Enabling Standards Development Through Public-Private Partnerships

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EXECUTIVE SUMMARY

In May 2024, the American National Standards Institute (ANSI) began work on a project aimed at enhancing the practical understanding of public-private partnership (PPP) models. The work included examining their use to support standards development for critical and emerging technologies (CETs) and the role of government in the related activities, as well as identifying key elements of effective collaborative mechanisms for addressing standardization needs in CET areas. This effort was executed as part of a cooperative agreement with NIST and aligns with the desired outcomes found in the United States Government's National Standards Strategy for Critical and Emerging Technology (USG NSSCET).

The project sought to identify industry perspectives on research, standards and measurement needs, and to inform U.S. government participation, coordination, and cross-agency information sharing. ANSI staff reviewed prior industry feedback to NIST about the implementation of the USG NSSCET, obtained through a Request for Information (RFI) and listening sessions. This feedback, combined with additional contributions from the ANSI membership - consortia, industry associations, and standards development organizations (SDOs), aided ANSI staff in the development of standards-driven public-private partnerships (SD-PPP) use cases, SD-PPP models, and standards readiness phases.

The SD-PPP models and standards readiness phases were developed to help gather feedback about what SD-PPP objectives and work products would be most beneficial during the various phases of standards development. The five SD-PPP models identified are direct participation, standards acceleration, funded standards development, funded participation, and policy and conformance driven. Each of the SD-PPP models identified potential work products across three phases of standards development (pre-standardization, standards development, and implementation). Five sub-phases further parse out the three main standards readiness phases, outlining relevant activities and the level of information sharing that stakeholders are likely open to at a given point. The five sub-phases include premature, exploratory, planning, development, and implementation. Overall feedback highlighted the importance of a standards acceleration SD-PPP model during the planning phase and direct-participation during the development and implementation phases. Funded standards development, with a focus on research and development (R&D), was seen as beneficial in the exploratory through implementation phases.

In addition, ANSI hosted two stakeholder events in July 2024 to explore the challenges, opportunities, and standards readiness for specific CETs. Both discussion-based sessions explored the use of PPPs to share information and identify priority standards development activities. The first event focused on artificial intelligence and machine learning (AI/ML) in healthcare and manufacturing, and the second on automated and connected infrastructure supporting air and ground vehicles. Discussions at both events highlighted the importance and presence of public-private partnerships in standardization activities today. Although the application of AI in healthcare and manufacturing, and automation in the automotive and aviation sectors is maturing at different paces, there are ongoing standards development activities relevant to each as well as existing public-private coordination efforts. Attendees emphasized that standards development and market integration would be accelerated through effective information sharing and coordination, standards education for all stakeholders, and development of landscape analyses and standards roadmaps.

When properly designed and executed, SD-PPPs can facilitate timely action to assess standardization needs in a particular industry or technology area and model innovative, high impact approaches to address these needs. This can create efficiencies for both government and private sector stakeholders. As with traditional forms of PPPs, having a clear mission, motivated partners, a governance framework, mechanisms to engage other organizations (including standards developers), and committed resources are critical to the success of any SD-PPP. Lastly, since CET lifecycles vary widely, with some maturing more rapidly than others, stakeholder organizations may suddenly form, merge, or dissolve abruptly, and resources can be very limited at specific stages of technology development. For this reason, any SD-PPP should be agile and flexible enough to maintain course through the full CET lifecycle.

Read the full project Conclusions and Recommendations in Section 6.

1. BACKGROUND INFORMATION

1.1 ANSI Project to Explore the Role of Public-Private Partnerships to Support Standards Development for Critical and Emerging Technologies (CETs)

1.1.1 Project Background and Objectives

In May 2024, the American National Standards Institute (ANSI) began work on a project aimed at enhancing the practical understanding of public-private partnership[1] (PPP) models. The work included examining their use to support standards development for CETs, the role of government in the related activities, and identifying key elements of effective collaborative mechanisms for addressing standardization needs in CET areas. This effort was executed as part of a cooperative agreement with NIST and aligns with the desired outcomes found in the United States Government's National Standards Strategy for Critical and Emerging Technology (USG NSSCET) Objective 2 on Participation, Line of Effort #4 to "improve communications between public and private sectors on standards." ANSI's efforts sought to identify industry perspectives on research, standards and measurement needs, as well as inform U.S. government participation, coordination, and cross-agency information sharing.

