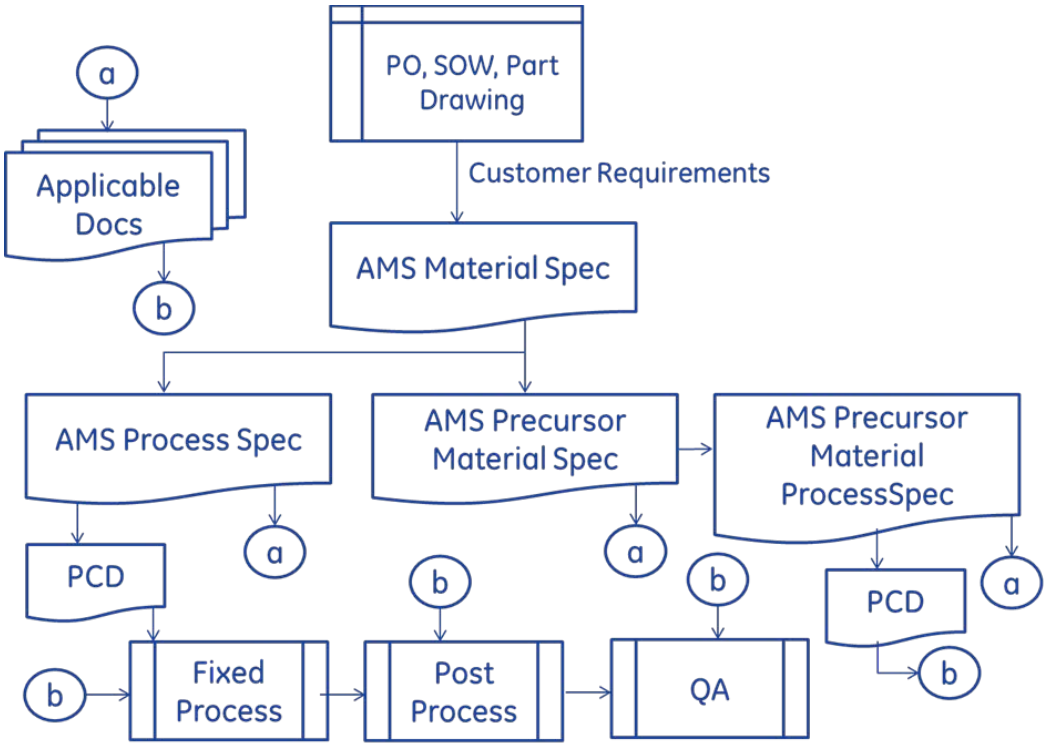

Figure 4: Flow diagram of control document precedence and customer requirements flow-down

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:

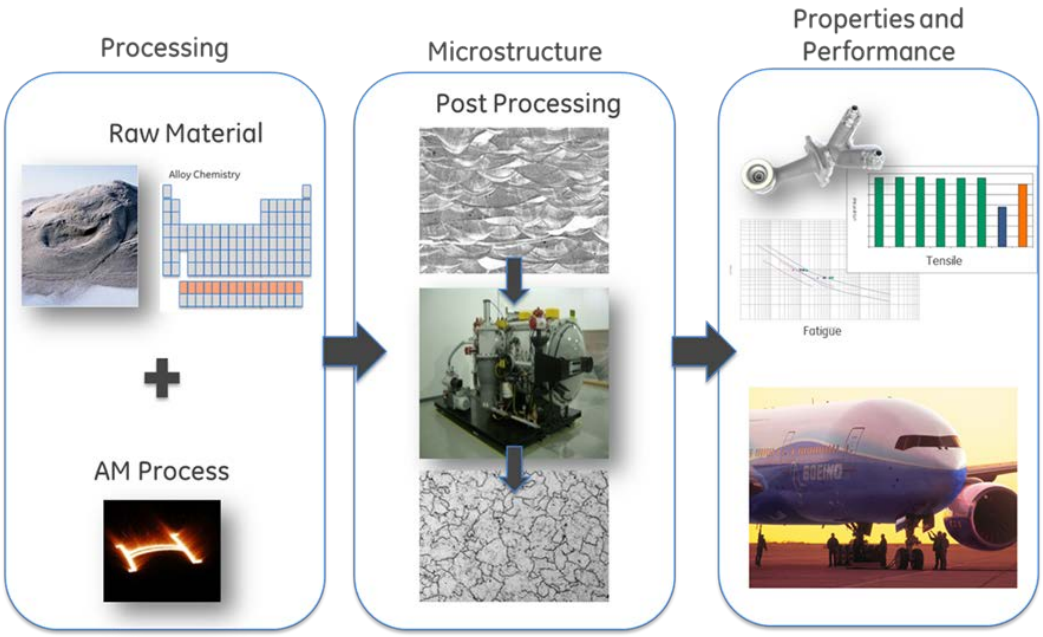

Figure 5

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.

References

General Information on the AMS-AM Committee:
http://www.sae.org/servlets/works/committeeHome.do?comtID=TEAAMSAM.

Published documents will be listed under the "Documents" tab on the metals and polymers subcommittee websites:

Metals: https://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-M
Polymers: https://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-P

Projects under development:

Metals:
https://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-M&inputPage=wIpS
Polymers:
https://www.sae.org/servlets/works/documentHome.do?comtID=TEAAMSAM-P&inputPage=wIpS

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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 will be discussed as well 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

Organization: ISO/ASTM, AWS, SAE

Gap D2: Decision Support: Additive Processes. Currently 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. ASTM and ISO are developing a standard "WK38342 New Guide for Design for Additive Manufacturing" that is expected to be released in late 2016 or early 2017; 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: Complete work on WK38342. There will still be a need to develop a standard for reporting process inputs and capabilities.

Priority: Medium

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 develop guidelines following the standards development framework they have agreed to (Figure 2). Accordingly, process-specific design guidelines are beginning to be developed. ISO/ASTM F42 JG57 is developing a standard on design for powder bed fusion (PBF) (similar in concept to an existing German standard VDI 3405), with an expected release date of early to mid-

2017. 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 guideline for PBF is currently the sole process-specific design guideline under development by ASTM and ISO. 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.

Recommendation: Complete work on the ASTM/ISO JG57 design guideline for PBF. Develop guidelines for the six other AM processes defined in ISO/ASTM 52900.

Priority: Medium

Organization: ISO/ASTM, AWS

Application-Specific Design Guides for AM

Following the ASTM/ISO framework (Figure 2), the next generation of design guidelines are expected to be application specific. As of August 2016, such efforts had been proposed but were not yet underway. Candidates for early application-specific guidelines include Design for Aerospace, Design for Medical, Design for Automotive, etc. The current landscape suggests that such standards are most likely to be developed under ASTM F42 and ISO/TC 261. ISO/TC 44/SC 14, Welding and brazing in aerospace, has recently formed a WG 1, Additive manufacturing in Aerospace. While this group is application-specific, the design implications are unclear.

Gap D4: Application-Specific Design Guidelines. 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

Organization: Various SDOs and/or industry consortia, ASTM

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, designers should have mechanisms available to them that will provide operation constraints on their available AM processes. Designers should understand what geometric and process liberties might be taken for their particular implementation.

Priority: Medium

Organization: ISO/ASTM

Gap D6: Software-encodable/Machine-readable Guidelines. In addition to design guidelines, complementary efforts have been initiated under ASTM 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. The "WK54856 Principles of Design Rules in Additive Manufacturing" work item 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 of late 2017/early 2018.

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

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

Design Guide for Surface Finish Post-processing

AM is challenged with meeting the surface finish requirements of many fatigue critical parts. The relatively rough surface finish has reduced the fatigue limit to an unacceptable level. As a result, many third party surface enhancement processes have been used to bring the finish to an acceptable level. These processes include micro-machining, Isotropic Super Finishing, Drag Finishing, and laser micromachining. Most of them will remove material from the surface. A design guide is required to provide a means to design for these third party finishing enhancement techniques.

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: New Surface Finish Capabilities. There is a need for a design guide for new surface finish capabilities.

R&D Needed: Yes

Recommendation: Develop a design guide for new surface finish capabilities.

Priority: Medium

Organization: ASME

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 inputs and capabilities is needed to enable design tools to determine manufacturing feasibility.

R&D Needed: No

Recommendation: Develop a standard for reporting machine inputs and capabilities that will clearly delineate the performance constraints of the machine, to include size, geometric complexity, material properties, tolerances, and other factors that would dictate the suitability of a particular machine to fabricate a particular implementation. See also Gap D20 on neutral build format.

Priority: Medium

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 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 verification and validation.

Priority: Low

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

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 Assembly

For purposes of this roadmap, "AM design for 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. No assembly is required. AM assemblies built in this fashion range from simple tools such as the National Aeronautics and Space Administration (NASA) wrench[4] 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 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 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 assembly also depend on how the assembly is used. The NASA wrench, built with material extrusion, might not require tight tolerances to function properly. It may only be used a few times. Conversely, an AM assembly of gears built with metal PBF might have to carry high loads and endure many usage cycles.

Published standards related to this topic include:

- ISO/DIS 8887-1, *Technical product documentation -- Design for manufacturing, assembling, disassembling and end-of-life processing -- Part 1: General concepts and requirements*

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

Standards in development include:

- ASME Y14.46, *Product Definition Practices for Additive Manufacturing*.

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

Gap D10: Design for Assembly. Guidelines do not exist for AM design for 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 regards to parameters sets, factors of interest could include feed rate and diameters (for 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 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 assembly.

Recommendation: ISO/DIS 8887-1 and other DFMA standards can be reviewed and further developed to address AM related issues.

Priority: Low

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 under development 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-2221 and IPC-2222 for the rigid sections of rigid-flex circuits as per IPC-2223. 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 Printed Electronics. There is a need to develop standards on design for printed electronics.

R&D Needed: No

Recommendation: Complete work on IPC-2292, Design Standard for Printed Electronics on Flexible Substrates.

Priority: Medium

Organization: IPC, ASTM

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 are able to 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. These are described below.

Input Data (CT, MRI and Ultrasound scan)

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 will have to be developed specifically for that device. However, a set of consensus best practices for developing these plans could reduce the overhead in developing them and reduce the burden on imaging sites because individual plans would follow a single well-defined framework. 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.

Priority: Medium

Organization: NEMA/MITA, RSNA (Radiological Society of North America)

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 separated by the process of segmentation. This segmentation process is not semi-automated and requires manual editing. Variabilities of output depend on factors such as grey scale resolution of the images which in turn depends on the x-ray dosage, operator capability, and low and high resolution on 2D to 3D conversion algorithms.

R&D Needed: Yes. Develop standardized, physiologically relevant imaging phantoms that can be used to challenge all types of segmentation techniques (manual, semi-automated and automated techniques).

Recommendation: Develop a standard test method to use 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 facilitate size, orientation and color normalization in post-processing of data.

Priority: Medium

Organization: Methods: NEMA/MITA, ASME V&V 40, ASTM. Phantoms: NIST, FDA

3D Modeling

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

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 Complex Geometries

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.

Standards in development include: *ISO/NP TR 52912, Design of functionally graded additive manufactured parts*

Gap D14: Designing to be Cleaned. Medical AM parts, like others must be cleaned of manufacturing residues. For patient contacting devices (especially implants) this cleaning must allow the device to pass tests for biological reactivity such as cytotoxicity and inflammation. Residues left on the parts may include cooling fluids or AM materials (powder or uncured monomer), among others that may be stuck within small geometric features or lattice structures. Under conditions in the body, it is often unclear if residuals will be removed or cause adverse reactions.

R&D Needed: Yes, in terms of metrics to confirm how clean a part is and ways of determining 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.

Priority: High

Organization: AAMI, ASTM, ISO, FDA

Gap D15: Design of Test Coupons. Medical devices have complex geometries and contours and in addition may have lattice structures. 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. No standards are available for the design of test coupons.

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.

Priority: Low

Organization: ASTM

Gap D16: Verifying Functionally Graded Materials. 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

Organization: ASTM F42, SAE AMS-AM, ASME

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 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.

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 because these manufacturing processes have been standardized over time and are performed to specifications and standards that bound their use that can be referenced as part of the TDP. Additive manufacturing processes have not yet been standardized, and as a result the use of a typical TDP content is not sufficient to procure parts made via AM processes.

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. This highlights the need to develop specifications and standards that can be invoked within a TDP to ensure that the materials, process, and any post-processing are performed within an established framework that provides repeatable and high quality results.

R&D Needed: Yes

Recommendation: Develop a standard (or revise Mil-STD-31000) 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

Organization: ASME, ISO, ASTM, DoD

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.

Standards in development include:

- ASME Y14.46 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.

- 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 does provide some capability in addressing some of the challenges in documenting AM designs, significant gaps still remain. ASME Y14.46 is a standard in development that will address these gaps. A first draft should be available as a guide in the next year.

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

Organization: ASME

An Organization Schema Requirement

Standards in development include:

- ASME Y14.41.1 which establishes a schema for organizing information in a 3D model within a digital product definition data set when conveying the product definition in a Model-Based Enterprise (MBE). The schema defines a common practice to improve design productivity and to deliver consistent data content and structure to consumers of the data.

Gap D19: Organization Schema Requirement. A schema for organizing information in an AM digital product definition data set is required to define common practices and to deliver consistent data content and structure to consumers of the data.

R&D Needed: No

Recommendation: ASME Y14.41.1 will address this gap and a standard should be available by the first quarter of 2018. ASME Y14.41 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 Y14.41.1. See also Gap D25, Configuration control of digital part design.

