

MEETING SUMMARY

America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC)

Design for Additive Manufacturing (AM) Virtual Event

Wednesday, March 31, 2021, 11:00 am – 4:00 pm Eastern

This virtual event brought together subject matter experts from industry, government, and academia for a discussion that will help to lay the groundwork for further development/refinement of the AMSC [Standardization Roadmap for Additive Manufacturing](#), last published in June 2018. This included discussion of the following:

- Standards that have been published or that are in development to fill gaps identified in the roadmap
- Potential focus areas for standards development based on new technology developments and applications
- Design considerations for additive manufacturing

Presentations from the event are available as a single zip file [here \(8MB\)](#) and they are posted individually [here](#). The embedded links in the remainder of this report point directly to the individual presentations.

- View the [Final Draft Agenda](#) and [Speaker Biographies](#)

Discussion Topic and Speaker

Welcome

Jim McCabe, Senior Director, Standards Facilitation, ANSI

Jim McCabe welcomed participants, noting it was 5 years to the day since the first AMSC kickoff meeting. The AMSC has produced two version of its standards roadmap. Today's dialogue is meant to inform future work by asking what progress has been made on standards over the last few years, how have the priorities changed, what remains to be done, and what are we seeing in terms of new AM deployments.

Brandon Ribic, Ph.D., Technology Director, America Makes

Brandon Ribic offered welcoming remarks, reviewed the agenda for the day, and encouraged attendees to ask questions and to participate in the networking opportunities that the platform afforded.

Session 1: Development of Industry Standards and Guidance Documents

This session featured presentations on AM design-related work in ASTM F42/ISO TC 261, NIST, ASME, MMPDS, and CMH-17, followed by a question and answer (Q&A) period.

Moderator: Jim Williams, President, All Points Additive, and AMSC chair

Jim Williams introduced each of the speakers in turn, invited them to make their presentations, and to answer questions submitted by audience members. (**Note: throughout this report, speaker remarks are abbreviated and summarized to note key points.**)

David W. Rosen, Ph.D., Professor, George W. Woodruff School of Mechanical Engineering, Georgia Institute of Technology [Presentation Link](#)

David Rosen gave a presentation covering a number of topics: the ASTM F42.04 Design Subcommittee, AM file format, design for AM, general design requirements and guidelines including ISO/ASTM 52910, process-specific design guides (e.g., powder bed fusion (PBF) for both metals and polymers, directed energy deposition (DED), binder jetting, material extrusion), the ASTM International Additive Manufacturing Center of Excellence (AMCOE), design for post-processing, and simulation and modeling.

Relative to data/information exchange, F42.04 is responsible for the AMF – additive manufacturing format standard ISO/ASTM 52915. They are also involved in solid modeling technologies and more formal digital product definition and data management that Paul Witherell will talk about. The other chunk of activity is around design guidelines and decision support. Committee F42.04 works cooperatively with ISO/TC 261 WG4 on design for AM which has a similar portfolio. The first design standard is ISO/ASTM 52910 Standard Guidelines for Design for AM (DFAM), an umbrella document. There's also a Standard Guide for Design Decision Support ISO/ASTM 52923. Paul Witherell is working on a Standard Guide for Principles of Design Rules for AM WK54586. Then there are process specific design guides. There are 2 published in the area of PBF, one for polymers, one for metals. There's a third under development for electron beam-based metals. A guide on design for DED was published last year. In development are guides on material extrusion, post-processing for PBF metal parts, and binder jetting. Future work could involve other processes and application specific guides.

Dr. Rosen discussed ways to leverage AM's capabilities through opportunistic and restrictive design, and different design methods. He reviewed the main elements and design process found in ISO/ASTM 52910. Using the design guide for PBF, he illustrated how certain issues like support structures have been addressed. The guides also aim to show how people have taken advantage of the unique aspects of AM.

AMCOE is the research and knowledge gathering branch of ASTM headquartered at Auburn University. Elements of the research program align well with the F42 work programme. Projects have to be related to standardization. The guide for post-processing for designers focused on PBF is funded by AMCOE. The guide addresses a gap identified in the AMSC roadmap.

The last topic Dr. Rosen covered was AM process simulation. Vendors are working on this. Users are wondering are there standards for software validation and how can the software be used for process and part qualification. These are potential topics for investigation with respect to standards.

Q&A

Who are the intended users for the data package standards?

Industry. People who are developing new products. It becomes relevant when you want to transfer the design information to the manufacturer, e.g., within an OEM or between an OEM and a supplier.

Are there process specific design guides/standards which provide information outlining interrelationships between component geometry and orientation on product surface finish?

Yes. We provide general levels of what surface finish can be achieved but don't go into specific materials and machines.

Do any of the mentioned design guides or standards address design factors for improvement in AM process productivity/throughput?

These are part design standards, not process standards. We talk a bit about some aspects.

How does 52910 address buildability (preventing build failure)? Does it provide factors which can be leveraged to mitigate distortion?

Build failure is mentioned, not sure about distortion. We talk about limitations of the process and process characteristics without going into too much detail.

What guidance exists for design of AM products for coating operations?

None.

How does one get involved in such design guides for the less common AM processes?

We depend on volunteers to lead work items and to participate on committees, or to informally provide input. We have some processes we haven't yet gotten into.

How are the guidelines provided in these efforts differentiated or more value added than some of the openly available information - for example - <https://www.3dhubs.com/knowledge-base/design-guidelines/>

Other service bureaus have design guides that are pretty basic. We try to be more comprehensive in terms of coverage and specific processes including design opportunities.

Do you think our technical data packages should be able to accommodate multiple states of the part aggregated through CAM packages to include advanced machining techniques (AFM for example)

The first part of that, yes. There are elements of data packages for each step of the workflow. Not sure we'll get into AFMs.

Paul Witherell, Ph.D., Mechanical Engineer, National Institute of Standards and Technology [Presentation Link](#)

Paul Witherell gave a presentation on ASTM F42/ISO TC 261 JG 73 work on design for data packages and NIST work on a common data dictionary (CDD) for AM data.