Effective implementation of the USG NSSCET will rely on a clearer understanding of PPP models, and ensuring that the government plays an active and appropriate role in the private sector-led system (see NSSCET Objective 2 Participation). This could be achieved by expanding communication with the private sector, including through strategic partnerships, information sharing arrangements, and other cooperative efforts between U.S. government agencies and private sector standards stakeholders, such as standards developing organizations (SDOs), industry associations, civil society, and others that participate in international standards activities.

When properly designed and executed, PPPs can facilitate timely actions to assess standardization needs in a particular industry or technology area and model innovative, high impact approaches to address these needs, creating efficiencies for both government and private sector stakeholders. Focused stakeholder input on best practices in public-private partnerships, enhancing U.S. participation in international CET standards activities as well as measuring the effectiveness of this participation are key to informing a robust U.S. government implementation plan.

1.1.2 ANSI's Role in Standardization Activities and Supporting Innovation

The American National Standards Institute (ANSI) is a New York not-for-profit [501(c)(3)] corporation whose mission is to enhance both the global competitiveness of U.S. business and U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity. ANSI serves as administrator and coordinator of the U.S. private-sector system of voluntary standardization, and is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC). ANSI's membership is comprised of businesses, professional societies and trade associations, standards developers, government agencies, and consumer and labor organizations. The Institute represents and serves the diverse interests of more than 270,000 companies and organizations and 30 million professionals worldwide.

One of ANSI's key roles is to serve as a bridge between the public and private sectors, facilitating public-private partnerships where government and industry together develop standards to achieve policy objectives. The United States Standards Strategy (USSS) provides a high-level framework for ANSI activities. Over 70 government agencies or departments, at both the federal and state levels, are members of the ANSI federation. Their representatives serve at all levels of the U.S. voluntary standards system, including ANSI policy advisory groups, national and international standards

[1] ANSI offers a definition of PPP in Section 2.1 as "collaborations between one or more government agencies and one or more private-sector organizations for the purposes of delivering a project or service, and which involve the sharing of resources, responsibility, risks, and benefits."

development committees (frequently in leadership positions) and as members of ANSI delegations to international meetings.

Since 1994, ANSI has convened approximately 20 standardization collaboratives and workshops (as part of the standards coordination program) as a mechanism to advance cross-sector coordination in the development and compatibility of standards and conformance programs needed to support critical and emerging technologies (CET) and national/global priorities. These workshops and collaboratives have assembled interested private- and public-sector stakeholders to help clarify the current standards landscape, foster coordination of effort, and focus standards participation resources. Often, this is at the request of federal government agencies or in close partnership with them.

Resulting work products of these activities include published standardization roadmaps, progress reports, and workshop reports to accelerate standards development. These work products have been influenced by the specific needs of a given sector or requesting organization(s), although a common thread is increased awareness of those needs, which in turn serves the U.S. private-sector system of voluntary standardization and its position in the national and international marketplace.

1.1.3 Project Methods

Literature Review and Interviews: ANSI reviewed prior feedback to NIST from industry through their Request for Information (RFI) and listening sessions. Summaries of that feedback is provided below in section 1.1.5. ANSI built upon feedback to NIST, which identified examples of existing coordination between the public and private sectors on standardization activities, with additional feedback and research on activities from the ANSI members and network of consortia, industry associations, and standards development organizations. Many of these examples are now outlined as standards-driven public-private partnership (SD-PPP) use cases found in Appendix D.

Brainstorming Sessions: ANSI hosted two stakeholder events in July 2024 to explore the challenges, opportunities, and standards readiness for CETs. Both discussion-based sessions explored the use of PPPs to share information and identify priority standards development activities. The first event focused on artificial intelligence and machine learning (AI/ML) in healthcare and manufacturing, and the second on automated and connected infrastructure supporting air and ground vehicles. In addition to being listed in the USG NSSCET, these specific areas were chosen because while AI/ML and automation technologies alone are complex, their integration (or convergence) with various sector applications, while enabling significant innovation and enhanced functionality, also adds another layer of unique challenges for standardization and conformity assessment. Detailed summaries of approaches and results from both brainstorming sessions can be found in Section 4 and Section 5.