Priority: High

Organization: ASME

A Neutral Build 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, 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 (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 Format. No published or in development standards or specifications have been identified that incorporate laser path or powder 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, laser path, and power, 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

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.

Standards in development include:

- **ASME Y14.46.** ASME Y14.46 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 Y.14.46 has identified over 100 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.

Priority: Medium

Organization: ASME, ISO/ASTM

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 this data can be used to give assurances that a part was made to a required specification. Currently, it is not possible to reliably take process monitoring data and convert it into an accurate 3D file representing the part manufactured. However, this technology is growing rapidly. Further, the only way to get the data necessary for the qualification of critical parts is through computed tomography (CT) scanning. This process is very expensive and represents a significant barrier to the industry. As long as 100% CT scanning of parts is required, a business case for AM will be difficult to justify.

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

Gap D22: In-Process Monitoring. 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.

Recommendation: Develop a new standard for the incorporation of process monitoring data into a single 3D file that represents a parent made through AM. This file will include all of the imperfections, porosities, and manufacturing errors that may have occurred and were captured through the monitoring during the AM process and would be constructed from data such as laser power, melt pool size and other applicable parameters which are now capable of being monitored during the AM process. See also Gap PC16 on process monitoring.

Priority: Medium

Organization: ASTM F42, ASME, IEEE-ISTO PWG

Documentation of New Functional Surface Features

Additive manufacturing offers the opportunity to design for new surface features never before conceived.

No published standards have been identified. Standards in development include:

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

Gap D23: Documentation of New Functional Surface Features. There is a need for a specification on design documentation for new surface finishes.

R&D Needed: Yes

Recommendation: ASME should continue its work to develop B46 to address design documentation for new surface finish capabilities.

Priority: Low

Organization: ASME

An Acquisition Specification

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

Standards in development include:

- ASTM WK51282, *New Guide for Additive Manufacturing, General Principles, Requirements for Purchased AM Parts*, which covers "the definition and communication of requirements for purchased parts made by additive manufacturing."

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

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. 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.[5]

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 ISO 21748 and ISO 5725 (managed by ISO/TC 69/SC 6) provide guidelines for this approach; further information can be found in ISO/TR 12888 (ISO/TC 69/SC 7).

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

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
    - 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 also 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	Ti-6Al-4V
ASTM F42	F3001	Ti-6Al-4V Extra Low Interstitial (ELI)
ASTM F42	F3055	Nickel Alloy UNS07718
ASTM F42	F3056	Nickel Alloy UNS06625

- Verification and validation that requires the definition and evaluation of unique features:

- ASME Y14.5M – Dimensioning and Tolerancing
- ISO 17450-1 (ISO/TC 213) – Geometrical Product Specification
- ASME B89.4.23 – Dimensional Metrology
- ASME Y14.41 – 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	Standard Practice for Radiographic Examination of Metallic Castings
	E1570	Standard Practice for Computed Tomographic (CT) Examination
	E1814	Standard Practice for Computed Tomographic (CT) Examination of Castings
ASTM E07.02*	E466	Radiographs for steel castings up to 2 in. in thickness
*ASTM E07.02 contains numerous references 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 are being developed by ASTM F42:

Committee	Standard	Title
ASTM F42	WK48732	New Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion
ASTM42	WK51329	New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion1

- ASTM F42 and ASME are also in the process of producing AM design guides, which may provide guidelines for design verification.

Committee	Standard	Title
ASTM F42	WK54856	Principles of Design Rules in Additive Manufacturing
ASTM F42	WK38342	New Guide for Design for Additive Manufacturing
ASME Y14, Subcommittee 46		Product Definition for Additive Manufacturing

Gap D25: Configuration control of digital part design. AM parts are intrinsically tied to their digital definition. In the event of a design modification, proper methods of configuration and version control are needed for verification. This could include verification of the digital process parameter definitions, or software version, if applicable.

R&D Needed: No

Recommendation: ASME Y14.41 and ISO/TC 10 could incorporate the digital configuration control into their developing standards if they have not already. See also Gap D19, Organization Schema Requirement.

Priority: Medium

Organization: ASME Y14.41, ISO/TC 10, ISO/TC 261/ASTM F42

Gap D26: 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. This will likely be relevant when measuring AM features such as helixes or other complex shapes, or internal features that are not compatible with common methods such as Go/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.

Recommendation: As GD&T standards continue to develop, perform parallel investigations of validation methods to ensure verification and validation is possible.

Priority: Medium

Organization: ISO/TC 261/ASTM F42, ASME Y14.46, ISO/TC 10

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 according to the four subgroupings that the AMSC organized itself around starting with Precursor Materials, moving on to Process Control, then Post-processing, and, finally, Finished Material Properties.

2.2.1 Precursor Materials

2.2.1.1 Introduction

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, 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 light source, laser, or electron beam gun. 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.

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.

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. 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 section of this roadmap.

Polymers

The precursor materials for additive 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 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, 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.

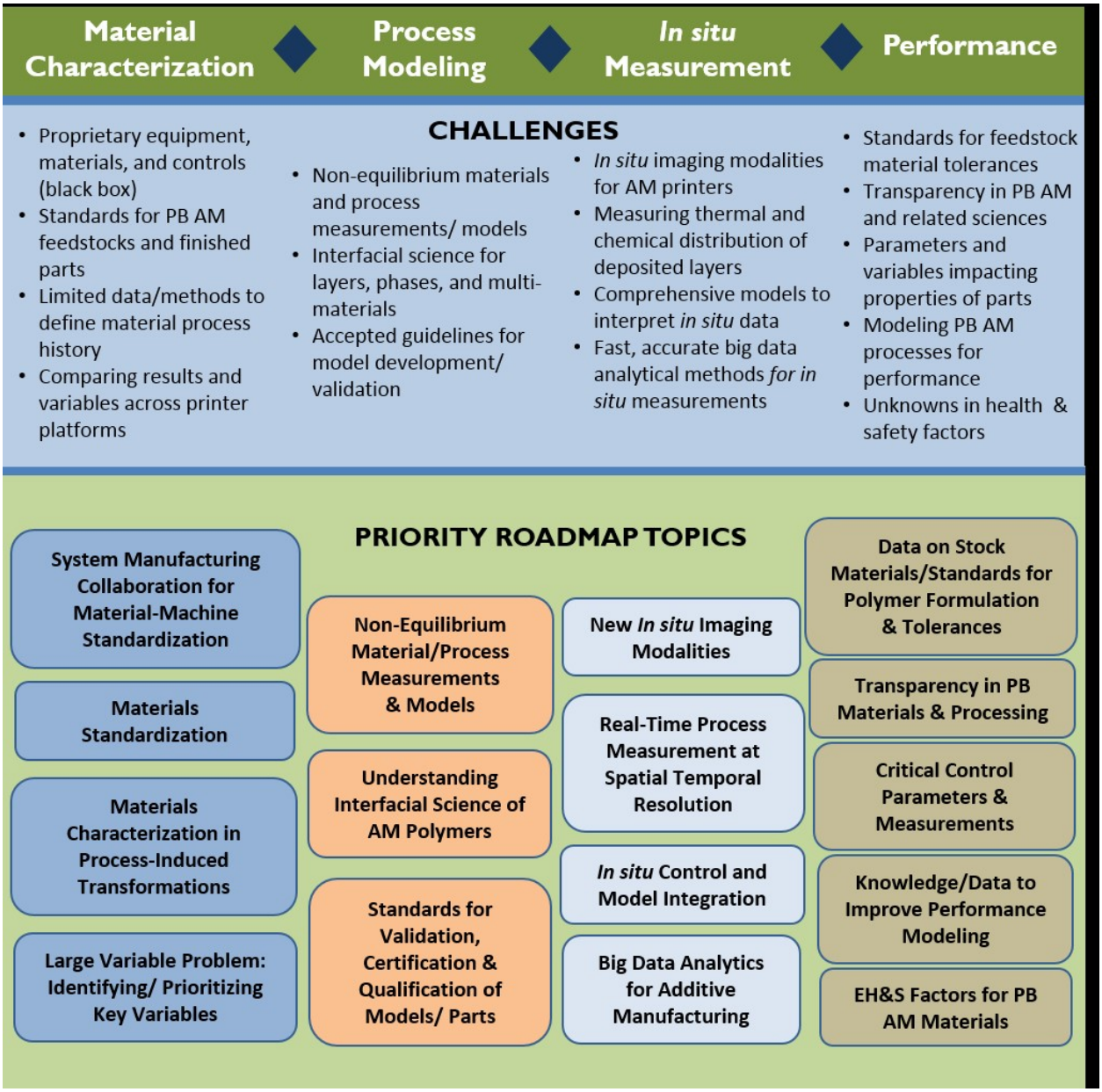

Figure E-2. Key Priority Topics and Challenges for Polymer-Based Additive Manufacturing
Used with permission of NIST from *Measurement Science Roadmap for Polymer-Based Additive Manufacturing*

* * *

The AMSC Precursor Materials working group discussion herein is primarily focused on powders and not filaments or liquids. The working group noted other materials used in AM include ceramics (with application to casting molds and next generation parts) and conductive inks. The working group aspired to include a discussion of these materials in this section but concluded that it did not have sufficient subject matter expertise at this time to adequately cover the topics.

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

2.2.1.2 Storage, Handling, and Transportation

Metals[6]

In any manufacturing process, proper handling of raw materials is paramount to safety and the quality of the resultant product. Dust generated through the handling of powders is inherently dangerous so 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 Z129.1, *American National Standard for Hazardous Industrial Chemicals – Precautionary Labeling*
- ANSI Z400.1, *American National Standard for Hazardous Chemicals – Material Safety Data Sheets – Preparation*

The National Fire Protection Association also maintains a number of relevant standards supporting the safe storage and handling of metal powders as follows:

- NFPA 68, *Standard on Explosion Protection by Deflagration Venting*
- NFPA 69, *Standard for Combustible Metals*
- NFPA 70, *National Electric Code*
- NFPA 77, *Recommended Practice on Static Electricity*
- NFPA 91, *Information about exhaust systems*
- NFPA 499, *Recommended Practice for the Classification of Combustible Dusts and of Hazardous (Classified) Locations for Electrical Installations in Chemical Process Areas*
- NFPA 654, *Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing and Handling of Combustible Particulate Solids*
- NFPA 484, *Standard for Combustible Metals*
- NFPA Fire Protection Handbook, 19th Edition

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. 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.

[6] This section does not discuss metal wire.

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 polymer raw material (powder or filament) is equally important as in the case of metal precursor material for AM. 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;
- proper handling of powder or filament waste; and
- exposure to nanomaterial component of specialty compound material.

Among the standards listed above for metals, the ones that are most relevant to polymers are ANSI Z129.1, ANSI Z400.1, and NFPA 654. In addition, NFPA 652, *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

Ensuring that precursor materials are fit for purpose presents a need for a comprehensive understanding of their chemical composition, physical morphology and structure, and mechanical, thermal, and other properties relevant to the AM process and the manufactured product. Characterization is often referred to as a broad and general process by which the composition, structure and properties are probed and measured. This often incudes several analytical techniques (spectroscopic, microscopic, macroscopic) appropriate to the type of materials and the intended purpose of the study. Provided below are some of the material characteristics influencing their handling, AM process steps, and the finished product quality and integrity. A list of applicable test methods to obtain the material information is listed, and possible gaps in the test method development are identified.

2.2.1.3.1 Chemical Composition

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, *Analysis of Low-Alloy Steels and Cast Irons by Wavelength Dispersive X-Ray Fluorescence Spectrometry*
- ASTM E1085, *Analysis of Low-Alloy Steels by Wavelength Dispersive X-Ray Fluorescence Spectrometry*
- ASTM E572, *Analysis of Stainless and Alloy Steel by Wavelength Dispersive X-Ray Fluorescence Spectrometry*
- ASTM E353, *Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel, and Cobalt Alloys*
- ASTM E1019, *Determination of Carbon, Sulfur, Nitrogen, and Oxygen in Steel, Iron, Nickel, and Cobalt Alloys by Various Combustion and Fusion Techniques*
- ASTM E2465, *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, *Analysis of Nickel Alloys by Inductively Coupled Plasma Mass Spectrometry*
- ASTM E1479-16, *Standard Practice for Describing and Specifying Inductively-Coupled Plasma Atomic Emission Spectrometers*
- MPIF Standard 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 66, *Method for Sample Preparation for the Determination of the Total Carbon Content of Powder Metallurgy (PM) Materials (excluding cemented carbides)*
- MPIF Standard 06, *Method for Determination of Acid Insoluble Matter in Iron and Copper Powders*

Applications using titanium alloy powder are emerging, and volume consumed is growing rapidly. Chemical analysis techniques, like 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, *Analysis of Titanium by XRF*
- ASTM E2371, *Analysis of Titanium by Direct Current Plasma and Inductively Coupled Plasma AES*
- ASTM E1941, *Determination of Carbon by Combustion*
- ASTM E1447, *Determination of Hydrogen in Titanium by Inert Gas Fusion Thermal Conductivity/Infrared Detection*
- ASTM E1409, *Determination of Oxygen and Nitrogen in Titanium by Inert Gas Fusion*

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

- ASTM E34, *Test Methods for Chemical Analysis of Aluminum and Aluminum-Base Alloys*
- ASTM E1251, *Test Method for Analysis of Aluminum and Aluminum Alloys by Spark Atomic Emission Spectrometry*
- CEN EN 14242, *Aluminum and Aluminum Alloys - Chemical Analysis - Inductively Coupled Plasma Optical Emission Spectral Analysis*

Polymers

Specifications and standards are well established to determine molecular weight (MW) 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.