Dr. Witherell went through the table of contents for the data packages for AM parts standard PWI 52923. The standard looks at the uniqueness of AM, the facility and machine requirements, material data, security, and configuration management. We do not want to duplicate what already has been published.

Dr. Witherell discussed the activity model set forth in the standard. The AM workflow goes from design to testing of the part, establishing the digital thread/pedigree. The data package educates the user of the standard on what types of information they might find at different activities. The data package is meant to be configurable by use case and by organization. Sometimes we use AM for prototyping vs. full-fledged production. You might have different requirements for each. You also might have different levels of process/part maturity and the standard aspires is to accommodate that. The data package is also meant to be configurable by criticality/capability.

Part security and cybersecurity considerations are now being developed, along with configuration management. This includes the type of file format. There are lots of ways to accomplish the same goal. The idea is introduced that, when you're developing data packages, here's how you might find the information provided and the consequences of providing the information a certain way.

The draft standard is about 45 pages right now. Terms are not yet defined. Vetting needs to take place. We're hoping to get it done and out for ballot in the next month. Next steps include completing the work on configuration management and other aspects noted on the slide. There's a lot of interest from the U.S. DOD side. The data package is an identified gap in the AMSC roadmap.

Having more structured data for data sharing/data formats is also an AMSC gap. NIST has established an ad hoc working group (WG) for a common data dictionary for AM data. The work is led by Yan Lu at NIST. The objective is to provide a common set of concepts, data elements in AM domain which define the basis of AM data collection, integration, management and exchange. The CDD is synthesizing various efforts. The audience is AM product users, service providers, machine vendors, et al. The WG is making use of the NIST AM Material Database. They are moving toward a model hierarchy and to improve machine readability. The focus is on PBF and standards development. A draft document has gone out for ballot within ASTM and feedback is being integrated.

A NIST workshop in October focused on making AM data findable, accessible, interoperable, and reusable (FAIR). This led to the creation of an ASTM subcommittee F42.08 on data. The workshop included discussions on new opportunities for how we manage and share AM data.

Q&A

What about data & process models for additive manufacturing for tooling?

For tooling, it may be application specific but process agnostic. It could be implementation or process dependent.

What is the timeline for completion of this standard?

We're hoping to go to ballot on the data package standard by summer. The basic concepts are there.

**Are there specific products or applications in which data management is a regulatory or legal requirement?
What are the benefits to these approaches for those applications?**

Yes and No. This is an ongoing discussion. Different agencies are looking at different requirements and AM considerations. In terms of the benefits, the more requirements vary, the harder it is to navigate. A standard can provide basic guidelines that are universally recognized.

Are these documents going to discuss which elements of the data packages / data flow need to be configuration-controlled in the context of Q&C?

Yes and no. Criticality of risk can be looked at. Risk depends on the user and application scenario. Identifying risk depends on the portfolio being deployed and how the users want to implement it.

Are you working closely & collaboratively with the America Makes/ANSI Standards activities?

We hope so. We keep them aware of what we're doing. On the CDD more so than the technical data package (TDP). We're very aware of what folks in DOD are doing without necessarily engaging them on day to day activities. For the CDD, we're very much engaging America Makes who recently wanted to leverage the CDD. We're also monitoring the AMSC gaps.

George Rawls, P.E., Senior Fellow Engineer, Savannah River National Laboratory (SRNL) [Presentation Link](#)

George Rawls gave a presentation on ASME's criteria for powder bed fusion AM. ASME is looking at ways to use AM for its codes and standards, especially in the application specific context of pressure equipment. Today, the industry uses forging and welding. There will continue to be a need for subtractive manufacturing for various aspects, but AM will be complementing conventional methods. AM is finding a niche in the nuclear arena. Fatigue properties and corrosive environments are a concern.

ASME is looking at both PBF and DED. It started with PBF as that was where the interest was among committee members. DED may be easier to get codified than PBF. Work has started on DED criteria using electron-beam (EB) for things like pressure vessel heads. Some PBF applications include: valves, compact heat exchangers, compact boilers for field sterilizers, replacing small castings for instrument valves, etc.

A criteria document, not a standard, is being developed. It will be used across pressure technology standards (pressure vessel components, piping, flanges, valves) to provide a common methodology and set of requirements. The work is taking place in a joint committee of the board on pressure technology and the board on nuclear codes and standards. Mr. Rawls highlighted areas covered by the document.

The scope of the document is PBF using both laser and EB technology. Hybrid technology is being looked at. There is a current set of design rules. Key concerns include safety, structural integrity, and quality control. The issue is how to integrate AM into an ASME process that has been used for years to produce pressure equipment. The committee has stayed away from time-dependent property regimes. It has not found data to justify the use of AM at high temperatures. Some of the data may be proprietary. Material toughness is one of the big challenges. Another issue is whether there is a need to increase fracture toughness testing for AM.

In terms of design in general, the committee has stayed away from design for AM (e.g., how do you optimize a component to be printed). That is seen as the purview of the AM manufacturer. The committee wants to focus on what is needed for structural integrity of the part, looking at things like the effect on stress from supports. That is specific to AM (i.e., removal of internal supports). Other concerns include: fatigue critical processes, surface finish, and cosmetic material. Most AM will be complex and will not fit established geometries. Any AM part should have a stress analysis.

In terms of an AM procedure, the committee wants to have 95% confidence that 99% of the material is in accordance with an ASME material specification. They identify limiting material locations. These are places where they want to do fracture toughness testing.

The end result of the work will be a pressure technology book (a general reference for other ASME codes and standards). ASME has initiated a notification with ANSI that it will be developing a standard. It will contain codifiable rules for AM for pressure codes and nuclear codes.

ASME section V deals with nondestructive testing. A new article will cover CT scanning for the 2021 edition for AM parts. On a related note, SRNL has started a collaborative project with the University of Michigan to evaluate fatigue criteria for AM pressure vessel equipment. It was a project that started at Battelle. Fatigue data is needed.

Q&A

How are allowables determined? Statistical analysis of data? How much data is required?