1.1.4 United States Government National Standards Strategy for Critical and Emerging Technologies (USG NSSCET)

The Biden-Harris Administration released the United States Government's National Standards Strategy for Critical and Emerging Technology (USG NSSCET) on May 4, 2023. The strategy is intended to strengthen both the United States' foundation to safeguard American consumers' technology and U.S. leadership and competitiveness in international standards development, with a focus on CETs. Standards underpin economic prosperity across the country and strengthen U.S. industrial leadership. Businesses rely on standards to reduce the cost of product development, expedite market entry, and open new markets at home and abroad.

The government strategy stresses the importance of ensuring that the "rules of the road" for CET standards embrace transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and broad participation—to support standards that are technologically sound and help American industry compete on a level playing field. It recommends increased engagement in international standards for CETs and outlines how government will prioritize efforts for a subset of CETs essential to U.S. competitiveness and national security.

The USG NSSCET outlines four objectives and calls out USG actions. Several lines of effort are also included in each of the objectives. This project focused on Objective 2, line of effort #4. Actions associated with each objective are as follows:

- **Objective 1: Investment / USG Action**: The USG will bolster its support for R&D in CET and further increase investment in pre-standardization research. Innovation, cutting-edge science, and translational research will remain the drivers of U.S. influence and leadership in international standards development.
- **Objective 2: Participation / USG Action**: The USG will work closely with the private sector and academia to minimize gaps in coverage within SDOs, work collectively to address challenges to accelerate standards development in CET, bolster private-sector participation, and ensure that the government plays an active—but appropriate—role in the private sector-led system. The U.S. government will also continue to meaningfully contribute to multilateral, treaty-based standards organizations such as the International Telecommunication Union (ITU).
- **Objective 3: Workforce / USG Action**: The USG will invest in educating and training a cadre of professionals that can effectively contribute to and drive technical standards development. The USG will work with the private sector to find innovative ways to educate and train those in academia and industry.
- **Objective 4: Integrity and Inclusivity / USG Action**: The USG will harness the support of like-minded allies and partners to promote the integrity of the international standards system and work to ensure that international standards are established on the basis of technical merit and fair-processes. The USG will also promote greater inclusion in the international standards system, and look to facilitate broad representation from countries across the world, in order to build inclusive growth for all.

The USG NSSCET calls out a subset of CETs where the USG will prioritize standards development efforts. This subset, which is intended to be updated periodically, is drawn from a wider list of CETs maintained and updated by the White House Office of Science and Technology Policy (OSTP). The February 2024 CETs list was developed by the Fast Track Action Subcommittee on Critical and Emerging Technologies of the National Science and Technology Council (NSTC). This 2024 document expands upon that original CET list by identifying subfields for each CET with a focus, where possible, on core technologies that continue to emerge and modernize.[2]

1.1.5 Feedback to National Institute of Standard and Technology (NIST) on USG NSSCET Implementation

Together with the Office of Science and Technology Policy (OSTP) in the Executive Office of the President, NIST has been charged with leading implementation of the strategy across the U.S. government. To develop an effective implementation plan, NIST collected feedback through a Request for Information (RFI) and several Listening Sessions held across the country. The RFI and the Listening Sessions received a wide response across several CET sectors, industries, and non-governmental organizations, and raised some follow-on questions regarding how to best structure public-private partnerships that can accelerate standards development in CET. The following summary of feedback on both initiatives focuses on the use of public-private partnerships and the role of the U.S. government in enabling standards development.

Summary of Feedback from NIST Request for Information (RFI)

In September 2023, NIST published an RFI in the Federal Register seeking public input on how best to implement the USG NSSCET, partner with relevant stakeholders, remove barriers to participation in international standards development, and enhance the U.S. government's support for an international standards system that is open, consensus-based, and led by the private sector. The 22 RFI questions tie to the USG NSSCET broadly and to each of its four objectives.

[2] The White House. February 2024. Critical and Emerging Technologies List Update. https://www.whitehouse.gov/wp-content/uploads/2024/02/Critical-and-Emerging-Technologies-List-2024-Update.pdf

All the feedback can be viewed online**.** ANSI evaluated the feedback submitted from 68 organizations with a focus on the topic areas related to this project. There was significant reference to the importance of the U.S. standardization system as private-sector led (53%), the significance of public-private partnerships (40%), and suggestions for improving information sharing (32%).