No gaps have been identified at this time on the need for new or revised standards or specifications addressing chemical composition of materials used in 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 include:

- ASTM B213-13, *Standard Test Methods for Flow Rate of Metal Powders Using the Hall Flowmeter Funnel*
- ASTM B855-11, *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 03, *Method for Determination of Flow Rate of Free-Flowing Metal Powders Using Hall Apparatus*

- ASTM D7891-15, *Shear Testing of Powders Using the Freeman Technology FT4 Powder Rheometer Shear Cell*

Identified standards in development include:

- Draft document ISO/ASTM WK55610 (formerly WK49272), *New Test Methods for Characterization of Powder Flow Properties for AM Applications*, being jointly developed as JG63 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. WK55610 (not specific to metal powders) addresses dynamic flow, aeration, permeability, consolidation and compressibility test procedures using for example a powder rheometer. Completion of WK55610 is recommended in order to fill this gap. See also Gap PC12 on precursor material flow monitoring.

Priority: Medium

Organization: NIST, ISO/ASTM

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, D6682, D6773, and D7891).

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

Organization: NIST, universities, ISO/ASTM

2.2.1.3.4 Density (Apparent vs. Tapped)

The powder 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 B212-13, *Standard Test Method for Apparent Density of Free-Flowing Metal Powders Using the Hall Flowmeter Funnel*
- MPIF Standard 46, *Method for Determination of Tap Density of Metal Powders*
- MPIF Standard 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. 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 AM 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 B215, *Test Method for Sieve Analysis of Metal Powders*
- ASTM B822, *Test Method for Particle Size Distribution of Metal Powders and Related Compounds by Light Scattering*
- MPIF Standard 32, *Method for Estimating Average Particle Size of Metal Powders Using Air Permeability*
- ISO 9276, *Representation of Results of Particle Size Analysis*
- ISO 13320, *Particle size analysis – Laser diffraction methods*

No standards in development have been identified.

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, there are no known standards that link requirements for these attributes to the specific AM deposition process or fusion mechanism.

R&D Needed: Yes. Pre-standardization research is needed to look at acceptable ranges of powder size and distribution for various AM processes.

Recommendation: See R&D needed.

Priority: Medium

Organization: ISO/ASTM

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. Moreover, 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, *Terminology of Powder Metallurgy*, that defines typical powder shapes. ASTM B09 is planning to add AM-specific terms to B243. In addition, ISO 9276 – Part 6, *Descriptive and Quantitative Representation of Particle Shape and Morphology*, provides rules and nomenclature for describing and quantitatively representing particle morphology.

No standards in development have been identified.

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 may be addressed indirectly by standards governing flow and spreadability requirements for a powder.

Priority: Low

Organization: NIST, ISO/ASTM

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, ASTM F3049-14, *Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes*, references existing powder metallurgy sampling practices covered in ASTM B215, *Practices for Sampling Metal Powders*. MPIF Standard 01, *Method for Sampling Metal Powders*, has similarities to ASTM B215.

No standards in development have been identified.

Gap PM5: 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: No

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

Organization: ISO/ASTM, SAE

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.

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.

Priority: Low

Organization: For R&D: NIST, ASTM, America Makes, Oak Ridge National Laboratory, universities. For standards: ISO/ASTM and SAE

2.2.1.4 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 a specification to procure and accept metal powder so that compliance can be independently verified.

No AM metal powder standards have been identified. 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 Cb (Nb) Annealed*. 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

Organization: ISO/ASTM, SAE, AWS, industry OEMs

2.2.2 Process Control

2.2.2.1 Introduction

Process control in AM is a broad and significant topic. 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 repeatedly 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*
- ISO/ASTM CD 52903-2, *Additive manufacturing -- Standard specification for material extrusion based additive manufacturing of plastic materials -- Part 2: Process -- Equipment*
- AWS D17.1/D17.1M:2010, *Amd1 Specification for Fusion Welding for Aerospace Applications*
- ASTM F3187-16, *Standard Guide for Directed Energy Deposition of Metals*

Process control standards in development include:

- SAE AMS7003 WIP, *Laser Powder Bed Fusion Process*
- AWS D20.1, *Standard for Fabrication of Metal Components using Additive Manufacturing*

2.2.2.2 Digital Format and Digital System Control

Process control of digital format throughout CAD, CAM, and additive programming systems is critical to maintain production quality. In the event of software revisions and upgrades, the complexity of the systems requires the user to confirm that parts produced maintain the same level of quality: form, fit, and function/material properties. Inexperienced operators may not be aware of automated or OEM installed system upgrades and may assume status quo when restarting operations.

Published standards 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

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

2.2.2.3 Machine Calibration and Preventative Maintenance

Machine calibration and preventative maintenance can impact output quality and requires periodic measurement in addition to any OEM maintenance that is as critical as software revision control. No published standards have been identified. The draft standard AWS D20.1, *Standard for Fabrication of Metal Components using Additive Manufacturing*, contains placeholders for machine calibration and preventative maintenance requirements but at the time of this writing these were still being drafted.

Users must confirm that an AM machine continues to generate products meeting 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. This issue is closely linked to digital format and digital system control, and machine qualification.

Gap PC2: **Machine Calibration and Preventative Maintenance.** There are no known industry standards addressing machine calibration and preventative maintenance. 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.

R&D Needed: No

Recommendation: Complete work on AWS D20.1. 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.

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

Organization: AWS, ASTM, OEMs, SAE, end users

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 and ISO 13381-1. Additional information can be found in NISTIR 8012, Standards Related to Prognostics and Health Management (PHM) for Manufacturing.[7] 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.

Priority: Low

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 be qualified.

No published standards have been identified.

The draft AWS D20.1 document does not currently have specific requirements for machine "qualification." However, it does identify machine model, serial number, and software versions as variables that are essential to the AM procedure qualification (i.e., if the software is upgraded, the AM procedure must be re-qualified using the new software version). 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.

Machine qualification is also included in the SAE process control draft AMS7001.

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, and application-specific recommended practices is needed.

R&D Needed: Yes

[7] http://dx.doi.org/10.6028/NIST.IR.8012

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

Organization: NIST, AWS, SAE, ASTM

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 provides 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 is drafting extensive lists of process parameters 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 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 process parameters produces an acceptable part, and for ensuring that those process parameters remain consistent from build to build.

R&D Needed: No

Recommendation: Develop a standard that identifies key process parameters for AM machines. Complete work on AWS D20.1. See also Gap QC3 on harmonizing Q&C terminology for process parameters.

Priority: Medium

Organization: AWS, ASTM, 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 and pressure. AM machines need to be qualified not only for the manufacture of a set population of parts, but to operate in the requisite environment. For example, a machine could be resident 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 for these environments needs to be performed by or under the guidance of qualified AM operators and 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

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

2.2.2.7 Precursor Material Handling: Use, Re-use, Mixing, and Recycling Powder

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 keep these properties along 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 contains the following terms and definitions: Material supplier; Feedstock; Part cake; Powder batch; Powder blend; Powder lot; Used powder; and Virgin powder. 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

Organization: ISO/ASTM, MPIF, SAE, NIST, 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

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, guidance must be provided to ensure the environmental conditions in which the material is used and stored remain within acceptable ranges. 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

Organization: ISO/ASTM, Powder Manufacturers/Suppliers

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

R&D Needed: Yes

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

Priority: Medium

Organization: ISO/ASTM

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

R&D Needed: Yes

Recommendation: Develop a standard for re-use of material that was already printed 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 printed 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

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, *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

Organization: NIST, ISO/ASTM

Inkjet (Material Jetting)

Monitoring and control of all flow-related parameters for material jetting is critical to maintain the high quality of the prints 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.

- Expending 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

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.

No published standards or standards in development have been identified specific to EHS aspects of AM. 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.

Gap PC14: Environmental Health and Safety: Protection of Machine Operators. There is a need for standards to address 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).

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

Organization: UL, ISO/ASTM, OSHA

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:

- NIST Special Publication 800-82 Revision 2, *Guide to Industrial Control Systems (ICS) Security, May 2015*
- UL 2900-1, *Outline of Investigation for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements*
- UL 2900-2-1, *Outline of Investigation for Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare Systems*
- UL2900-2-2, *Outline of Investigation for Software Cybersecurity for Network-Connectable Products, Part 2-2: Particular Requirements for Industrial Control 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

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

2.2.2.11 Process Monitoring

Process monitoring is generally in a low technology readiness level. While systems are emerging and much research is being conducted, an analysis of the data will need to take into account the operator's level of knowledge of the process, the component being manufactured, and the ability to adapt the analytical tools to the given process.

Gap PC16: Process Monitoring. No published standards or standards in development have been identified to address process monitoring. More than likely, there will be no "one size fits all" standard for any given additive process or material. It would be highly dependent on end user analytics of OEM or internally developed sensing systems.

R&D Needed: Yes

Recommendation: Issue standard practices to qualify in-process sensed data to physical measurements of finished components. See also Gap D22 on in-process monitoring.

Priority: Medium, given the relatively low technology readiness level (TRL) state of the art

Organization: ASTM

Gap PC17: Motion Control. AM machines have many mechanical components that are similar to conventional subtractive machinery. The motion control components are blindly trusted to provide accurate positioning. This is important during machine qualification and could be addressed in a standard.

R&D Needed: Yes, with respect to Galvanometer-driven mirrors

Recommendation: 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: Low

Organization: OEMs, Experts in machine metrology

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 parts, machining or dissolving supports, and machining of the part to final dimensional tolerances and 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 surface finishing may contain gaps 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 homogenous microstructure compared to the as-built part, improve surface finish, reduce internal 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 should be 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: A standard should be issued that requires consistent post-processing to be applied for qualification and production builds. Complete AWS D20.1.

Priority: Medium

Organization: AWS D20, ISO/ASTM

2.2.3.2 Heat Treatment (metals)

Introduction

Post-build heat treatment (HT) subjects the part to a specific thermal cycle involving heating and cooling to a specific time/temperature profile at a specified rate. Heat treatments may involve several different thermal cycles. 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, and is usually applied for critical components. 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 make the properties more uniform and isotropic. Heat treatment is frequently done in an inert atmosphere or vacuum, depending on the material involved.

Standards for Heat Treatment of AM Parts

There are many generic HT standards for metals, many of which can be used for additively manufactured parts, either as is or with modifications. The majority of these HT standards are designed for wrought, cast or welded metals in consideration of their chemistry and microstructure. The layered build process, unique microstructure, and directionally-dependent properties 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 furnaces, procedures, and HT cycles for various metals also currently exist that are specific for 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, F3001, F3055 and F3056); however, more standards are needed for other materials and other processes. SAE AMS4999A, *Titanium Alloy Direct Deposited Products 6Al–4V Annealed,* includes thermal processing information.

In-Development Standards

There are several standards under development by ASTM that contain HT information for other materials produced by PBF (ASTM WK51329, ASTM WK48732, ASTM WK53423).

Gap P2: Heat Treatment (HT). 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 HIP processing is used to consolidate AM material, 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

Organization: R&D: universities, OEMs, government research labs, and others. Standards development: ASTM F42, SAE. ASTM F42 should continue to develop new standards to address these needs and modify existing standards as required. Given the aerospace community's strong preference for SAE International standards to meet unique regulatory requirements, SAE plans to develop standards that specifically address aerospace needs. SAE has an extensive list of aerospace heat treatment standards. Close coordination with other standards development organizations is necessary to reduce duplication of effort.

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 pressure utilizing an inert atmosphere and then cooling it. The HIP vessel heating and pressurizing sequence can be optimized, depending on the type of material and part configuration.

HIP is important for additively manufactured parts. It significantly improves material properties, especially ductility and fracture and fatigue properties, by healing internal discontinuities such as lack of fusion, voids, porosity, and cracks. 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.

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 metals, billets, and preforms produced by powder metallurgy technology, sintered components, or metal injection molded parts, and should not therefore be automatically considered for additively manufactured parts. In order to maximize AM material integrity without compromising microstructure properties relationships, the HIP parameters need to be optimized, especially for structural, flight safety parts and other demanding applications.

Published Standards

- ASTM Committee F42 standards that contain specific HIP process parameters for specific metals include:
    - ASTM F2924, *Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion*
    - ASTM F3001, *Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion*
    - ASTM F3049, *Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes*
    - ASTM F3055, *Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion*
    - ASTM F3056, *Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion*
- ASTM A1080, *Standard Practice for Hot Isostatic Pressing of Steel, Stainless Steel, and Related Alloy Castings Standards*
- ASTM A988/A988M, *Standard Specification for Hot Isostatically-Pressed Stainless Steel Flanges, Fittings, Valves and Parts for High Temperature Service*

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 Fusion*
    - ASTM WK47205, *New Guide for Hot Isostatic Pressing (HIP) of Aluminum Alloy Castings*
    - ASTM WK48732, *New Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion*
    - ASTM WK53423, *New Specification for Additive Manufacturing AlSi10Mg with Powder Bed Fusion*
- SAE AMS7000
- Concern has been expressed that HIP parameters may be subject to export control by the USA, making transfer of these parameters from companies to SDOs to include in standards a matter of concern for some U.S. companies.