Allowable stresses? Those are always a factor on the yield stress, tensile stress. We look at a combination of those to come up with an allowable stress. We also look at the degree of inspections.

Any indication as to when this criteria document will be available to the public?

Hopefully, later this year. By June. We are going through the last round of peer review comments.

@ George, do you envision these criteria to be applicable to a specific industry ? (example, industrial Vs aerospace Vs automotive).

Pressure equipment industry (boilers and pressure vessels), petrochemical, nuclear, pharmaceutical

Darrell Wallace, Ph.D., Deputy Director and Chief Technology Officer, SecureAmerica Institute, Texas A&M University [Presentation Link](#)

Darrell Wallace gave a presentation on the ASME standard on product definition for AM (Y14.46). The standard is intended to address the unique product definition capabilities associated with AM. These are not covered by the Y14.5 product definition standard, as AM fundamentally changes what can be made. It is a new, rapidly evolving standard that has taken 5 years to reach its current state due to the rapid pace of AM technology development.

The voting membership of the committee developing the standard is diverse and highly respected, with expertise in standards development and AM. People are encouraged to get involved if they have interest.

The origins of the standard go back to 2012. Dr. Wallace previously worked at America Makes and reached out to ASME about the limitations of Y14.5 relative to AM. For example, AM has internal features that might not be accessible and would not be easily addressed by the other standard. AM has the ability to create one assembly (manufactured as a single component). AM is also simultaneous material production and geometry production. It includes a lot of process dependent properties that can be controlled.

In crafting the standard, ASME looked at the 7 ISO/ASTM AM processes. Traditionally, product definition standards don't go into the material and process. It is left to the manufacturer to figure out the process that will achieve the end result. With AM, by changing the parameters, you can vary microstructure, anisotropy, etc.

Wherever the Y14.5 standard works, it will be used. Other standards are looked at for different aspects. They've identified some of the features that need to be addressed to include: multiple coordinate systems, supplemental geometries, build direction and gravity, theoretical supplemental surfaces (TSS), bounded volumes, transition regions and gradients, repeating structures (lattices and infills), integrated assemblies, and process parameters.

In terms of the current status of the project, the 2017 version of the document is a draft standard for trial use. It is the first one published by ASME under this procedure. It is a mechanism to accelerate the development time, to get the standard out into the community for feedback. Revisions have been made as a result and the next version is now under formatting review. It will go back to the full committee for balloting and the hope is that it will be released very soon.

Q&A

At some point do you think standards should be developed to declare requirements for in-process inspection, i.e. During the build without requiring post-manufacture inspection? How might that look?

There are ongoing discussions about the inspectability of things. Whether it fits into the product definition standard, I don't know, but somehow it will have to be addressed.

Very good activity. Where to find the current version of document?

From whatever source you get your ASME standards.

Has DoD been a part of the development? Will they adopt this standard?

Defense folks has been involved, including NAVAIR. The expectation is that they will adopt the standard.

Doug Hall, MMPDS Program Manager, Sr. Mechanical Engineer, Battelle Memorial Institute [Presentation Link](#)

Doug Hall gave a presentation describing MMPDS and activity on additive metals. The history of the Metallic Materials Properties Development and Standardization (MMPDS) handbook goes back to the 1930s. The FAA took it over in 2003 and renamed it MMPDS. MMPDS 15 is the current version and over a dozen licensees around the world distribute it. The group meets twice a year to approve statistical analyses and guidelines. The 37th meeting was just completed last week.

The current handbook contains more than 600 A and B basis properties which are accepted by government agencies, regulators, and certifiers around the world for the design of airframes and other aerospace products. There are also 1000 S basis properties covering 400 unique metal specifications. Each year, depending on the developments in industry, 2-5 new alloys are added. For more information, visit the MMPDS webpage.

The general coordination committee is composed of government and industry representatives. The current government sponsors are the FAA, the U.S. Air Force, U.S. Navy, NASA, and DOD DLA. More than 40 companies are members of the industry steering group. There are task groups (TG) responsible for various aspects of the project. An emerging technology TG will review and approve new content for the handbook, based on guidelines approved by the guidelines TG. Steering groups (SG) and working groups (WG) fill out the structure. The V2WG is focused on emerging technology and additive manufacturing.

MMPDS is recognized around the world as the gold standard for metal allowables for aerospace design. It is not hard to get into the handbook. You must have a public specification of interest to at least two aerospace companies. Data must be submitted and analyzed to see if it meets the handbook requirements. Mr. Hall went through the balance of the process of reviewing submissions for creating new entries in the handbook.

There was a meeting last week. Two definitions got approved: material allowable and design value. Minimum data requirements for volume II were also approved. These include: sample size, number of heats, and number of manufacturing lots. For AM, they have added the number of machines and the number of build cycles. There are both mandatory properties and strongly recommended properties. C and D basis allowables for metal AM are being introduced for volume II and will require "further showing" compared to A and B basis allowables for conventional alloys in volume I.

The current status is that volume II is under development. As new data is submitted, new or revised guidelines will likely be written. Several critical items were completed at last week's meeting including definitions. There are minimum content requirements for a public specification and data submission requirements. Data analysis methods from volume I will be used for the time being while volume II is being developed.

The group works closely with a number of standards developing organizations (SDOs) and others, including ASTM (test specifications), the National Institute for Aviation Research (NIAR) which serves as secretariat for CMH-17, NIST, and SAE (acceptable lot release values).

Q&A

Is there a standard for the process parameters required for manufacturing the samples?

The specification requirements section of the handbook talks about control of the material, feedstock, and process. The test standards talk about required geometry for making those specimens. The handbook will talk about where you can cut those specimens from to generate bulk allowables.

Machines referring to different types/models/OEM?

The specification requirements section is machine agnostic. We only require that the machine that is used is capable of replicating the process defined in the specification. This will include controls on thermal processing and lot release values.

How does your standard address material toughness?

There's a long list of recommended properties including fracture toughness, crack growth, fatigue for load control, fatigue for strain control, etc. but that is not a mandatory property from FAA and DOD's perspective.