Private-Sector Led

Thirty-six of the organizations responded in support of a private-sector led U.S. standardization system. Some remarks spoke to the success of this model and others provided some recommendations. Examples of that feedback are as follows:

FEEDBACK	RESPONDENT
Departments and agencies should rely on organizations that develop international standards to develop CET requirements or recommendations that are needed for their mission (or assigned through the Executive branch or legislation) – rather than establishing a government-led process that competes for the limited time/resources of an organization. Departments and agencies should publicize where they are taking such work and encourage interested parties and allies to participate in the effort.	American National Standards Institute (ANS)
The private sector, with its intimate knowledge of CETs, the associated R&D, and its awareness of use cases, will always be in a better position to lead the development of fast-moving CETs, respond to market needs and developments in a timely manner, and to support this work through the development of voluntary consensus standards. Further, our competitors often prioritize a government-lead approach to standards development, treating it as a form of engagement in international organizations. They are consequently not as nimble or competitive. Therefore, NIST and the Administration should recognize this inherent U.S. competitive advantage, continue supporting it, and work to strengthen it.	Consumer Technology Association (CTA)
Standardization in most critical and emerging technologies is led by the private sector with participation by government in a public-private partnership. INCITS seeks to support and strengthen that partnership	InterNational Committee for Information Technology Standards (INCITS)
ITI members strongly support and compliment NIST for undertaking an open and inclusive process to gather stakeholder input for implementation on of the Strategy. This approach is consistent with the U.S. private sector-led, public-private partnership model of standards development that has resulted in strong U.S. leadership in standards. We encourage the U.S. government to continue soliciting input from industry stakeholders during the implementation process to garner broader support for the NSSCET from stakeholder groups that expressed concerns during development of the Strategy.	Information Technology Industry Council (ITI)
A significant risk to the U.S.'s economic success based on the benefits of an effective, public/private partnership-led, voluntary standardization system, however, can arise when government representatives regulate or otherwise make decisions in terms of what should be standardized, as this may predetermine or inappropriately influence marketplace outcomes. Government stakeholders should refrain from going beyond their role as an important partner and valued participant in the development of open and voluntary consensus standards, as doing so can put the public/private partnership and the relevant standardization systems into a disequilibrium.	Microsoft
US competitiveness, underpinned by standards, has historically thrived from a private sector-led and consensus-based approach built on openness and transparency; this is codified in legacy US legislation and White House policy guidance.	UL Standards and Engagement (ULSE)

Public-Private Partnerships

Twenty-seven of the organizations who responded emphasized the importance of public-private partnership (PPPs) to support the U.S. standardization system. Some remarks spoke to the impact of PPPs and others provided some recommendations. Examples of that feedback are as follows:

FEEDBACK	RESPONDENT
USG should coordinate early and closely with the private sector when engaging internationally on CET topics to identify areas where private-sector led standards can be promoted and applied to facilitate trade, market access, and technology adoption internationally. USG can do this through new or existing government programs and public-private partnerships that encourage government-private sector dialogue to assess U.S. industry's international needs and priorities vis-à-vis standards.	American Petroleum Institute (API)
Standardization in most critical and emerging technologies is led by the private sector with participation by government in a public-private partnership. INCITS seeks to support and strengthen that partnership	InterNational Committee for Information Technology Standards (INCITS)
As acknowledged in the USG NSSCET, the remarkable effectiveness of the U.S. standardization system (and engagement by U.S. stakeholders in internationally based standardization efforts) is due in large measure to the related, ongoing, and healthy U.S. public-private partnership. For this reason, we encourage the U.S. government to take particular care in aligning its actions with the 2020 version of the American National Standards Institute ("ANSI") United States Standards Strategy ("USSS").	Microsoft
We encourage NIST to recognize the many dynamic and impactful industry consortia that (a) generally do their work in alignment with the principles of open, inclusive, and rules-based standardization governance but act independently from the ANSI accreditation framework, and (b) may have a material role to play in connection with critical and emerging technology (CET)-related standardization.	Microsoft
Leveraging existing PPPs to do so enables greater reach with less effort. Partnerships can also facilitate the pooling of resources, knowledge, and expertise from different sectors, leading to more effective and relevant standards.	MITRE
An answer to balancing concerns about too much government involvement can be establishing public-private partnerships that are hosted and managed by a neutral organization (not the government itself, nor an entity that's a builder, buyer, or investor in the CET). The federal government's support and participation in such endeavors will signal commitment, while having a third-party lead can alleviate apprehension.	MITRE
The USG should increase its support for public-private partnership funded projects focused on standards readiness in CET topics, with the goal of exploring and identifying critical standard's needs.	SEMI
Strong partnerships must be at the core of any successful standardization strategy, and government action on standardization policy should be constantly calibrated in consultation with stakeholders from industry, academia, and civil society.	Telecommunications Industry Association (TIA)