Gap P3: Hot Isostatic Pressing (HIP). 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. 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 (XXX temperature for more than XXX hours)
- Effect of cooling rate
- Discontinuities extended to the surface
- Incipient melting with and without voids
- Discontinuities larger than XXX 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 (Example: In 718 laves phase, delta phase morphology, etc.)
- Number of discontinuities larger than XXX in per certain view area (Example: within 1 sq. inch)
- Number of discontinuities in subsurface area (XXX microns from the surface) larger than XXX inch
- Linear formation of discontinuities (other than interconnected porosity) and minimum distance of XXX inches between adjacent discontinuities

Priority: Medium

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

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

Introduction

Parts processed using PBF display as-built surface asperities containing partially fused powder and a degree of striation or stair-stepping typical of layered deposition. Surface asperities can affect functional properties such as pressure drop in air-oil or oil-oil heat exchangers. A mismatch between core and surface (e.g., contour, upskin, downskin) beam scanning patterns, or non-optimized surface parameters, could potentially produce very small areas with un-melted powder, 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 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 roughness 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 powder feedstock (such as particle size distribution and morphology), layer thickness, and build orientation.

Standards for Surface Finish of AM Parts

The total thickness of material removal that includes both surface asperities and subsurface porosity can be estimated to exceed 250 microns or ~0.010." That said one of the main challenges in internal surface polishing is uniform material removal, including surface asperities and subsurface porosity, without deteriorating material integrity, such as Intergranular Attack (IGA)/Integranular Oxidation (IGO). Other important considerations include edge retention, surface roughness (Ra) variation down the length of the internal passage, extent of bell mouthing in internal passages, surface roughness variation throughout the length of internal passages and achieving the required final Ra 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 Ra, 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	Surface Texture: Profile Method – Terms, definition, and surface texture parameters
ASME B46.1*	Surface Texture (Surface Roughness, Waviness, and Lay)
ISO 1302	Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation
ISO 12085	Geometrical Product Specifications (GPS) – Surface texture: Profile method – Motif parameters
SAE AS291F	Surface Texture, Roughness, Waviness and Lay
ASME Y14.36M	Surface Texture Symbols

*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	Surface Texture (Surface Roughness, Waviness and Lay)
ASTM D7127	Shop or field procedure for roughness of surfaces for painting
ASTM D4417	Standard Test Methods for Field Measurement of Surface Profile of Blast Cleaned Steel
ISO 4288	Geometrical Product Specifications (GPS) – Surface texture: Profile method – Rules and procedures for the assessment of surface texture
ISO 8503-2	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

Standard	Title
NACE SP0287	Field Measurement of Surface Profile of Abrasive Blast-Cleaned Steel Surfaces Using a Replica Tape
MPIF Standard 58	Method for Determination of Surface Finish of Powder Metallurgy Products
SAE AMS03_2	Cleaning and Preparation of Metal Surfaces
SAE J911**	Surface Roughness and Peak Count Measurement of Cold-Rolled Sheet Steel

**For materials of roughness 20 ≤ Ra ≤ 80 µin

- ASME B5 Technical Committee 65 on Micromachining also is working on post-processing.
- To physically achieve a specific surface roughness, there are numerous methods available. These include mechanically abrasive techniques, electro-chemical polishing, micro-machining, and thermal techniques.
- Mechanical techniques such as shot peening or media blasting (e.g., ASTM B851 and F1330, respectively) 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.
- Commercial options exist for the remaining categories listed, but most methods are proprietary and not standardized.
- Requirements for surface finish in ASTM standard specifications (e.g., ASTM F2924, F3001, F3055, and F3056) 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, are more easily manufactured using AM versus subtractive machining. However, the applicability of current measurement methods to these features is not clear or captured in standards. For example, features such as helixes or lattices may produce wire-like structures that are not as easily measured using stylus instruments as flat surfaces.

- Also, the suitability of current specification methods must be investigated for AM. ASME Y14.6 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.
- 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

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

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

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)

Sometimes cured polymers require a secondary post-cure operation to further advance crosslinking to impart favorable changes in the material. This is particularly useful when using thermoset resins for polymer parts. In contrast to thermoplastics, which soften when heated and harden when cooled, thermosets irreversibly crosslink. The increased polymerization from post-curing can result in improved properties, such as: increased stiffness, better chemical resistance, higher temperature stability, reduced toxicity (due to reduction of unreacted constituents), or increased strength. Post-curing can also reduce outgassing, and has been shown in some resins to influence the dielectric properties (e.g., relative permittivity and loss factor) of polymers by directly influencing plastic density, ion viscosity, or increasing dipole relaxation.

Many traditional polymer processing methods utilize heat and external pressure to form plastics into a final shape. Examples include: transfer molding, blow molding, direct injection, and casting. Other

methods utilize liquid resins and require radiation, such as ultraviolet light, as a catalyst for the polymerization reaction (i.e., photopolymers). AM cures resins or deposits plastics selectively layer by layer using various methods such as heated jets, binders, focused ultraviolet radiation, or laser heating.

Compared to AM, traditional fabrication methods provide a larger "pool" of material available for polymerization and potentially different molecular arrangements versus materials built layer by layer. This difference is in addition to the higher potential for voids and gas or liquid entrapment in AM. Furthermore, the use of photopolymers in AM processes such as stereolithography may also present cases where unfinished reactions can affect final part performance (i.e., degradation or warpage), especially if these materials are exposed to sunlight or other radiation sources during use or storage.

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 process. For example, photopolymers require a light source, commonly ultraviolet, to initiate polymerization. These polymers must also be post-cured using a light source. Thermosets that cure via heat generated during an exothermic reaction can be further post-cured in an elevated temperature environment. Manufacturers commonly provide post-cure recommendations, which are based on the cure kinetics of the polymer and desired end properties.

Assuming the plastics are no longer in a resin state, there are several methods of characterizing the degree of cure, which is often correlated to:

- Glass transition temperature (Tg) (for semicrystalline and amorphous polymers)
- Thermal-related mass loss (i.e., physical degradation or loss of volatile content)
- Dielectric response
- Elastic modulus or rheological properties
- Chemical composition or volatile content

There are several techniques available for measuring these properties such as thermogravimetric analysis (TGA), thermomechanical analysis (TMA), dynamic mechanical analysis (DMA), and differential scanning calorimetry (DSC). Elemental techniques such as mass spectrometry or evolved gas analysis can provide insight if the chemical reaction during cure is well characterized.

Many of these properties are indirect measurements of degree of cure, as they measure the response of polymer chains to some input (i.e., force, heat, electric fields). These responses are influenced by molecular chain length and stability, both of which can be considered indicators of the progress of polymerization.

Tg is a temperature region in which a polymer transitions from an ordered, glassy state to a rubberlike state due to molecular relaxation. Many things can influence Tg, but it is often used to gauge the degree of cure for thermosets and thermoplastics as it is related directly the crosslinking completion and

relative chain movement. The latter can be influenced by polymer chain length, the content of low molecular species (which can act as plasticizers), and the formation and frequency of branch points.

In addition to the mechanical relaxation of the bonds, crosslinking—and therefore degree-of-cure—also affects the mass loss characteristics due to bond stability, the elastic response, and dielectric properties, as these are dependent on the molecular behavior of the polymer.

As these properties are used for measuring the degree of cure, they are also applicable to measuring the effects of post-cure on a plastic.

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	Standard Test Methods for the Assignment of the Glass Transition Temperature by Modulated Temperature Differential Scanning Calorimetry
ASTM E37.10	ASTM E1356	Standard Test Method for Assignment of the Glass Transition Temperatures by Differential Scanning Calorimetry
ASTM D20.10	ASTM D4473	Standard Test Method for Plastics: Dynamic Mechanical Properties: Cure Behavior
ASTM D30.04	ASTM D7028	Standard Test Method for Glass Transition Temperature (DMA Tg) of Polymer Matrix Composites by Dynamic Mechanical Analysis (DMA)
ASTM E37.10	ASTM E1640	Standard Test Method for Assignment of the Glass Transition Temperature By Dynamic Mechanical Analysis
ASTM E37.10	ASTM E1824	Standard Test Method for Assignment of a Glass Transition Temperature Using Thermomechanical Analysis: Tension Method
ASTM E37.10	ASTM E1545	Standard Test Method for Assignment of the Glass Transition Temperature by Thermomechanical Analysis
ASTM E37.01	ASTM E2550	Standard Test Method for Thermal Stability by Thermogravimetry
ASTM E37.01	ASTM E2160	Standard Test Method for Heat of Reaction of Thermally Reactive Materials by Differential Scanning Calorimetry
ASTM D20.30	ASTM D3795	Standard Test Method for Thermal Flow, Cure, and Behavior Properties of Pourable Thermosetting Materials by Torque Rheometer
ASTM D01.55	ASTM D3732	Standard Practice for Reporting Cure Times of Ultraviolet-Cured Coatings

Committee	Standard	Title
ASTM	ASTM MNL45	Radiation Curing of Coatings (Koleske JV)
ASTM F04.11	ASTM F2042	Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II-Crosslinking and Fabrication
ASTM D09.12	ASTM D150	Standard Test Methods for AC Loss Characteristics and Permittivity (Dielectric Constant) of Solid Electrical Insulation
ASTM D01.55	ASTM D5403	Standard Test Methods for Volatile Content of Radiation Curable Materials
ASTM D01.24	ASTM D4144	Standard Test Method for Estimating Package Stability of Coatings for Ultraviolet Curing
ASTM D09.12	ASTM D257	Standard Test Methods for DC Resistance or Conductance of Insulating Materials
ASTM D20.10	ASTM D638	Standard Test Method for Tensile Properties of Plastics
ASTM F42.05	ASTM F3091/ F3091M	Standard Specification for Powder Bed Fusion of Plastic Materials
ISO/TC 51/SC 12	ISO 14322	Plastics – Epoxy resins – Determination of degree of crosslinking of crosslinked epoxy resins by differential scanning calorimetry
ISO TC138/SC 5	ISO 10147	Pipes and fittings made of crosslinked polyethylene (PE-X) – Estimation of the degree of crosslinking by determination of the gel content
ASTM E21.05	ASTM E1559	Standard Test Method for Contamination Outgassing Characteristic of Spacecraft Materials
ASTM E21.05	ASTM E595	Standard Test Method for Total Mass Loss and Collected Volatile Condensable Materials from Outgassing in a Vacuum Environment

In Development Standards

Committee	Standard	Title
ASTM F42	WK53878	Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 1: Feedstock materials

Gap P5: **Use of Post-cure to Reduce Toxicity of UV Polymers.** An evaluation of the toxicity 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.

Priority: Low

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

Gap P6: Guidelines for Post-curing AM Plastics to Address Outgassing. Guidelines for evaluating the outgassing 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.

Recommendation: Extend existing methods with AM-specific recommendations.

Priority: Low

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

2.2.4.2 Mechanical 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 application, the load bearing capabilities of a part/component must meet certain mechanical properties limits. 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 and uniformity of bulk material structure, 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.

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. 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	Test Standard Number	Title
ASTM F42	F2924	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
	F3001	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
	F3055	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion
	F3056	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion

Committee	Test Standard Number	Title
SAE AMS-AM	AMS 4999A	Directed energy Titanium alloy laser deposited products

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), a standard on how to report data (ASTM F2971), 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	Test Standard Number	Title
ASTM B07	ASTM B557	Test Methods for Tension Testing Wrought and Cast Aluminum- and Magnesium-Alloy Products
	ASTM B645	Linear-Elastic Plane-Strain Fracture Toughness Testing of Aluminum Alloys
	ASTM B646	Fracture Toughness Testing of Aluminum Alloys
ASTM E04	ASTM E384-16	Standard Test Methods for Microindentation Hardness of Materials
ASTM E08	ASTM E399-12e3	Standard Test Method for Linear-Elastic Plane-Strain Fracture Toughness KIc of Metallic Materials
	ASTM E466-15	Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
	ASTM E561-15a	Standard Test Method for KR Curve Determination
ASTM E28	ASTM E8/E8M-16a	Standard Test Methods for Tension Testing of Metallic Materials
	ASTM E9-09	Standard Test Methods of Compression Testing of Metallic Materials at Room Temperature
	ASTM E10-15a	Standard Test Method for Brinell Hardness of Metallic Materials

Committee	Test Standard Number	Title
	ASTM E18-16	Standard Test Methods for Rockwell Hardness of Metallic Materials
ASTM F42	ASTM F3122-14	Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes
	ASTM F3184	Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion

In Development Standards

There are several new standards under development that state guaranteed 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. The standard being developed by the American Welding Society (AWS) will specifically prescribe the testing required to ensure the repeatable production of metal AM components that meet functional requirements (i.e., mechanical properties).

Standards in Development with Minimum Mechanical Properties for AM Parts

Committee	Work Item Number	Title
ASTM F42	WK51329	Standard Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion
	WK53423	Standard Specification for Additive Manufacturing Aluminum AlSi-10Mg with Powder Bed Fusion
ASTM F42/ISO TC261 JG61	WK49229	Guide for Anisotropy Effects in Mechanical Properties of AM Parts
SAE AMS-AM	AMS7000 WIP	Additive Manufacture of Aerospace parts from Ni-base Superalloy 625 via the Laser Powder Bed Process

Committee	Work Item Number	Title
AWS D20	AWS D20.1/D20.1M:201X	Specification for Fabrication of Metal Components

Some of the ASTM standards under development in this area are being considered for conversion to joint ISO/ASTM standards.

The SAE AMS-AM Committee is actively working on development of a finished material specification that will include minimum values for tension at room temperature and elevated temperature for Inconel 625. These values will be lot acceptance minimums, not design allowable numbers.