Can you elaborate more on the specifics of the "number of machines" requirement? Does it require machines from multiple OEMs or is multiples of the same make/model acceptable?

It is machine agnostic so you can use different models if they can make the same material.

Curtis Davies, Senior Research Engineer, Federal Aviation Administration [Presentation Link](#)

Curtis Davies gave a presentation on the Composite Materials Handbook (CMH-17) work, specifically in relation to additive manufacturing. CMH-17's mission is to provide reliable engineering information and standards to develop technical guidance to support the development and use of advanced materials. Its vision is to be a worldwide focal point for technical information on these advanced materials.

In terms of objectives, CMH-17 provides information and guidance necessary to design, fabricate, and support products made from advanced materials. This includes standardizing engineering methodologies. The handbook provides material property data in a manner similar to MMPDS. The technology and materials being developed are fast moving. The handbook endeavors to keep pace so that it reflects the current state of the art.

Mr. Davies reviewed the handbook's history. It began as "ANC Bulletin 17 Plastics for Aircraft" in 1943. In the '80s and '90s, it looked at reinforced plastics and expanded into metal matrix composites and ceramic matrix composites. In 2005, DOD transitioned the stewardship of the handbook to the FAA and the name was changed to Composite Materials Handbook. In 2018, an additive manufacturing coordination group was created. It intends to put together a volume specific to non-metallic AM materials.

In terms of goals, there are three areas of focus. The first is to provide specific material data (physical and mechanical properties that are tied to a material specification and a process specification) to assure that they can be reproduced. The second is to generate information on the processing of material to develop this data (looking at the material and process control, test matrices that are required, and statistical methods). It is very similar to what Doug Hall described. The third area is a little different from the metallics side. CMH-17 has developed a lot of information on how to use the materials through design guides (proven methodologies for coupon level data and how you substantiate up to full scale), best practices, and sustainment efforts. It also looks at the manufacturing side. All this provides a baseline for what to do with respect to AM.

Regarding the development cycle for handbook content, Mr. Davies noted that CMH-17 has recently formed an industry advisory group that will provide input. Most of the writing is done by volunteers in coordination meetings, working groups, and teleconferences. Comments are then reviewed, and approved content moves toward publication. After publication, the focus turns to education within CMH-17 and other conferences, and

the creation of additional training tutorials. There's no existing content for the AM handbook at this point. However, periodic review to review, reaffirm, or revise the content as necessary is part of the development cycle.

CMH-17 is divided into technical subject areas: data review, design and analysis, materials and processes, testing, and statistics. A major focus of the handbook is "how you do it," looking at all the standards, specifications, and data to make a product. The two major WGs that deal with the goal 3 guidance side are the design and analysis WG, which looks at design requirements and methodologies that can be applied, and the materials and processes WG, which addresses how you make things and quality control issues. Goals 1 and 2 are mostly addressed by the testing WG which identifies appropriate test methods and analyzes the suitability and limitations of those methods. The statistics WG does a lot of the same statistics that Doug Hall described, using methodology applied from the polymer matrix volumes which will be adjusted for AM materials as needed. The data review WG serves as a "sanity check" that provides final review. For more information or to get involved, contact info@cmh-17.org at NIAR.

You mentioned that CMH-17 is working on guidelines for design and analysis of parts made with polymer-based AM, both independent of and unique to specific processes. How do these efforts align with . . .

Looks like the question got cut off. CMH-17's intent is to keep the guidelines high level, looking at polymer and other non-metallic based materials.

Session 2: End User Perspectives on Design for AM Considerations

This session was a panel discussion featuring industry and government representatives from the aerospace, defense, and medical sectors.

Moderator: Lauralyn McDaniel, Industry Events Manager, ASME, AMSC vice chair

Lauralyn McDaniel introduced each of the speakers in turn, invited them to make opening remarks, and to answer prepared questions as well as those submitted by audience members. **(Note: throughout this report, speaker remarks are abbreviated and summarized to note key points.)**

Opening Remarks

Opening remarks were invited on considerations when designing for AM and priorities.

Jesse Boyer, Fellow, Additive Manufacturing, Pratt & Whitney

Uses cases include: part repair substitution, after market AM, part unitization, and optimized design. Manufacturing and engineering design aides include reduction in non-recurring engineering (NRE) for development parts and accelerating design. Each use case is enabled by different tools and unique requirements related to that design, whether it's cost reduction, performance improvements, or enabling capabilities. Our priorities are metals in propulsion applications. We focus more on unitization and optimized design than part substitution and repair. Sustainment is very important to us, especially with legacy engines. Other areas of importance include: material properties, understanding integration of design standards and design tools with legacy tools. When designing a part, we ask: Is it right to use additive for the job? Does it provide reduction in cost, NRE, lead time? Does it enable performance or capability? And, finally, what are the material properties?

Steven Floyd, Space Additive Manufacturing Engineering Lead, Northrop Grumman

We look at the applications and finding the right fit. Where is there increased complexity? Where is there a good business case in terms of a cost opportunity? We look more at the applications than the capabilities. The benefits of complexity with AM ties in with the applications and the tools in terms of defining the priorities. We're starting more in subsystem parts and things that are less critical in nature. Key things include understanding that each of the additive processes is different, and learning the nuances for doing really detailed design of a specific material and process. That's where standards come in.

John Schmelzle, P.E., NAWC Lakehurst Additive Manufacturing and Model Based Definition Initiative Lead, Support Equipment Dept., Naval Air Warfare Center Aircraft Division Lakehurst, NAVAIR

We wrote a DFAM standard work package. Considerations include: weight saving and topology optimization. Another is being able to replace parts with existing parts (we have a part shortage). You would think that AM would help but there are a lot of constraints. You can't change the stiffness of a part because you could change the load structure down the path. You can't change the natural frequency, the interface. You can't add weight. It's a real challenge. Surface texture is another big challenge in DFAM, and how that plays to fatigue. Is there a metric for a surface that correlates to fatigue? We used to use RA which had a good correlation to fatigue for a specific machining operation. But that doesn't work very well for additive. Other things that are priorities for NAVAIR as an acquisition organization include how do we buy parts and part classification. We have this at NAVAIR and have found that other service branches and prime manufacturers are going the same way. While some do it by risk, we classify AM parts by consequence of failure. The classification affects how that part is handled throughout the acquisition cycle, how we would prepare a TDP, how we qualify vendors for these classes of parts. We are pushing for a common DOD solution for an AM TDP. Standards are a big priority and we are involved in a number of standards organizations. Guidelines are good but from an acquisition standpoint, we'd like to procure to standards. Part certification is another area. Integrated Computational Materials Engineering (ICME) may be an approach. Maybe a standard on how you can look at ICME data to qualify a part.