Information Sharing

Twenty-two of the organizations who responded emphasized the importance of information sharing to support standards development. Remarks provided feedback about approaches to increasing information sharing and what information would be most helpful to share. Examples of that feedback are as follows:

FEEDBACK	RESPONDENT
Industry is eager to participate in and contribute to such partnership initiatives and has valuable expertise, information, and insight on global standardization activities, but clear and timely communication of U.S. government expectations is critical to effective participation by and contributions from U.S. industry.	Alliance for Telecommunications Industry Solutions (ATIS)
Clear and accessible articulation of what the CET standards are in the U.S. and other countries via a streamlined platform, where this information is regularly updated, could be helpful to exporters. Being a leader of open and public information sharing will likely result in other countries adopting the practices set by the U.S., or at least using them as a baseline, making domestic standards and best practices more relevant in global markets.	Engineering Biology Research Consortium (EBRC)
Developing a robust, real-time, searchable, keyword-based dashboard with information about standards in progress, for comment, and published would be helpful. It could be a one-stop shop for information about what is being developed by ANSI-accredited SDOs, ISO, IEC, ITU, etc. Identifying opportunities for early engagement through such a portal or dashboard could help increase private sector engagement.	National Electrical Manufacturers Association (NEMA)
Informing various private sector elements regarding the essential role standards have internationally will be valuable. Encouraging international regulatory development bodies to consider the incorporation by reference of open, consensus standards in lieu of standards developed not in an open consensus SDO.	SAE International
Awareness of various standards development activities for CET is one of the most important challenges faced by the private sector. Despite the efforts of standards development organizations (SDOs) to promote initiatives or outreach, awareness of even those taken on by participating members has room to improve	SEMI
These efforts to expand engagement (and improve information sharing) may include: - Creating federal advisory committees focused on standards development in different CET areas to solicit input from private sector entities and share U.S. government views; - Convening regular meetings with private sector entities not directly involved in international standards activities; - Establishing one or more federal grant programs to enable SMEs and startups to participate in international standards activities; and - Continuing to improve mechanisms to make information publicly available for those unable to participate directly in international standards activities.	Software & Information Industry Association (SIIA)
With respect to the private sector, our core recommendations are for the U.S. government to create channels to improve communication with industry around standards development and promote involvement of SMEs and startups in international standards activities through grant programs.	Software & Information Industry Association (SIIA)

Summary of Feedback from NIST Listening Sessions

NIST also held a series of listening sessions and stakeholder events about the USG NSSCET while the RFI was open. Feedback was compiled from both sources and used to inform and guide the development of the Implementation Roadmap. To support ANSI in this project, NIST provided ANSI with a compiled list of feedback from all the listening sessions, separate from the publicly available summaries. There was limited feedback with regards to the role of public-private partnerships during these sessions. However, there was ample discussion about increased information sharing, support for small-and-medium enterprises, as well as strategic engagement with academia and consortia. Lastly, there were several suggestions to help educate leadership (both public and private stakeholders) on understanding the value of standards, including the development of use cases to tell this story. NIST developed summaries of some of the sessions, which readers are encouraged to review.

USG NSSCET Implementation Roadmap

The USG NSSCET Implementation Roadmap was published following a White House Standards Summit on July 23, 2024 that brought together government and private-sector leaders in standardization and participants representing a range of federal agencies, industry, and technology sectors. The Implementation Roadmap includes immediate and long-term actions for the USG to reinforce its support for the private sector-led system and collaborate with private sector stakeholders to address opportunities and challenges related to standards development activities for CET.