Gap FMP1: Mechanical Properties. Many machine manufacturers offer general values for parts made from select powders in their machines. However, these values are not statistically validated and do not have the pedigree required for material design. Standards for 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 made by a given AM system using a given set of AM parameters for a given AM build design, and for non-metals made by various processes. 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: Medium (Metals, Polymers); Low (Ceramics)

Organization: AWS, ISO/ASTM, SAE

The American Welding Society D20 Committee is presently drafting a standard to specifically establish qualification requirements for fabricating metal components using AM. These requirements will be such that the minimum mechanical properties of a given AM build made on a given AM system are ensured.

Another potential developer for all of these standards is ASTM Committee F42, which 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 TC261 and will be usable in Europe where regulations favor ISO standards. ASTM F42.01 may have interest.

SAE International is a potential developer for the aerospace industry. Due to unique aerospace regulatory requirements, SAE aerospace material specifications include statistically-substantiated material properties and do not permit downgrading.

2.2.4.3 Component Testing

Additive Part Qualification: Aerospace Perspective

Once form and fit have been qualified, the end user of an AM component must validate the compatibility and function of the machine that the AM component is being integrated into. The part should be designed for the AM material properties otherwise established through material, process, and part finishing specifications and standards. Reasonable component level destructive testing methods (e.g., in addition to specimen-derived material properties, parts destroyed to validate dimensional, material morphology at critical locations, fatigue, etc.) and nondestructive testing methods (e.g., X-ray/computed tomography, pressure, impact, life testing, etc.) should be used to qualify the AM component function. Frequently, the nondestructive tests continue into production and evolve into a statistically-based plan for long term and ongoing validation of AM part quality.

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.

Gap FMP2: Coupon Testing. For any given application there is not a clear method or best practice document to help determine the applicability and validity of coupon testing to a specific type of component or feature.

R&D Needed: Yes. It is currently unknown how well a coupon will represent a final part due to uncertainty around reproducibility with a printer. Additionally, computational models of the heating and cooling of a part during a build based on surrounding parts and material properties would facilitate creation of guidelines in the recommendation.

Recommendation: Within the medical space, SDOs that publish topic-specific or device-specific standards should analyze existing manufacturing systems and good manufacturing practices to determine the alterations or modifications from existing practices that should be made to accommodate the way finished materials are created in a printer. There is FDA Guidance on the use of coupons to test implant porous coatings made with traditional manufacturing using standard test methods and scientifically determined acceptance criteria.[8] Two outstanding issues are: 1) there is no specific guidance on how to determine what effect the coupon will have on other parts in a build when added to the build platform of a powder bed printer, and 2) there is no guidance on how to verify or validate that a minimalistic coupon accurately represents the intended feature of the part when built with an additive manufacturing process. Guidelines or standards should be developed to address these issues.

Priority: Medium

Organization: ASTM (design/specification of coupons for specific applications), ASME V&V 50 (computational modeling Verification and Validation). ASTM F42.01 may have interest.

2.2.4.4 Biocompatibility & Cleanliness of Medical Devices

Biocompatibility

Recent industry and government workshops on 3D printing for medical applications have discussed the evaluation of biocompatibility and cleaning of AM devices. Discussions on biocompatibility revolved around one consistent fact. Materials used by AM technologies are made from the same base elements and chemistries as other types of devices. It is generally thought that biocompatibility standards such as ANSI/AAMI/ISO 10993-1 have already been developed to address a broad range of materials and therefore should still be sufficient to assess the biocompatibility of AM materials. Even so, the printer may alter the chemistry or bioactivity of the raw materials as part of the build process, which could necessitate additional testing of the final finished products using the same biocompatibility standards.

8 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107699.pdf

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*
- FDA's Use of International Standard ISO 10933-1, *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf

No gaps have been identified with respect to biocompatibility.

Cleanliness of Medical AM Parts

Cleaning may be a larger challenge, however. The complex geometries facilitated by AM, such as lattice structures and tortuous internal channels, can make it very difficult to clean parts of remaining raw material or manufacturing residues. 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*.

Standards in development include:

- ASTM WK50782, *New Practice for /Guide for Standard Test Soils for Validation of Cleaning Methods for Reusable Medical Devices*
- ASTM WK53082, *Characterizing the Cleaning Performance of Brushes Designed to Clean the Internal Channel of a Medical Device*

Gap FMP3: Cleanliness of Medical AM Parts. 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 on the application of 3D measurement techniques to discern clean from uncleaned parts; specifically, to reliably distinguish unsintered, unmelted, and uncured material from the intended part.

Recommendation: Develop standard test methods for measuring complex 3D geometries that are based on existing standards but focus on AM-specific considerations. ASTM F04 already has work in progress.

Priority: High

Organization: ASTM F04, AAMI, ISO

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-build 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	Test Standard Number	Title
ASTM F42	F2924	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
	F3001	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
	F3055	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion

Committee	Test Standard Number	Title
ASTM F42	F3056	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
	F3184	Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion

In Development Standards

Specifications in Development Including Chemical Composition Requirements for AM Parts

Committee	Work Item Number	Title
ASTM F42	WK51329	Standard Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion
	WK53423	Standard Specification for Additive Manufacturing Aluminum AlSi-10Mg with Powder Bed Fusion
SAE AMS-AM	AMS7000 WIP	Additive Manufacture of Aerospace parts from Ni-base Superalloy 625 via the Laser Powder Bed Process

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 are published for use with additively manufactured materials:

Committee	Test Standard Number	Title
ASTM F42	ISO/ASTM 52900	Standard Terminology for Additive Manufacturing – General Principles – Terminology
ASTM F42	F2924	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
ASTM F42	F3055-14a	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N07718) with Powder Bed Fusion
ASTM F42	F3056-14e1	Standard Specification for Additive Manufacturing Nickel Alloy (UNS N06625) with Powder Bed Fusion
ASTM F42	F2971	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing
ASTM F42	F3122	Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes
ASTM F42	F3184	Standard Specification for Additive Manufacturing Stainless Steel Alloy (UNS S31603) with Powder Bed Fusion
ASTM F42	F3187-16	Standard Guide for Directed Energy Deposition of Metals

Committee	Test Standard Number	Title
ASTM F42	ISO/ASTM 52921	Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies

Although the material standards 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.

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

Committee	Test Standard Number	Title
SAE AMS-AM	AMS7000	Additive Manufacture of Aerospace parts from Ni-base Superalloy 625 via the Laser Powder Bed Process
SAE AMS-AM	AMS7001	Ni Base 625 Super Alloy Powder for use in Laser Powder Bed Add Mfg Machines
SAE AMS-AM	AMS7002	Process Requirements for Production of Powder Feedstock for use in Laser Powder Bed Additive Manufacturing of Aerospace parts
SAE AMS-AM	AMS7003	Laser Powder Bed Fusion Process
ASTM F42	WK49229	New Guide for Orientation and Location Dependence Mechanical Properties for Metal Additive Manufacturing
ASTM F42	WK55297	Additive Manufacturing – General Principles – Standard Test Artefacts for Additive Manufacturing

Committee	Test Standard Number	Title
ASTM F42	WK51282	Additive Manufacturing, General Principles, Requirements for Purchased AM Parts
ASTM F42	WK51329	New Specification for Additive Manufacturing Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion1
ASTM F42	WK53423	Additive Manufacturing AlSi10Mg with Powder Bed Fusion
ASTM F42	WK53878	Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 1: Feedstock materials
ASTM F42	WK53879	Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials - Part 2: Process-equipment
ASTM F42	WK53880	Additive Manufacturing - Material Extrusion Based Additive Manufacturing of Plastic Materials: Final Part Specification
ASTM F42	WK56649	Standard Practice/ Guide for Intentionally Seeding Flaws in Additively Manufactured (AM) Parts
AWS D20	D20.1	Standard for Fabrication of Metal Components using Additive Manufacturing

Gap FMP4: Design Allowables. Current standards and underlying infrastructure/technology are not mature enough to support the development of design allowables. For metallic additive 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. Other

organizations (CMH-17) are beginning to look at the development of design allowables, with several projects in the initial research planning stages.

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 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.

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 additive materials. ASTM F42.05 may also have interest.

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 guidance on minimum data requirements and statistical processes.

Test methods: Test standards organizations, such as ASTM, 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: Material specifications: High. Data requirements and statistical analyses: Medium. Test Methods: Medium.

Organization: SAE, ASTM, MMPDS, CMH-17

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 10s 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 - 16a	Standard Test Method for Evaluating the Microstructure of Graphite in Iron Castings	This can be a guide to image based evaluation of microstructures due to the similarity in heterogeneity of graphite in iron to various phases of heterogeneities in AM alloys
ASTM Subcommittee: E04.01	ASTM E3-11	Standard Guide for Preparation of Metallographic Specimens	
ASTM Subcommittee: E04.01	ASTM E407 - 07(2015)e1	Standard Practice for Microetching Metals and Alloys	The procedures in this standard can be followed for inspecting AM metals
ASTM - Subcommittee: E04.08	ASTM E112-13	Standard Test Methods for Determining Average Grain Size	Does not account for heterogeneous microstructure
ASTM - Subcommittee: E04.08	ASTM E930-99(2015)	Standard Test Methods for Estimating the Largest Grain Observed in a Metallographic Section (ALA Grain Size)	Does not account for spatial location of ALA grain and the alignment relative to the build direction
ASTM - Subcommittee: E04.08	ASTM E1181-02(2015)	Standard Test Methods for Characterizing Duplex Grain Sizes	It may partially work for TiAl alloys but not for the gradient from surface to core of AM parts
ASTM - Subcommittee: E04.11	ASTM E2627 – 13	Standard Practice for Determining Average Grain Size Using Electron Backscatter Diffraction (EBSD) in Fully Recrystallized Polycrystalline Materials	Not suitable for AM grain structure
ASTM - Subcommittee: E04.14	ASTM E562-11	Standard Test Method for Determining Volume Fraction by Systematic Manual Point Count	Partial use in AM because volume fraction is not enough
ASTM - Subcommittee: E04.14	ASTM E1382-97(2015)	Standard Test Methods for Determining Average Grain Size Using Semiautomatic and Automatic Image Analysis	An average is not suitable for AM
ASTM Subcommittee: E04.14	ASTM E1268-01(2016)	Standard Practice for Assessing the Degree of Banding or Orientation of Microstructures	Not suitable for AM. While banding is a sort of heterogeneity, in AM there is size heterogeneity in addition to orientation banding

Committee	Test Standard Number	Title	Notes
ISO/TC 202	ISO 13067:2011	Microbeam analysis — Electron backscatter diffraction — Measurement of average grain size	It does not address the size of EBSD scan to have reliable statistics of grains in AM material

In Development Standards

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

Organization: NIST, ASTM

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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 may also appear elsewhere in this roadmap.

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.[9]

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.
>
> **Competence:** Ability to apply knowledge and skills to achieve intended results

[9] 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

- 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.

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*.[10]

A formal definitional distinction therefore is that certification describes something done by a 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).*[11]

> **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 has adopted AS9100, a sector variation of ISO 9000. The defense industry approach to certification of parts/criticality of parts aligns with the aerospace industry practice except for terminology. The aerospace industry qualification procedure equates to what the defense industry describes as "certification."[12]

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[10] *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.

[11] http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

[12] 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.

Though not specific to Q&C aspects, AM terminology documents include:

- ISO/ASTM 52900, *Additive manufacturing – General principles – Terminology*
- ISO/ASTM 52921, *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[13] 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

Organization: ISO/ASTM, SAE, ASME

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.

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.

[13] https://www.iso.org/obp/ui/#home

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. For each topic, FDA outlined its initial thinking, invited panelists discussed their experiences, and attendees offered feedback in the form of interactive breakout sessions. Feedback obtained at the workshop along with internal research and literature reviews served as the basis for a draft AM guidance document. On May 10, 2016, the FDA announced for public comment the *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff* (AM draft Guidance).[14]

Goals and Results of the FDA Effort

The FDA has three closely related goals in publishing the draft AM Guidance document.

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 draft Guidance is an addendum to existing guidance documents that focus on a specific submission type or a single device category. There are no specific acceptance criteria or prescriptive actions in the document, only recommendations and advisories for different aspects of the

[14] https://federalregister.gov/a/2016-10924. You can also find this and other information on the FDA's 3D printing information web page at www.fda.gov/3dprinting/.

manufacturing workflow. 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.

Premarket clearance or approval from the FDA is necessary to market many medical devices in the U.S. FDA does not certify any aspect of medical devices or their production. Devices are reviewed according to general criteria set by statues and regulations[15] and more specific criteria detailed in device-specific guidance documents. The Agency aims to provide transparency about the information required or recommended for a given device or submission. This transparency is especially important with emerging technologies such as additive manufacturing.

Result: The AM draft Guidance document outlines technical information needed to show a medical device is safe and effective. More specific criteria may be outlined in device-specific guidance documents. The AM draft Guidance also gives consideration to ensuring that the manufacturing processes are validated as well as information on how to maintain controls on those processes.

Continuing actions from the FDA: The FDA will use comments on the draft document to ensure that stakeholder concerns are considered. The FDA will continue to monitor and review practices and evaluate existing guidance documents for those that need to be updated. Regulatory policies were not covered in the AM draft Guidance and will be addressed with additional documents or updates to existing documents as needed.

Goal 2: Provide stakeholders that are new to the medical device industry a foundation for how to design their AM process and quality systems based on best practices that the Agency has seen in the last decade.