Douglas N. Wells, NESC Deputy Technical Fellow for Materials, Damage Tolerance Assessment Branch, NASA MSFC

NASA is a certifying agency that purchases technology or capability (e.g., launch capability) so we have a responsibility to certify that those vehicles are meeting our requirements. AM has rapidly become a major part of that effort. We look at it from the perspective of our role as a government certifying agency but also from the perspective of the designer. What do our designers need to be able to do to properly integrate AM parts into our systems and do it in a reliable fashion? One of the big challenges that comes up is the large amount of integration and planning relative to AM parts, particularly as the technology is evolving and there aren't necessarily firmly held design practices for additive yet. A certified design includes the designer doing original CAD work, stress analysis, fracture analysis, and engineering planning that might go into inspection to demonstrate the reliability of the part. You need to have integration across the entire design team: from those who understand processes and what machines are capable of, to those who are developing part geometries and understanding how they can innovatively use additive in their part designs, to nondestructive evaluation teams figuring out how to verify the quality of the part. It's that integration that we find very important from a design perspective and to be successful. We've been working on standardization both within the agency and across SDOs and AMSC.

Ryan O'Hara, Ph.D., Technical Director for Aerospace and Defense, nTopology

nTopology is a new geometry company. We can create fancy designs that lend themselves to AM. We enable designers to design the next generation of parts. That uses all types of manufacturing—it is not limited to additive. Design tools are kind of unrestricted. The designer has to know the downstream processes, maybe the certifications, regulations that go with that. Everyone would like a magical DFAM button but at the end of the day it's about education. Oftentimes, we are educating customers on what's possible and what's practical. On the software side, there's things that we can do to enable and inform things like overhang angles and areas that have geometric complexity that might be difficult to fabricate. Ultimately, it's up to the designer and manufacturer to know their processes. We're all working to get these leading-edge products into the market, safely and effectively.

Laura Gilmour, Senior Healthcare Development Manager, EOS North America

My background is in medical devices and using the technology for orthopedic implants. EOS uses powder bed technology. Historically, design in the medical world has been about porous structures. Design enabling technologies like nTopology's have made what was an arduous process much easier and more accessible. As others have mentioned, you need to think about what you're designing and how you're going to get to your final product. So, for example, you may have powder in really small structures. How do you get it out so that it may be cleaned, sterilized, and appropriate for the patient population? We've pushed the boundaries in some

areas with some supportless design so that you don't have to do as much post-processing. COVID has provided new experience with needing things in a digital format, where you could be using both conventional subtractive technologies as well as additive for emergency situations and local environments.

James Coburn, CDR, USPHS, Senior Advisor for Emerging Technologies, Food and Drug Administration

As a regulator, FDA has a slightly different perspective. We are very interested in the integration of design and production capabilities. In other words, how do you show that you can make the thing that you're designing within the limits of your production capabilities and build that into your design workflow. This is especially so when you have patient-specific or personalized medical devices where you need to demonstrate that you can make something to a reasonable, high-risk ratio. You also need to consider what are the effects on the final product. With small parts and lattice structures, all post-processing steps must be incorporated into the design. You can design anything, but can you make it? This is a little different from conventional manufacturing where there's more experience with the design and production limits. FDA priorities include education on integration and how regulations apply. Others include: optimized topology, lattice structures, patient matching, and the validation of all of those. In terms of COVID, what has come up is near point of care or at point of care (distributed) manufacturing. So, for example, where you're making something at a hospital instead of at a good manufacturing practice (GMP) facility where you normally do your AM production. FDA is working on this internally and talking to industry about it.

Michael Gorelik, Ph.D., Chief Scientist, Fatigue and Damage Tolerance, FAA

My technical expertise is in fatigue and damage tolerance. Particularly, looking at metal AM for higher criticality applications. Historically, for introduction of almost any new structural material system, fatigue, damage tolerance, and certification requirements typically are significant challenge areas. This consideration is not limited to just additive. John mentioned some of the AM-specific challenges. FAA's primary focus is on the safety and certification of aviation products. We're not producing, purchasing, or maintaining AM parts. For any material system, not just additive, designing a new part is solving an engineering problem of optimization with constraints. All companies want to produce parts that are safe and reliable, but not excessively expensive, overly heavy, etc. This is where the concept of optimization with constraints comes into play. Due to the inherent manufacturing capabilities, AM significantly opens up the degrees of freedom in the notional design space. The concepts are similar but the considerations and implementation may be more challenging. Even with some of the older implementation strategies and designs for conventional materials, people don't always properly consider the elements of a constraint system. This includes design for manufacturability and design for maintainability, in addition to the primary design objectives of meeting the primary application requirements. These considerations are equally important for AM.

Moderated Discussion

How have the needs for design changed in the last couple of years? What priorities have changed?

(Laura) From the medical space perspective, two changes are point of care printing and solving very specific patient needs. There was a recent press release that the Hospital for Special Surgery is doing printing in the hospital partnering with an Italian medical device company. This is a very different environment where design is happening "as you go." This is a big change from ten years ago in terms of the need for education, software, standards, etc. You want to make sure you are giving the same quality of care as if you were printing in a facility with GMP.

(Steven) From the aerospace perspective, usage. A few years ago, AM wasn't as well known. Now lots of people are excited about it and want to use it. Standards are still being developed. The more people figure out how to use additive, the more it will help to drive the standards development. Another area of change is with tools. Software is making it easier to do complex structures like lattices and integrate those into products. People are pushing the boundaries of what you can do with additive and the tools are catching up.