The Roadmap highlights the public-private partnership that supports the private-sector-led standardization system in the United States. According to the accompanying White House fact sheet, "Through SDOs, the U.S. private sector leads standardization activities globally to respond to market demand, with substantial contributions from the U.S. Government, academia, industry, and civil society groups. Industry associations, consortia, and other private sector groups work together within this system to develop standards to solve specific challenges and respond to national priorities."

1.2 United States Standardization System

The U.S. standardization system is one of the most wide-reaching, inclusive, and impactful public-private partnerships in our nation's history. The system is market driven, flexible, and responsive and highly integrated with the global standards system. It has evolved over time to meet new needs as they emerge, embracing a range of standards development models. Stakeholders in both the private and public sectors have a choice of where they take standards work items at any stage in the technology cycle. This has enabled the rapid advancement of standards deliverables when needed.

The fact that the U.S. system is open, market-driven, voluntary, and private-sector-led is critical to achieving the widely shared policy goals of expanded U.S. leadership and innovation on the global stage, while enabling the U.S. to deliver responsive, globally relevant solutions in connection with critical and emerging technology.

There is a longstanding recognition in the U.S. that standards are a building block for U.S. innovation, competitiveness, security, and quality of life. This fact has been formally recognized in both U.S. law and policy, in the *United States Standards Strategy* (USSS), and now in the NSSCET.

1.2.1 United States Standards Strategy (USSS)

The USG NSSCET commits to increasing U.S. government support for the private sector–led standards system, and calls out its alignment with the USSS, which is updated by ANSI every five years with broad input from the standardization community. The USSS serves as a statement of purpose and ideals resulting from a reexamination of the principles and strategy that guide how the United States develops standards and participates in the international standards-setting process. It provides a vision for the future of the U.S. standards system to support U.S. competitiveness, innovation, health and safety, and global trade.

The USSS was developed through the coordinated efforts of a large and diverse group of constituents representing stakeholders in industry, standards developing organizations, consortia, consumer groups, government, and academia. Throughout each revision cycle, participants expressed a commitment to developing the USSS in a way that was open, balanced, and transparent. The result is a document that represents the vision of a broad cross-section of standards stakeholders, reflecting the essential diversity of the U.S. standards system.

The first of 12 USSS strategic initiatives is to "strengthen participation by government at all levels in the development and use of voluntary consensus standards through public-private partnerships." This first strategic initiative emphasizes

the criticality of participation and speaks to the roles of standards developers, government, industry, and ANSI on activities including[3]:

- Coordinating on solutions where government interest could be addressed by voluntary consensus standards
- Cooperating to ensure reasonable access by affected parties to voluntary consensus standards
- Providing state and local governments methods to identify where their interests are being addressed and mechanisms to participate
- Raising awareness of policy makers about the benefits of standards and importance of active participation
- Working with USG and private sector to address standards needs and actively participate in standards development
- Using USG relationships with state and local government, and responsibilities under National Technology Transfer and Advancement Act of 1995 (NTTAA), to support greater use of voluntary consensus standards

The next edition of the USSS is expected to be published in 2025.

1.2.2 Standards Development Organizations

There are more than 100,000 recognized standards in the United States—including over 13,000 approved American National Standards—and more than 30,000 globally recognized international standards. Standards are developed by diverse standards developing organizations, trade associations, industry and consortia groups, academic institutions, domestic and international committees, and other consensus bodies in the United States (see Figure 1).

In accordance with the *U.S. Standards Strategy*, the relevance of a standard is not determined by who developed it, but rather by market/societal need and compliance of the developer's process with recognized principles of open and equitable voluntary standards development, as reflected in ANSI's *Essential Requirements: Due process requirements for American National Standards* and the World Trade Organization's *Agreement on Technical Barriers to Trade* (WTO/TBT).