The Center for Devices and Radiological Health (CDRH) anticipates that by providing this draft Guidance, many researchers and early stage companies will be better able to incorporate good laboratory 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.

Continuing actions from the FDA: During the National Week of Making in June 2016, the FDA committed to provide additional information to non-traditional innovators about early interactions and assistance for the development of medical devices. The FDA AM Working Group continues to perform outreach and coordinate internal research.

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

[15] CFR for med devices (21 CFR 800-1099)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=800&CFRPartTo=1099

inspected or reviewed (i.e., Class I Medical Devices) and those who may not be traditional medical device manufacturers (e.g., researchers, hobbyists).

Since the AM draft Guidance document represents the Agency's current thoughts on the best practices for AM design, manufacturing, and validation processes, the Agency believes that it can be applicable to all types of medical device development and workflows regardless of the regulatory requirements.

Continuing actions from the FDA: The availability of high quality 3D printers to hospitals, clinics, rehabilitation centers, and other stakeholders may change the industry landscape in the near future. The FDA aims to promote safe innovation and use of AM by creating a foundation based on best practices and introducing aspects of the FDA Quality System regulations into groups that have not traditionally used them. This includes designers (spec developers), those with 3D printers (hospitals, contract facilities), and end-users.

Next Steps

The FDA will continue to work with stakeholders to develop sensible technical recommendations and considerations for AM medical devices. Gaps that the FDA identified, and that are further elaborated on in the industry sector discussion below, are the need for well-established material control data and procedures, and performance evaluation standards (e.g., nondestructive evaluation of geometric tolerances, in-process monitoring). The FDA is actively developing metrics for performance testing and is collaborating with SDOs to write and implement AM and measurement standards. Additionally, the need for trained AM professionals and technicians who can do AM process design and control was highlighted continually during outreach sessions. This is not something the FDA is positioned to address but would welcome from external groups.

Where necessary, the FDA will develop regulatory policies and publish guidance documents that provide clarification for aspects of AM technologies that may not fall cleanly within commonly established regulatory procedures.

2.3.2.2 Lockheed Martin AM Supplier Quality Checklist Overview

In 2016, design, manufacturing and quality engineers from across Lockheed Martin's (LM) four business areas (Aeronautics, Space Systems, Rotary and Mission Systems [RMS], and Missiles and Fire Control) held a quality summit addressing the AM process and its impact on the company's supply base. The company took a detailed look at the CAD-to-print additive build process with particular interest on inspection and end item delivery. One of the outputs from the summit was a set of detailed LM process checklists for use in two key areas:

1. Supplier approval: Initial AM supplier approval
2. Supplier surveillance: Supplier manufacture execution

Lockheed Martin wanted to create a higher level of engagement between design, manufacturing, and quality, while maintaining control of supply base, in order to maximize resources and enable affordability of AM produced parts. Areas that were looked at included:

- Industry shaping
- Supplier approval and oversight
- Metrics and data availability
- Focus of resources
- Administrative capacity
- Visibility across industry

Normally, checklists are based on different standards to show supplier capabilities (e.g., AWS D1.1 or AWS D1.2 for different types of welding process capability). Since many of the AM qualification standards are under development and vary by industry, three classes of supplier AM process capabilities were identified: Low, Medium, and High (or Class 1, 2 and 3).

Lockheed determined that the machine and materials process shall be established and repeatable by means of an acceptance test procedure, and that each available additive manufacturing opportunity may require a different level of part acceptance testing based on part category or class.

1. **Class III High – Flight-critical - primary structure**
    - Structural, Primary loads, Full Environmental, Safety of Flight
    - Full exposure to operational loads and environment
    - Quality of workmanship inspection Dimensional Analysis of mating and critical surfaces, Form, Fit and Function compatibility
    - Parts ***shall*** require X-Ray, CT or Laser Scanning, Proof (Tensile) Loading, Micro-Structure, Density, Porosity, Chemistry of First Article part.
    - Thermal, Shock/Vibration, Environmental and Program Specific testing ***are*** required to validated process and design.
2. **Class III Medium – Flight - secondary structure**
    - Secondary Structure, Multiple Load Paths, Partial Environment, High Margins
    - Limited exposure to operational loads and environment. Dimensional Analysis may include CM, mating and critical surfaces, Quality of workmanship inspection.
    - Parts ***may*** require X-Ray, CT or Laser Scanning, Proof (Tensile) Loading, Micro-Structure, Density, Porosity, Chemistry of First Article part.
    - Thermal, Shock/Vibration, Environmental and Program Specific testing ***may be*** required to validated process and design.
3. **Class II Support – Non-structural**
    - Limited exposure to environmental conditions
    - Ground station, Lab environment, test equipment
    - Limited Dimensional Analysis: mating and critical surfaces only – Quality of workmanship inspection

4. **Class 1 Low – Non-critical**
    - Non-structural, No consequence of failure, No Mission Impact
    - Working prototypes/models
    - Quality of workmanship inspection
5. **Class 1 Prototype/Models**
    - Engineering use only
    - Form, Fit, Function, concept parts
    - Visual inspection

Within Lockheed Martin there are 6 checklists currently available covering 3 of the part category classes: 3 for additive metals processes, laser powder bed fusion (PBF-L) and electron beam powder bed fusion (PBF-EB), and 3 for material extrusion processes. Figure 6 is a list of the checklist sections within the Lockheed Martin structure.

Cleaning Materials, Chemical Solvents & Etching Solutions
Shield Gas
Gas Certifications
Powder Material
Storage/Release
Control In Shop
Identification
EQUIPMENT
PROCEDURE CONTROL
PROCESS CONTROL
PERSONNEL
INSPECTION AND ACCEPTANCE CRITERIA
PERIODIC MAINTENANCE
Laser Maintenance Plan
Electron Beam Maintenance
General Maintenance Plan
Maintenance Records

Figure 6

Nadcap (formerly, NADCAP, the National Aerospace and Defense Contractors Accreditation Program) has developed a similar checklist structure for Class III powder bed metals only but does not have any adopted for the other metals classifications or for Material Extrusion processes. Their initial focus is on metals using PBF-L and PBF-EB, while Lockheed is using a variety of AM processes and had the need to develop further checklists to support its manufacturing operations.

Nadcap's current development status as of August 2016 is listed below:

- AM Audit Survey Checklist
  - ✓ Laser & EB Equipment manufacturing companies review of checklist complete
  - ✓ Checklist out to Welding Task Group Approval Ballot
- Nadcap Management Approval, estimated completion date (ECD) December 2016
- AM Auditor Guidebook, started; ECD Q1 2017
- AM Auditor Test, started; ECD Q1 2017
- AM Audit Class Room Training, in review; 1st class October 2016
- AM Auditor Hiring, ECD Q2 2017
- AM Auditor Full Hands On Site Training, ECD Q2 2017
- AM Accreditation capability deployment, ECD Q2 2017

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)

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 included 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.

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. Recently, a group has formed to consider the addition of polymer based additively manufactured materials into the handbook. As part of this Federal Aviation Administration (FAA) led effort, data will be generated and submitted to CMH-17 for consideration. Submission to the handbook will likely occur in 2017 and will require substantial review prior to publication.

Metallic Materials Properties Development and Standardization (MMPDS) Handbook

The MMPDS Handbook also has a long history beginning with ANC-5 published in 1937. The United States Air Force (USAF) took over the primary responsibility of continuing development of the Handbook in 1954 and, subsequently, changed its name to MIL-HDBK-5 in 1956. In 1997 an Industrial Steering Group was formed to help provide funding support. 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. Battelle now maintains and publishes the Handbook. MMPDS-11 was released in October 2016; MMPDS-12 should be released in July 2017.

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.

The document contains design information on the mechanical and physical properties of metallic materials and joints commonly used in aircraft and aerospace vehicle structures. All information contained in the MMPDS Handbook has been reviewed and approved using a standardized process. The development and ongoing maintenance process involves certifying agencies, including the FAA, DoD, and NASA, and major material suppliers and material users worldwide. The Handbook typically has been revised on a yearly basis to include new alloys, updated guidelines, and to make revisions to existing sections as determined to be appropriate. Additively manufactured metallic materials are discussed in the Emerging Technology Working Group (ETWG) with guidance from the FAA. Initial efforts have been made on presentation of the data, equivalency determination methods, and other general guidance. Currently, the FAA proposes that these materials will reside in a separate volume or document. No date is currently set for the addition of these materials as further development of specifications and standards is needed. Submitted data will need to undergo adequate review, and analysis methods will need to be verified.

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 qualification of design, materials, processes, and personnel. 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 is creating a comprehensive document that identifies requirements for AM procedure qualification and AM machine operator qualification, as well as fabrication and inspection requirements for AM components. The D20 committee intends for the standard to cover 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.

As of its August 31-September 1, 2016 meeting, the AWS D20 committee was continuing to work towards finishing a complete draft of the AWS D20.1 standard. Once the draft is completed, it will be issued to the committee members for review. After the committee members have voted to approve the document, it will go to the AWS Technical Activities Committee (TAC) for vote.

2.3.2.6 NASA Marshall Space Flight Center (MSFC) Draft Standard for Laser Powder Bed Fusion (PBF-L) Additive Manufacturing (AM): "Engineering and Quality Standard for Additively Manufactured Spaceflight Hardware"

Motivations

NASA human rated spaceflight programs have quickly embraced the promise of AM to benefit design flexibility, cost, and schedule challenges of system development and manufacture. Each of NASA's current human spaceflight programs, the 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 draft 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 draft document has been publicly available since mid-2015. Early in the release, a diverse set of government and industry reviewers provided substantive comments that remain under consideration.

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.

Status

The draft document has been helpful in the guiding the process within the NASA programs to date. Adoption of the process has been gradual in some circumstances and nearly complete in others. As of August 2016, the document was in a focused revision having been static for the past year while the concepts were under review and early implementation evaluated. No major shifts in philosophy have been identified for the revision. The document may be split into two documents, a standard and an associated specification, to better match Agency policy on document content and development policies. At the time of this writing, the intent was to release the standard as a NASA center-level (MSFC) document in the Fall of 2016, eventually becoming an Agency level document, or having its content absorbed into existing, over-arching Agency standards.

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.

As of August 2016, the Y14.46 document was in editing preparation for a comment period in the October - November timeframe. The incorporation of comments was to follow with a target date for release of December2016/January 2017. Participants from all sections of the Y14.46 Product Definition for AM Standard participated in all AMSC working groups.

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 three sectors (aerospace, defense, and medical) 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: Qualification Standards by Part Categories. A standard classification of parts is needed, such as those described in the Lockheed Martin AM supplier quality checklist (2.3.2.2) and the NASA Engineering and Quality Standard for Additively Manufactured Spaceflight Hardware (2.3.2.6). This is a gap for the aerospace and defense industries.

R&D Needed: No

Recommendation: A classification of parts should be defined as well as a minimum set of qualification requirements and related technology readiness level (TRL) and manufacturing readiness level (MRL) metrics for each part category that takes into consideration the intended part usage/environment. It is suggested that mission critical parts be looked at first.

Priority: High

Organization: NASA, SAE, ISO/ASTM

Processes

Processes are validated and "certified." New processes are validated to ensure accurate representation of the manufacturing process. Validation is the process used to verify final proof that the execution of a work instruction or "how to" achieves the technical requirements (workable, reproducible, controllable, inspectable), meets contract and other requirements, and doesn't degrade reliability.

Processes certification involves obtaining objective evidence of process elements compliance or noncompliance. Process certification requirements are derived from specifications, practices, and lessons learned. If new materials or equipment are introduced the process certification is repeated. Procedures will exist on how to accomplish a process certification. Some OEM systems require part certification rather than process certification.

SAE AMS-AM addresses standards for the aerospace sector and AWS D20 addresses AM for metals (powder bed and directed energy deposition). AWS Subcommittee A focuses on qualification and certification of process, while subcommittee B deals with fabrication, and subcommittee C deals with inspection. SAE AMS-AM is establishing a Polymer Subcommittee to develop aerospace material and process specifications for polymer based AM which could be utilized for aerospace qualification and certification.

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 as well as the operator certifications 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 DSR 6 (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 (QA) 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.

Gap QC3: 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 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. See also Gap PC5 on parameter control.

Priority: Medium

Organization: ISO/ASTM, IEEE-ISTO PWG

Source (i.e., Vendor) Approval

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 B962, *Standard Test Methods for Density of Compacted or Sintered Powder Metallurgy 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 B962-15, ASTM E384-1. Standards in development include: ASTM WK51329, and other ASTM standards.

Gap QC4: DoD Source (i.e., Vendor) Approval Process for AM Produced 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. Today, 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, develop standards to assess required checks for levels of criticality and safety as part of the source approval process.

Priority: High

Organization: Service SYSCOMS, Industry, ASME, ISO/ASTM, SAE

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).

Gap QC5: Machine Operator Training and Qualification. Currently, there are no published standards or guidelines outlining AM training requirements, though AM machine manufacturers typically are available to provide training to new operators. The AWS D20.1 standard in development includes requirements for AM machine operator performance qualification based on training, written and practical examinations, and the demonstration of successful AM builds. In addition to training programs offered by OEMs, Underwriters Laboratories (UL), in cooperation with the University of Louisville, is offering a comprehensive AM training program initially focused on metals.[16]

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

Organization: AWS, UL, AAMI, OEMs, ISO/ASTM

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

[16] http://industries.ul.com/additive-manufacturing/ul-additive-manufacturing-competency-center

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
- Training in 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 Industry[17]

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.[18] 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.[19] 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 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.

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[17] 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.