(Ryan) A lot of innovation is happening where people want to push the bounds of design and add complexity. We need to be mindful of performance, the business value. It's exciting to see. However, a lot of small companies seem to be risk averse to innovation. Do you want to be bold in design, and have a competitive

advantage? If so, we're excited to work with you. If not, maybe stay with the tools you use today. It's about balancing R&D and technology readiness level (TRL), working with the government on technology demonstrators, balancing those needs and requirements.

Why do you think the needs are changing?

(Jesse) A lot of us are moving away from the hype that everything can be done with AM. We kind of know what we can do with AM. Most of us have a few parts under our belt. But we're not quite where we aspire to be with AM. So, getting out of that comfort zone, looking at the next innovative design. We're still trying to do what we need to do to satisfy FAA, et al. and really get that production goal, that cost reduction in place right now. We need to continue to advance our design standards and fill gaps. In addition, the maturity of the tools has advanced significantly. We're getting a more integrated workflow. We're moving beyond the initial crawl/walk phase and learning to walk/run.

(Steven) There's been a natural evolution of AM as the needs and tools become better understood, as people are trying to innovate and push the limits of what's possible. There's a business motivating factor. There's also better collaboration in some regards in terms of understanding among users and developers of the tools, the machines, and the parts that come out.

(Laura) People are getting more comfortable with the technology, wanting to go beyond the prototyping phase. Also, being in different locations, the point of care location, whether in an orthopaedic hospital or with orthoses and prostheses. Those locations are going to have different needs and boundaries.

Why are design standards important?

(Jesse) Design standards are not just geometric; they are integral to material data. We need standards to address that. We need consistent standards on how we assess material properties and how it affects overall design. Standards also help us to build confidence not just with FAA et al. but with our internal customer. Standards are a yardstick to help us measure commercial offerings. We've talked about changing paradigms. Standards help us communicate consistently and educate better when we have a good standard to follow.

(John) When we first started, we talked about the goals that we wanted to achieve. In a procurement package we want to be able to buy/make a critical safety part and put it on an aircraft. Without standards, we're not going to be able to do that. We need standards to control feedstock. We need new standards for nondestructive inspection (NDI). We talked about communicating the design to the manufacturer—Darrell talked about Y14.46. Again, we're an acquisition organization. We talked about part criticality as a standard to qualify vendors. NAVAIR has its standard but we're now developing an ASTM standard that just started last month to lay out different criticalities of parts.

(Doug) Design standards are important in AM because there is no common practice that has evolved and stabilized so to speak. Each entity – engineering organization, company, or even groups within companies – has a little different way of approaching the design process in AM, from the conceptual to what it takes to create a reliable part. Without some form of a standard, or common playbook, things get complicated. You end up with lots of variations in design approaches and methodologies. There's a lot of work to do to reinvent that wheel. From evaluating material properties to qualifying a machine. You may get lots of different answers. Having a common design and construction standard set is important to make things efficient, so we don't have to reinvent the wheel every time we're evaluating a design or working with a different organization. At the same time, there will always be differences and innovations that are happening very quickly. That keeps the design space ahead of this common practice. That's good but it's a two-edged sword and it makes those who are looking at it from a regulatory or certification point of view scratch our heads just a bit.

How does your organization use design standards?

(John) As I said, we use them in our acquisition process. We call standards out on drawings, we qualify vendors to standards, we communicate our design to standards. It's "all of the above."

(Doug) NASA is a certifying agency, so when we set up a program like Artemis to go to the moon, we're going to define what those design standards are and how to apply them to the project. Having a set of requirements gives us the guardrails by which to measure those who are creating designs for us and determine whether or not they are adequate. We're also asked to perform technical insights where we sit with AM teams that are developing parts to understand how they are doing it, what is their design process. Standards give us a framework to hold those conversations. It's really difficult to maintain consistency across a large program if each different entity is working to a slightly different approach and methodology for their AM program. Having some form of a common playbook is very helpful and important in terms of consistency and getting the reliability of the certification process well anchored.

(Michael) Design standards represent an important element of the overall ecosystem of AM. The better the key elements of the system are defined, you'd expect that the final product will be more robust, better quality, more reliable, safer, and so on. Over the past few years, FAA has been transitioning toward performance-based regulations. This essentially means that, instead of emphasizing the "how to" part of the regulations, we primarily define the key safety objectives. This gives companies a significant level of flexibility in developing the methods of compliance and how to achieve those safety objectives. This actually puts more emphasis on the public domain and consensus-based standards and specifications. So, companies either can develop standards and specs internally and treat them as proprietary documents, or use the public domain standards and specs. We see a lot of positive developments, with multiple SDOs filling the space with new standards and specifications. So, the plan going forward for FAA is to produce more high-level, performance-based regulations, but to also rely more heavily on the public domain standards, not just specific to design considerations but in the broader context as well.

(James) FDA also has broad use of standards. We design for performance a little more closely with additive than in the past. With things like patient matching, topology optimization, even with devices designed to work with a general category of size or shape of person. You have the performance criteria in there. Those kinds of standards are very important when we review these devices because we're not the spec developer. We look at what you've developed and assess the safety, risk, and performance of that. As others have said, if everyone is making their own, it's very hard for our reviewers, whereas if there's a standard it's much easier to do those reviews. There is a gap in the AMSC report on standards for cleaning medical devices. That is a huge issue that is not just specific to AM though there are specific AM design points which have to go into that. Terminology is also important. We often see people using a term we are not familiar with in a submission. It leads to questions and delays. Having terminology datasets and dictionaries is very useful and critical.

(Ryan) We see a lot of parts where it's hybrid, where one piece is additive but otherwise it's a traditional part. People struggle with hybrid. How do we fit in to these traditional processes and standards when there's overlap?

How are design considerations for additive different from other conventional technologies? What are the unique quality considerations for additive, particularly those that result from introducing progressively more complex designs?