1.2.3 National Technology Transfer and Advancement Act (NTTAA) & Office of Management Board (OMB) Circular A119

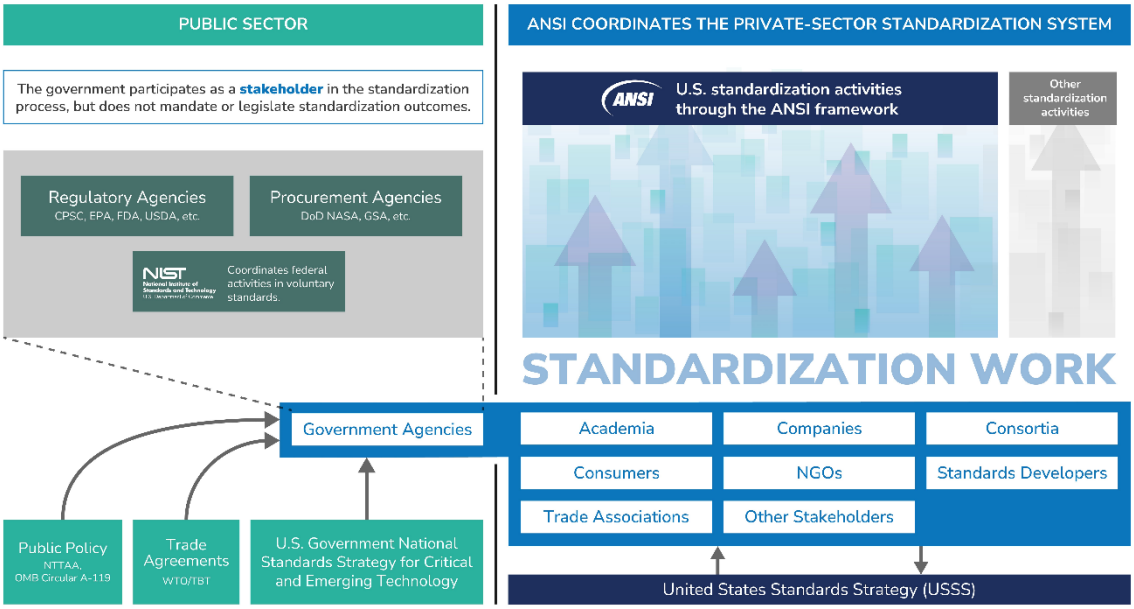
As one of the biggest users of standards, the U.S. government's active participation in standardization is of great importance. Reliance on private-sector leadership, supplemented by federal government contributions to standardization processes as outlined in Office of Management and Budget (OMB) Circular A-119, *Federal Participation in the Development and use of Voluntary Consensus Standards and in Conformity Assessment Activities*, remains the primary strategy for government engagement in standards development. The circular has guided federal agency implementation of the National Technology Transfer and Advancement Act of 1995 (NTTAA) for more than two decades. And through this public-private partnership, the United States can respond most effectively to the strategic needs of the nation on both domestic and international fronts (see Figure 1).

- **OMB Circular A-119** spells out the government strategy for standards development. It promotes agency participation on standards bodies, specifies reporting requirements on conformity assessment activities, and informs agencies of their statutory obligations related to standards setting.
- **NTTAA** directs federal agencies to adopt voluntary consensus standards wherever possible (avoiding development of unique government standards) and establishes reporting requirements.

Figure 1 shows the connectivity of public and private sector entities and related standards strategies, policies and legislation as described in Section 1.2.

[3] The full text of these abbreviated points can be found on page 13 of the USSS.

Figure 1: Connectivity of Stakeholders in the U.S. Standardization System



1.2.4 United States Engagement in International Standardization Activities

National Standards Bodies

Many nations around the globe have a national standards body (NSB), which may or may not be government sponsored. NSBs play different roles depending on their type of government and mission. A NSB, for example, may develop standards, collaborate, or participate in various SDOs around the world to represent their nation's interests, or serve as their nation's representative in ISO/IEC (e.g., as an ISO member).

Some examples of NSBs are the Association française de normalization (AFNOR, France); British Standards Institution (BSI, United Kingdom); Bureau of Indian Standards (BIS, India), and Deutsches Institut für Normung e.V. (DIN, Germany).

ANSI is not a government sponsored NSB, but instead is a private, non-profit organization that coordinates the U.S. voluntary standardization and conformity assessment system. Similar to other NSBs, ANSI is the official U.S. representative to the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). As part of its role, ANSI forms U.S. Technical Advisory Groups (TAGs) made up of experts and relevant stakeholders to advance U.S. positions in ISO/IEC committees or subcommittees as illustrated in Figure 2 and detailed further in the following sections.