[18] While the discussion herein focuses on AM of medical devices, the FDA has approved at least one AM pharmaceutical.

[19] See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/

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

Organization: DICOM, IEEE, ISO, ASTM

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

Organization: DICOM, IEEE, ASME, ISO, ASTM, 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.[20] 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.

Priority: Medium

Organization: Biomedical Engineering Society, NEMA/MITA, ISO, ASTM

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.

[20] 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."

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

Organization: SME, RSNA, ASTM

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.

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

Organization: ASTM, NEMA/MITA, AAMI, ASME, ISO

Medical Materials and Materials Processing

All current AM materials for medical applications fall into the category of implantable or non-implantable materials, with some of the current AM materials shown in Figure 7:

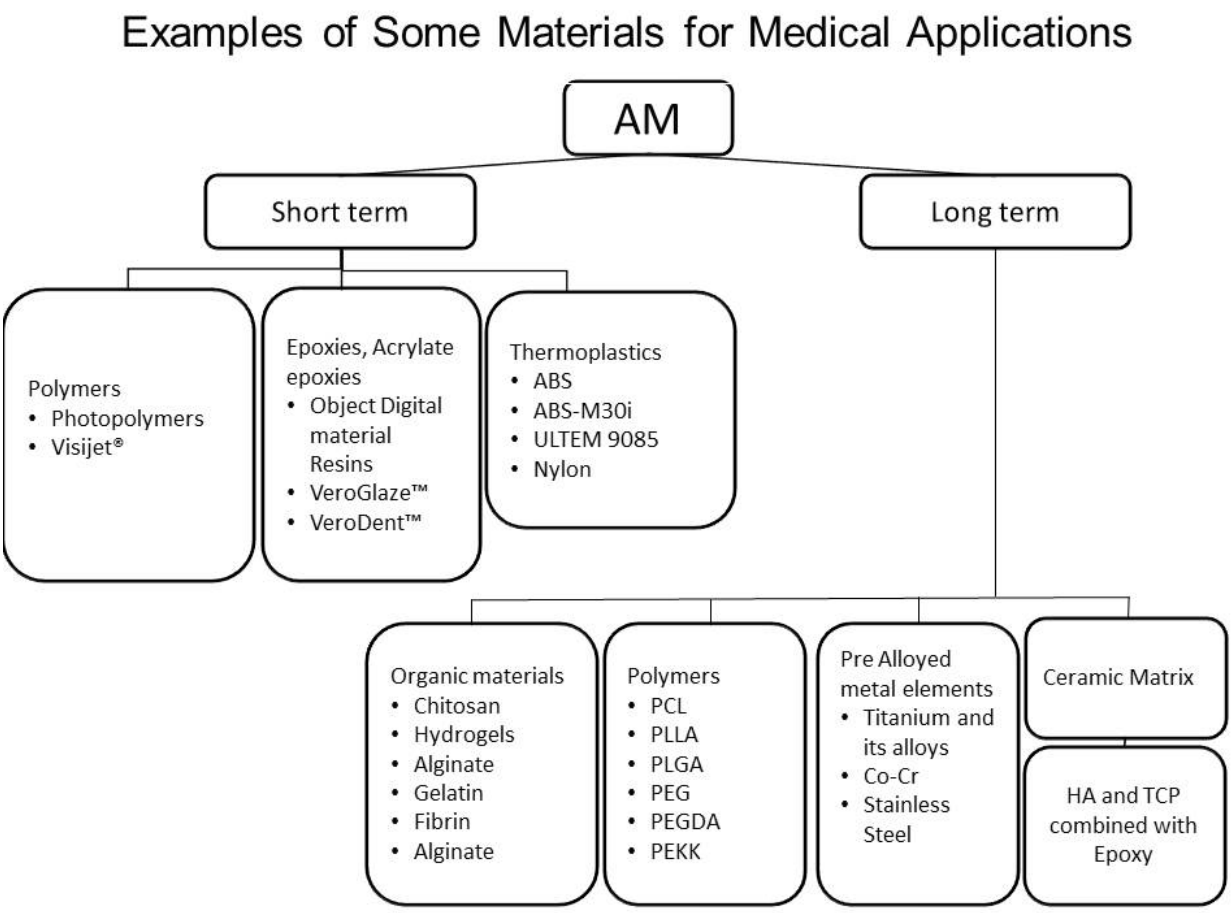

Figure 7: Examples of Some AM materials for medical applications. Figure courtesy of Dr. Jayanthi Parthasarathy and Lauralyn McDaniel

Qualification & Certification of Materials

As per FDA guidance, even if original material is certified by the supplier, the device manufacturer is responsible for qualification of the final material in a device. This is applicable to AM, as the raw material that is a powder, liquid, or wire, is converted to a 3D shape by using external energy in the form of heat, light, or chemicals. Post-processing also involves chemicals sometimes to remove the support structures that may change the original composition and/or be detrimental to body tissues or remain in the pores. Devices are in contact with the body tissues of the practitioner and his team, and with the patient for the short term, or they may remain in the patient's body for the long term.

Published standards (Non-resorbable materials) include:

- ASTM F2924-14, *Standard Specification for AM Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion*
- ASTM F3001-14, *Standard Specification for AM Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion*

Standards in development from include:

- ASTM WK51329, *New Specification for AM Cobalt-28 Chromium-6 Molybdenum Alloy (UNS R30075) with Powder Bed Fusion*
- ASTM WK53878, *AM - Material Extrusion Based AM of Plastic Materials - Part 1: Feedstock materials*

In addition to primary build material, pigments and processing aid materials (including support) also need to be qualified.

Gap QC11: Process Validation for Pigments and Processing Aid Materials. There is a gap in terms of qualification guidance for pigments (colorants) and processing aid materials. While ISO 13485, *Medical devices - Quality management systems - Requirements for regulatory purposes*, and 21CFR820 apply, process validation for these AM materials is not completely understood. Colorants add additional regulatory requirements.

R&D Needed: Yes

Recommendation: Develop qualification guidance for pigments and processing aid materials. Consider process validation.

Priority: Low

Organization: ASTM

Resorbable Materials

Some polymers, such as polycaprolactone, poly glycolic 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.

Relevant published standards include ASTM F1635 and there are provisions in ISO TR37137 to do toxicity testing.

Gap QC12: Resorbable Materials. There are few available standards for testing of degradation of the resorbable polymers in living tissues and therefore a standard needs to be developed.

R&D Needed: Yes

Recommendation: Develop guidance on how to test the degradation of resorbable polymers to support material selection for AM.

Priority: Medium

Organization: ASTM

Biocompatibility Testing Standards Available for Resorbable and Non-resorbable Materials

Existing standards include ISO 10993-1:2009, *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 Draft Guidance on Technical Considerations of AM Medical Devices for comment on May 10, 2016. This includes FDA recommendations for medical device submissions.

Material Control Data and Procedures

No published standards or standards in development specific to AM have been identified.

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 reporting template and data set for material pedigree, recommended testing, and handling procedures would simplify evaluation of material suitability.

Priority: Low

Organization: Material providers, ASTM

Qualification and Control of 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 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). 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: Draft Guidance for Industry and Food and Drug Administration Staff*. Food and Drug Administration;

2016 May. 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

Organization: RSNA, DICOM, ASTM

Validation of Sterilization Processes and Anatomical Models

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 devices 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.[21] 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).

[21] 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.

Validation of sterilization processes: A number of published standards govern the validation of sterilization processes used for medical devices, including ANSI/AAMI/ISO 11135 (ethylene oxide sterilization), the ANSI/AAMI/ISO 11137 series (radiation sterilization), the ANSI/AAMI/ISO 17665 series (moist heat sterilization), and ANSI/AAMI/ISO 20857 (dry heat sterilization). For animal tissue-based products sterilized via glutaraldehyde, ANSI/AAMI/ISO 14160 applies and AAMI TIR37 provides guidance for the sterilization of human tissue-based products using radiation.

For products requiring unique sterilization processes, ANSI/AAMI/ISO 14937 governs. For medical devices that cannot be sterilized to a Sterility Assurance Level (SAL) of 10^{-6}, ANSI/AAMI ST67 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 and 11607-2 provide requirements for packaging intended to maintain sterility, and ASTM standards provide packaging test methods (D3078-02, D4169-16, F1140/F1140M-13, F1608-16, F17-13a, F1886/F1886M-09, F1929-15, F1980-07, F2054/F2054 M-13, F2095-07, F2096-11, F2097-14, F2203-13, F2217/F2217 M-13, F2228-13, F2250-13, F2251-13, F2252/F2252 M-13e1, F2338-09, F2391-05, F2475-11, F2638-12, F2825-10, F88/F88M-15).

Validation of the ability to clean, disinfect, and sterilize products intended for subsequent processing: ANSI/AAMI 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 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 provides information on materials compatibility with sterilization processes.

Sterilization of tissue-based products: There are some recognized standards and guidance in this area (see above and see the work of ISO/TC 194/SC 1, Tissue-based products). Other standards exist (e.g., *ANSI/AAMI/ISO 13022/Ed.1, 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, 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/DTS 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.

Gap QC15: Anatomical Models: Sterilization. Anatomical models may require sterilization if they are to come into contact with compromised tissue of patients. There may be a need for guidance in this area.

R&D Needed: Maybe. Some has been done but more may be needed on whether/how traditional sterilization models work with AM.

Recommendation: Development of guidance for additive manufacturers on the application of existing standards may be the most feasible and productive goal in this area.

Priority: Low

Organization: R&D: OEMs. Guidance: AAMI, AOAC International, ASTM, ISO, USP

2.4 Nondestructive Evaluation (NDE)

2.4.1 Introduction

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.[22] 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: 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).

The scope of this section is generally focused on additive manufacturing of metal components, but the discussions may also have relevance to other materials. 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

[22] 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.

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 in 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.

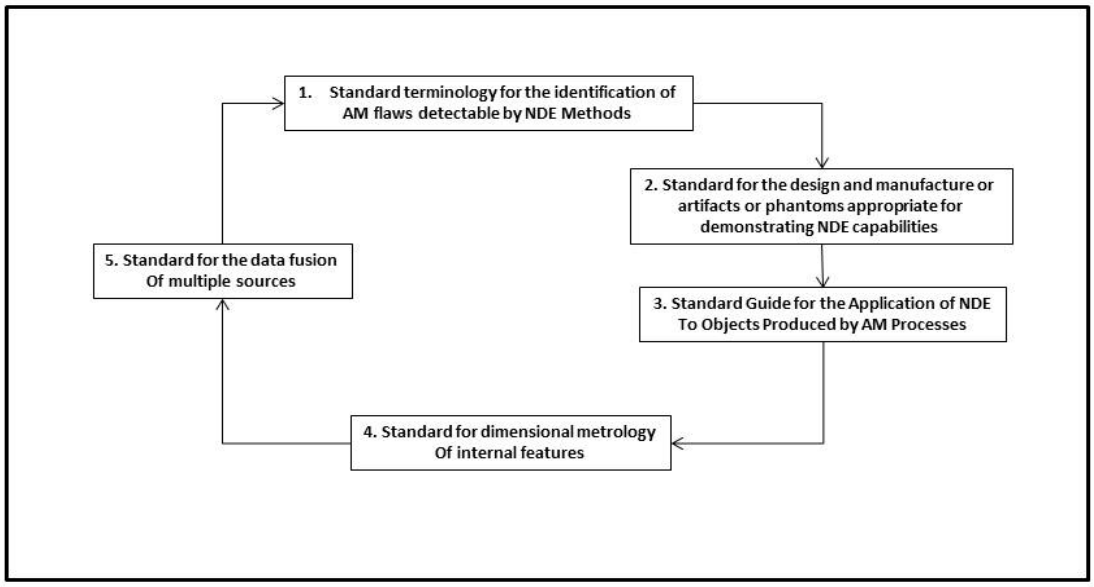

Figure 8: Evolving sequence of AM NDE gaps

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:

- 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 E1316-16a, *Standard Terminology for Nondestructive Examinations*

In terms of standards in development, there is an emerging consensus document ISO/ASTM NP 52902, *Additive Manufacturing – General Principles, Standard Test Artifacts*, addressing flaw types.

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

Organization: ISO/ASTM

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.

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, *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.

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.). 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 ASTM WK56649, *Standard Practice/Guide for Intentionally Seeding Flaws in AM Parts*, now proceeding as ISO/TC 261/ASTM F42 JG60, to establish flaw types and conditions/parameters to recreate flaws using AM processes.

Priority: Medium

Organization: ISO/ASTM

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. Each category produces a unique set of material flaws that are different from those produced by traditional manufacturing processes such as forging or casting. 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.

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 and ASTM E428 and implemented as acceptance classes in AMS 2154 and ASTM E2375. Similarly, X-ray inspection of titanium castings uses reference radiographs to measure severity as defined in ASTM E1320. Acceptance standards may be imbedded in the process standard or in a stand-alone standard such as MIL STD 1907 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 *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. 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 this document 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 in ASTM E07. 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 and ISO/ASTM JG59.

Priority: High

Organization: ISO/ASTM

2.4.4 Dimensional Metrology of Internal Features

The additive manufacturing process has its own challenges when it comes to dimensional metrology. There are many aspects when it comes to determining the quality and form, especially internal features of the parts produced via the AM process. Destructive measurement methods produce results that are different from the results generated from nondestructive methods. Therefore, the dimensional control is a challenge when it comes to the measurement of internal features of certain parts created in the AM process. The internal structures, tolerances and their limits, and material characterization of complex 3D structures cannot be measured with the standard metrology methods available today.