(Laura) We talk about quality quite a lot in the medical world. There's a lot of unique things about the quality side of additive. The idea of building your material at the same time that you're making a part is a piece of that. At EOS, we help customers bring additive into their quality system. We often find that organizations using additive technology may pigeon-hole themselves into thinking only about the one device that they may have in the market. Instead, they should think of their quality system as a company-wide topic, and where they may apply AM in the future. This includes how you can smartly create boundaries and do the testing needed to meet FDA requirements, while coming up with the next device or design. This can help with adoption. As designs become more complex and patient-specific – where it's not the same thing being repeated – these types of considerations are going to change some. How you qualify your machine and your operational system will be important.

(Jesse) In terms of how considerations are different, it's really how do we leverage what's out there already or modify it, adding new AM standards where needed. That's the first cautionary tale—don't disregard what we've done before. The one thing that's pretty unique with AM is that it's not just the manufacturing process, the part design, or the material properties—it's all three of those together. So, that makes it a little more challenging. The other thing is that current design tools are based on traditional manufacturing. How do we break some of those paradigms? That makes it tough to be competitive. We need better guidelines on part selection and application differentiation for AM. In terms of unique QC considerations, the biggest one's inspection. Parts are getting more complex—that's the uniqueness of AM. We're trying to verify material properties in situ or post. It has to be cost competitive. Also, AM is digital. It's one of the first all-digital processes. We have high expectations that we can move quickly, being able to adapt. Those are great things about AM but it's a double-edged sword. It took us quite a bit of time to get comfortable with castings, forgings, and things like that. We're trying to do that in a tenth of the time that it took us with conventional processes. It's still new and still something we need to investigate thoroughly to get to the point where we need to be.

(James) In terms of design considerations, we're seeing more design complexity. The question arises, Do you need to use AM or should you? Also, for hybrid parts, which part do you manufacture additively or not, how do you combine parts, etc. For QC, as Jesse said, it's inspection and validation. It's more complex, more difficult. Those are the major considerations we have, especially when you are manufacturing at the point of care or a remote location. How do you take that big process that you have in your factory and push it somewhere else? How does that happen?

(Doug) In terms of uniqueness, from a design perspective, AM is a process sensitive endeavor. You have to respect the process, understand its failure modes, and understand what types of things are variable in the process. By the same token, we've been putting process-sensitive manufacturing methods into service for a long time. One aspect that is unique that was brought up is the pace at which the technology has been integrated. The criticality, use cases, and complexity have grown so quickly. It's an interesting balance between that race of implementation and our ability to keep up with things such as quality controls, and understanding whether or not we have processes fully checked and that type of thing. From that perspective, I have a feeling that the next big enabler in additive will be reliable and proven forms of in situ monitoring. So that you can have a complex part that's not inspectable post-build and bring it out of the machine and have a certain defined level of confidence in it. If you cross that bridge, you've opened another gate. But that's a large quality control hill to climb. It's one that we're very interested in and have been paying a lot of attention to. It's not necessarily clear how we get out of that forest quite yet.

(Jesse) When we look at defects that we're trying to find, from an AM perspective, it should be parts-based. What does the part require from a defects analysis? A lot of times we get focused on what defect the process can produce. We need to leverage what we know and what we've done before, making sure that we align our inspection processes with what the requirements are of the part. We need that level of sensitivity when we're developing the process. But when we look at implementation/production, we need to look at the minimum or maximum flaw size of the part and make sure that's what we keep in mind.

(Ryan) From a design standpoint, a lot of people are afraid to just build and test. They get hung up on, "What if I have a critical flaw?" In that case, build the part, do the testing, and find out where it is failing. Then, do what you would do in a normal process—workaround those areas of high stress. Or, understand the process of why you are getting poorer material or high porosity. The standards are just processes, so that you understand the risks and make quality parts. On the customer side, they have to be willing to engage in those activities.

(Michael) With regard to the design aspects, at a high level, AM is not that different from other manufacturing and material technologies. But at the application-specific level, that's where some of the unique AM attributes need to be dialed in, whether it's high process sensitivity or the ability to produce much more complex geometric shapes and so on. What is unique about AM in terms of moving toward more complex designs and structures? When we're talking about these increased levels of complexity, it's useful to consider a couple of use cases. One is very fancy and complex, topologically-optimized parts. For example, taking a basic, monolithic

bracket and turning it into a fancy, highly complex geometric shape. The other part of it is that a lot of companies driven by pragmatic business considerations are moving toward a very significant level of parts consolidation. So, what was several parts is now one contiguous part. In terms of the qualification/certification considerations, AM is a highly process sensitive, process intensive technology. So, producing parts of high complexity may increase the likelihood of having to deal with location specific properties, perhaps with a higher degree of local anisotropy, perhaps with different populations of local material defects such as porosity. The other aspect is inspectability. It is more challenging for complex geometric shapes, whether they are produced using AM or other technologies. For high criticality, fatigue critical parts, we need to account for fatigue sensitivity (e.g., increase in stress hotspots, stress concentration features), damage tolerance assessment, etc. It's taking the existing regulatory and design concepts and tailoring them toward the unique and specific aspects of additive technology. It's a bit of a balancing act.

@John - Why does the failure consequence of an AM part require a different classification scheme than that used for the same failure consequence of a conventionally manufactured part?

(John) We always want to get AM to fit into our existing processes as much as possible. Our lowest class part is ten thousand dollars' worth of damage. AM is different because it gives us the capability to manufacture on-site—especially polymer parts—with very little expertise required. The Navy is deploying 3D printers to our carriers/ships. We have a long supply chain in terms of getting parts to our sailors. AM gives a remarkable capability where sailors can make these parts themselves. We need to be able to tell them what they can make without doing too much damage and ten thousand dollars just doesn't cut it. So, we really need classes of parts so we can say that they can do these things. Or, if they want to do things that have a greater consequence of failure, then we need to control that process better. Other services have moved toward this along with some of our primes. We're looking at putting together an international standard on this in the ASTM F42 aviation subcommittee.

Do the panelists see a need to modify how we teach design for AM to incorporate considerations for validation, certification, regulatory? Years ago, many organizations noted the importance of AM designer training. How has that progressed and how can those lessons learned benefit standards development?

(Jesse) On the question of training, it was important to do that to change the paradigm of how we design parts. Maybe we started too early on that, because we didn't quite know all the stuff about validation, certification, regulatory requirements. And they definitely affect how we design parts. Someone mentioned buildability. We had a lot of cool, innovative designs but they might have diluted our focus in the beginning a little bit because they were kind of difficult to build. We spent a lot of time trying to make those buildable where we probably could have focused on some of the ones that had larger impact. So, we have modified our training. The curriculum is different. A lot of it now is about part selection and application, a lot more than just using generative design and things like that. The tools have driven that as well. You look at orientation of what is buildable. The design training was good years ago. It wasn't wasted but we're a little bit smarter about it now.

(James) Regulatory is important for other aspects but not essential to the design process. Another question asks, Do you need a traditional manufacturing or design degree in order to do design for additive? Personally, I think it may be better not to have one in some ways so you don't have habits to break on things like machining. It's helpful to have both sets of skills. But having to reconcile two ideas at once might be why it took us a while to get from the idea of unlimited design freedom to the implementation of applicable and appropriate design freedom.

(Lauralyn) Just to note, there are other organizations, including ASME, that offer training on design for additive. ASME's is specific to metals. There are courses to get you started. Though it probably doesn't cover everything, they're a great place to start.

(Jesse) I don't disagree with James. It's good to have some insight into conventional though I think it biases us a little bit. He's right that regulatory is not essential to design but it helps us in picking the right part for additive. Again, we want people to be thinking out of the box. We don't want them to be stuck in that box from being on the regulatory side but it helps a little bit to get things a little more focused.

Are you observing a rise on the use of analytical / simulation tools specific for AM?

(Steven) Yes, in the last two to three years. They were in their infancy before that. We're really starting to see what they can do and we're excited to see where the developments are going. They're not a full, complete solution yet but we're definitely making some strides.

(Laura) Yes, I'd agree with that. We have looked at various software that do this type of work and one of my colleagues has published a piece on how it works with EOS powder bed technology.

(Ryan) It was a project we did with EOS and Ansys who has some of these tools. This is a geometry problem with constraints. When you talk about optimization, any time you can tie a design and simulation together, then you can get a better solution, a better design, a better product. A good practice is understanding all the pieces that go into a design and when to bring them in. Sometimes designers can have a very small window. Any time you can bring in information to help you make design decisions is important.

(James) I think the question meant the use of simulation in AM, not simulation tools specific for AM. We have definitely seen people using simulation in additive designs. You sometimes have to bring that in to make use of these performance-based optimizations. There's a need for education and training programs and experience in validation of those simulations and optimizations. There's little skill involved in pushing a button to simulate for a design; there's a lot of skill involved in doing it right, knowing what it entails, what are the limits, etc. There's a lot that goes into it that won't be picked up by out-of-the-box software. Groups like Laura's that are doing the validation work help to move the field.

(Lauralyn) There's a standard to validate your software, ASME V&V 40.

(Doug) It's encouraging to hear that others having been seeing an increase in this. We've not seen as much of it as we'd like. It could be that folks are not ready to come to an agency like NASA. There's been a lot of challenges. It's clear that there probably are process simulation tools even for things like thermal history that could help us to understand things like coupon depart performance relationships. We haven't seen it yet.

How can standards compliment the need to foster AM utility through design and performance improvements while mitigating the risks of AM only designs and maturing component to low volume production?

(Steven) There are a couple of places where standards could be helpful in reducing AM design risks. One is design rules and constraints. We've developed some of that content in our engineering manuals. The other part is with tools. There's room for standards that tie in additive process constraints or simulation tools into design tools to create producible designs.

(John) In terms of standards helping to eliminate risks, we have a lot of NDI standards that are coming out that will help us get a better understanding of what that risk is. We talked earlier about the need for a standard for surface finish. That would go a long way from the aerospace perspective in terms of fatigue. There's a lot of opportunity to bring standards in to eliminate risks, e.g., with feedstocks.

Like a Technology Readiness Level - Is there a need or merit to a Design Readiness Level? Whether an AM design capability has the regulatory or QC for safe and reliable deployment within your industry

(John) We don't need a special readiness level for an AM design. If a design is ready, it is ready. We should have all the quality control requirements for that design when we sign off on a technical data package.

(Jesse) TRL and manufacturing readiness level (MRL) should address this specifically. Don't re-create something new just because it's AM.

(John) We don't want to invent new things for AM unless we have to.

(Ryan) A key distinction is that you could be doing your TRL and MRL at the same time. You're trying to apply a

new material or process at the same time that you're trying to do the new design that leverages that, versus having an established material and then working with that.

(Jesse) Part of your MRL is to make sure your TRL is aligned. If one is too far out ahead of the other, you probably need to go back to address certain things.

(Michael) This goes to maturity assessment of the design for AM capabilities. That is not necessarily the same as making it a separate path of a TRL scale. The maturity assessment of the design tools has to be done, just like any other element of the engineering process. But we don't need to create a separate TRL assessment of just the design tools. It's already integrated into the existing system under the TRL or MRL.

Closing Remarks

Brandon Ribic commented that he really enjoyed the discussion and the great progress that is happening within SDOs. Also, hearing from thought leaders on how the design community views the merits of standards across industries and how AM is playing a role that can provide various benefits. It's exciting to see how much opportunity remains.

Jim McCabe thanked today's speakers, moderators, and participants for their engagement, and the America Makes staff for their support in organizing and hosting the meeting. He noted that AMSC expects to hold a similar event in the 2nd quarter so keep an eye out for details. In addition, AMSC is maintaining a document that will be published soon that tracks progress to address the identified roadmap gaps. To get on the AMSC mailing list, email amsc@ansi.org. Visit www.ansi.org/amsc for more info.

Brandon Ribic noted dates of several other events coming up. He thanked Mr. McCabe for building out today's agenda and coordinating the speakers. We look forward to continuing the dialogue begun today.