One of the main technologies of NDT in the AM world is X-ray computed tomography (CT), which is a leading nondestructive technology that can measure internal features of a part after part fabrication, while structured light is a leading technology that can measure external features of a part either during or after part fabrication. CT technology provides important measurements like wall thickness, porosity analysis, material structural analysis, and the ability to measure complex internal hollow structures that are otherwise impossible to measure.

In NDE dimensional metrology, one thing that has to be kept in mind is the design process itself. The traditional design mentality has revolved around traditional manufacturing processes but for the AM process the designer has to think unconventionally, in other words, keeping the AM process in mind. This applies to design of angles, fillets, rounds etc. Also loss of material needs to be kept in mind. Another issue to take into account is the finishing process for the AM parts. There is a strong need to define how to address the design process suited for AM.

One other important aspect is to determine what type of NDT process can be applied, knowing the Ra measurement. Ra might meet the print specifications but there might be abnormalities (uneven surface, etc.) from the build. Another key aspect of the design is what type of AM process will be used and what parts need to be manufactured. All these things have to be kept in mind when applying measurement techniques to AM parts.

Published standards on this topic include: ISO 15530-3:2011 and a German standard VDI/VDE 2630 Blatt 1.4. Standards in development include:

- ASTM WK47031, *New Guide for Nondestructive Testing of Additive Manufactured Metal Parts Used in Aerospace Applications*, by ASTM E07
- ISO/ASTM WK56649, *Standard Practice/Guide for Intentionally Seeding Flaws in Additively Manufactured (AM) Parts*

ASTM will soon be doing a guide for CT metrology under Committee E07.

In addition, research has been undertaken on the topic of dimensional metrology of internal features of AM parts including by 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.

Gap NDE4: Dimensional Metrology of Internal Features. Standards are needed for the dimensional measurement of internal features of AM objects.

R&D Needed: Yes

Recommendation: ASTM F42 and E07 should identify and address additive manufacturing related areas for alignment with current computed tomography dimensional measurement capabilities.

Priority: Medium

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 are needed for data fusion in AM NDT techniques
- Expert education, training, and certification for AM data fusion in NDT

Priority: Medium

Organization: ASTM

2.5 Maintenance

2.5.1 Introduction

Relative to additive manufacturing (AM), “maintenance” is defined as maintenance of AM machines; AM related to corrosion; condition based maintenance (CBM) and use of AM technology and equipment; inspection of repairs performed with AM technology; level of repair analysis (LORA) and reliability centered maintenance (RCM) analysis of AM technology parts, tools, equipment; impacts to training; and impacts to maintenance inspection.

For purposes of this discussion, tools/tooling refers to creation or repair of those artifacts needed to execute a parts repair, excluding fixed or capital assets. Repair includes direct material addition or removal using additive technology. Direct material applies to the materials used in the AM transaction.

2.5.2 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 can provide relief to weapon systems support required in the field by providing on-site repair capability. Considerations related to maintenance and repair procedures using AM technologies are addressed in two areas: (a) maintenance and sustainment of machines; and (b) maintenance and sustainment of parts.

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 machine repair procedures. These may include for example:

- Repair environments including power drops, water availability, flooring requirements, lighting, air flow, 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
- Hazardous materials related to AM machines
- Software maintenance and cybersecurity related to AM machines

Gap M1: AM Analyses in RCM and CBM. Standards for AM analyses in Reliability Centered Maintenance (RCM) and Conditioned Based Maintenance (CBM+) are needed.

R&D Needed: No

Recommendation: Update SAE JA1012 RCM, a guide to provide analytics for AM trade-offs in RCM and CBM+.

Priority: Medium

Organization: SAE, ISO, ASTM

See also Gap PC14 on environmental health and safety issues and protection of AM machine operators.

Maintenance and Sustainment of Parts

Maintenance of parts relates to the quality of the parts that are being produced in relation to design, the repeatability of the parts from machine to machine, and the form, fit, and function factor. Materials are also a factor since there are several types of materials that can be used, from thermoplastics to metal powder. There are several different AM materials that are currently being used including ABS/PLA/nylon/carbon, as well as aluminum, stainless steel, Inconel, and titanium, in addition to newer materials that are currently being developed. Ancillary equipment needs to be identified for finishing (touch labor), machining, or coatings needed to arrive at the final product. Other areas that need to be addressed include the results of AM repairs such as cold spray technologies and the logistics tail that needs to be in place to support high quality repairs. Other factors to be addressed include:

- Qualification of parts made from similar machines
- How to qualify, accept and repair parts or tools made from AM machines
- Maintenance related to non-AM parts or tools/tooling being repaired using AM technology
- AM restoration processes for end-use parts or tooling, including material preparation, standard cleaning, and handling
- 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 Analysis (LCC), LORA, and RCM[23]

[23] "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, LORA, and RCM will allow for new variables to be analyzed.

Existing standards that relate to this topic include:

- DoD: MIL-STD-3049 on DED metal remanufacture/restoration
- 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, *Specification for Fusion Welding for Aerospace Applications*
- AWS B2.1, *Specification for Welding Procedure and Performance Qualification*
- SAE AMS-AM (electron beam welding): SAE AMS2680C-2001, *Electron-Beam Welding for Fatigue Critical Applications* (Reaffirmed: March 2010)

Standards in development include: AWS D20.1, *Specification for Fabrication of Metal Components using Additive Manufacturing*.

Gap M2: Using AM to Print Tools. Current standards may not consider the variety of materials that can be used to create tools using additive manufacturing.

R&D Needed: No

Recommendation: Amend the ASME B107 series of standards to require specific strength/loads for hand tools to ensure that AM printed tools function like machined tools. Examples include:

- ASME B107.100-2010, *Flat Wrenches*
- ASME B107.110-2012, *Socket Wrenches, Handles, and Attachments*
- ASME B107.300-2016, *Torque Instruments*
- ASME B107.400-2008, *Striking Tools*
- ASME B107.410-2008, *Struck Tools*
- ASME B107.500-2010, *Pliers*
- ASME B107.600-2008, *Screwdrivers*

Also update SAE AS1390:2014, *Level of Repair Analysis (LORA)*, to include trade space of repairs including on AM. Trade space would address reduction of time and increase in skill set (e.g., for qualified printer operators).

Priority: Medium

Organization: ASME, SAE

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.

R&D Needed: No

Recommendation: Update SAE AS1390:2014 to address AM LORA.

Priority: Medium

Organization: SAE with input from DoD, ISO, ASTM

2.5.3 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, *Standard Practice for Radiographic Examination*
- ASTM E1444/E1444M, *Standard Practice for Magnetic Particle Testing*
- SAE AS1390, *Level of Repair Analysis*

No standards in development have been identified.

Gap M4: Physical Inspection of AM Parts and Tools for Defects. 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

Organization: SAE, ISO/ASTM

2.5.4 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, ISO 16792, 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 maintenance assessments and scheduling.

R&D Needed: No

Recommendation: Develop standard practices for assessing level of damage for end-use parts and AM machine "health" using model-based inspection. See also Gap PC3 on machine health monitoring.

Priority: Medium

Organization: ASME, ISO/ASTM, Dimensional Metrology Standards Consortium

2.5.5 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. The importance of tracking maintenance operations is 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

In terms of existing standards, DoD Directive 8320.03, *Unique Identification (UID) Standards for Supporting DoD Net-Centric Operations*, dated November 04, 2015, 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

Organization: AWS, ASTM

2.5.6 Cybersecurity for Maintenance

Issues related to cybersecurity/the 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 risk to 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, all 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*: http://dx.doi.org/10.6028/NIST.SP.800-53r4. 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: https://www.nist.gov/news-events/news/2015/02/nist-releases-update-industrial-control-systems-security-guide-final-public

- NIST Cybersecurity Framework: https://www.nist.gov/cyberframework/[24]

- 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": http://www.ndia.org/Policy/LegislativeandFederalIssuesUpdate/Documents/Cyber_for_Manufacturing_White_Paper_5May14.pdf

- NEMA White Paper, Supply Chain Best Practices: http://www.nema.org/Standards/Pages/Supply-Chain-Best-Practices.aspx

- NEMA/MITA White Paper, Cybersecurity for Medical Imaging: http://www.nema.org/Standards/Pages/Cybersecurity-for-Medical-Imaging.aspx

Published rules for DoD contractors and subcontractors include:

- Defense Federal Acquisition Regulation Supplement (DFARS) Publication Notice 20160802, *Detection and Avoidance of Counterfeit Electronic Parts – Further Implementation* (DFARS Case 2014-D005): https://www.gpo.gov/fdsys/pkg/FR-2016-08-02/pdf/2016-17956.pdf. 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.

[24] 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.

Guidance documents in development include:

- Draft Cybersecurity Framework Manufacturing Profile, currently out for subject matter expert review: http://csrc.nist.gov/cyberframework/documents/csf-manufacturing-profile-draft.pdf.

Other notable activities include:

- The Cybersecurity for Smart Manufacturing Systems project: http://www.nist.gov/el/isd/cs/csms.cfm within the NIST Smart Manufacturing Operations Planning and Control Program: http://www.nist.gov/el/msid/syseng/smopc.cfm

- NISTIR 8041, *Proceedings of the Cybersecurity for Direct Digital Manufacturing (DDM) Symposium* (April 2015): http://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8041.pdf

- The National Defense Industrial Association (NDIA) Cybersecurity for Advanced Manufacturing (CFAM) Joint Working Group (JWG): http://www.ndia.org/Divisions/IndustrialWorkingGroups/CybersecurityforAdvancedManufacturingJointWorkingGroup/Pages/default.aspx. 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 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: http://www.nema.org/Policy/Anti-Counterfeiting/Pages/default.aspx

- International Anti-Counterfeiting Coalition (IACC): http://www.iacc.org/, 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

Organization: NIST, NEMA/MITA, NDIA JWG, ASTM, IEEE-ISTO PWG

2.5.7 Finishing and Assembly, Welding, Grinding, Coating, Plating

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 and ISO/TC 107. However, no specific standards have been identified at this time.

Gap M8. Finishing and Assembly, Welding, Grinding, Coating, Plating. 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

Organization: ASTM, SAE, ISO

3. Next Steps

It is essential that this roadmap be widely promoted 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, a meeting with the SDO community is planned for the end of the first quarter of 2017 to discuss coordination, forward planning, and implementation of the roadmap's recommendations.

A follow-up industry conference in the second quarter of 2017 will provide further opportunity to promote the roadmap and for SDOs to recruit volunteers to help write the needed standards.

It is recognized that standardization activity will need to adapt as the ecosystem for additive manufacturing evolves due to technological innovations.

Depending upon the realities of the standards environment, the needs of stakeholders, and available resources, it is envisioned that this roadmap will be updated within a year after publication to report on the progress of its implementation and to identify emerging issues that require further discussion.

Ultimately, the aim of such an effort would be to provide a means 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

AAMI – Association for the Advancement of Medical Instrumentation

ABS – Acrylonitrile Butadiene Styrene

AM – Additive Manufacturing

AMF – Additive Manufacturing File Format

AMS – Aerospace Material Specification

AMSC – America Makes & ANSI Additive Manufacturing Standardization Collaborative

ANSI – American National Standards Institute

ASME – American Society of Mechanical Engineers

ASTM – ASTM International

AWS – American Welding Society

CAD – Computer-Aided Design

CAM – Computer-Aided Manufacturing

CBM – Condition Based Maintenance

CMH-17 – Composite Materials Handbook

CT – Computed Tomography

DED – Directed Energy Deposition

DICOM – Digital Imaging and Communications in Medicine

DoD – U.S. Department of Defense

EB – Electron Beam

FAA – Federal Aviation Administration

FDA – U.S. Food and Drug Administration

GD&T – Geometric Dimensioning and Tolerancing

HIP – Hot Isostatic Pressing

HT – Heat Treatment

IEC – International Electrotechnical Commission

IEEE – Institute for Electrical and Electronics Engineers

IEEE-ISTO PWG - IEEE Industry Standards and Technology Organization (ISTO) Printer Working Group (PWG)

IPC – IPC – the Association Connecting Electronics Industries

ISO – International Organization for Standardization

LORA – Level of Repair Analysis

MITA – Medical Imaging Technology Alliance

MMPDS – Metallic Materials Properties Development and Standardization Handbook

MPIF – Metal Powder Industries Federation

MRI – Magnetic Resonance Imaging

NACE – NACE International

NASA – National Aeronautics and Space Administration

NDE – Nondestructive Evaluation

NDI – Nondestructive Inspection

NDIA – National Defense Industrial Association

NDT – Nondestructive Testing

NEMA – National Electrical Manufacturers Association

NFPA – National Fire Protection Association

NIST – National Institute of Standards and Technology

OEMs – Original Equipment Manufacturers

PBF – Powder Bed Fusion

PBF-EB – Powder Bed Fusion – Electron Beam

PBF-L – Powder Bed Fusion – Laser

PLA – Polylactic Acid

PSDO – Partner Standards Developing Organization

Q&C – Qualification and Certification

R&D – Research and Development

Ra – Surface Roughness

RCM – Reliability Centered Maintenance

RSNA – The Radiological Society of North America

SAE – SAE International

SDO – Standards Developing Organization

SLA or STL – Stereolithography

SLS – Selective Laser Sintering

TAG – Technical Advisory Group

TDP – Technical Data Package

UL – Underwriters Laboratories, Inc.

UV – Ultraviolet

V&V – Verification and Validation

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