Figure 2: TAG's and "P" Membership in ISO/IEC

International Organization for Standardization (ISO)

Part of ANSI's responsibilities as the U.S. member body to the International Organization for Standardization (ISO) includes accrediting U.S. Technical Advisory Groups (TAGs), through the ANSI Executive Standards Council (ExSC), to serve as the national mirror committees in relation to ISO Technical Committees (TCs), Subcommittees (SCs), and Project Committees (PCs) developing standards. ANSI-accredited U.S. TAGs are comprised of the range of U.S. parties interested in and affected by specific ISO standards.

The primary purpose of U.S. TAGs is to develop and transmit, via ANSI, U.S. consensus positions and comments on activities and ballots of ISO TCs (and, as appropriate, SCs, PCs, and policy committees). These activities and ballots include the approval, reaffirmation, revision, and withdrawal of ISO standards. U.S. TAGs are also responsible for deciding on the delegates and experts to represent the U.S. at ISO committee meetings. They may submit New Work Item Proposals (NWIPs) for consideration and ISO member voting regarding the development of new standards in a relevant ISO committee.

International Electrotechnical Commission (IEC) / U.S. National Committee (USNC)

The U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC), a committee of ANSI, serves as the focal point for U.S. parties who are interested in the development, promulgation, and use of globally relevant standards for the electrotechnical industry. The USNC is also engaged in the assessment of conformance to standards, undertaking work in areas such as testing, certification, and accreditation.

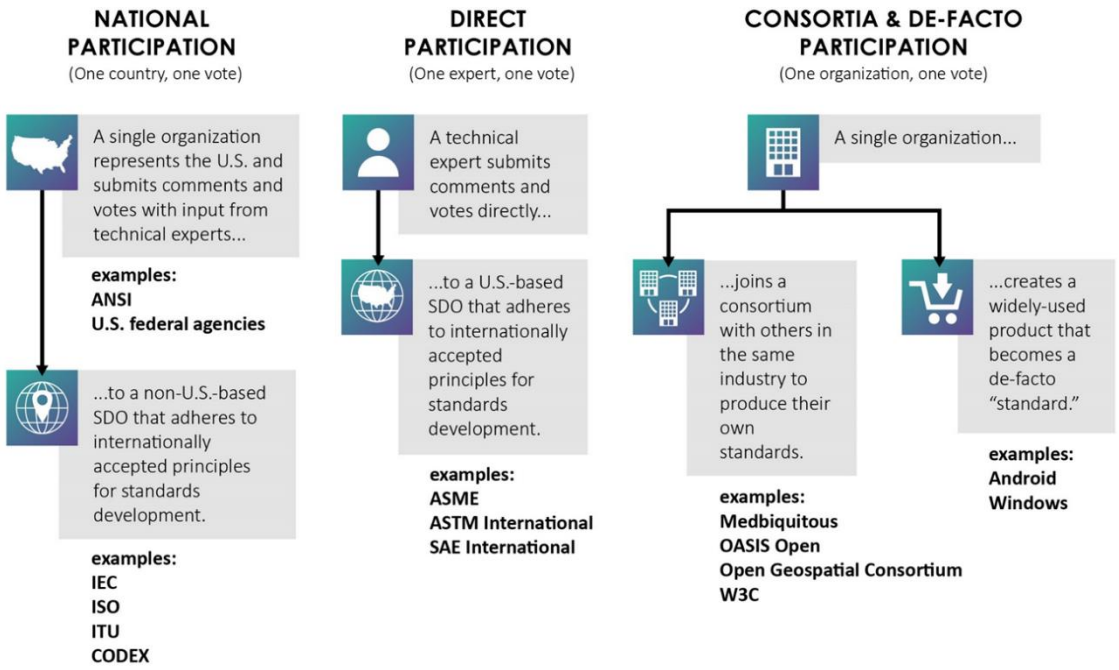
As the U.S. representative to the IEC and many related regional standardization bodies, the USNC serves as a conduit to the global standards-setting community for technical and policy positions arising in the U.S. In this capacity, the USNC brings issues from the global arena to the U.S. for review, consideration, and response. In the IEC the USNC operates via Technical Advisory Groups (TAGs), comprising volunteer experts working collaboratively to develop U.S. positions on technical issues under consideration within IEC technical committees.

1.3 Participation in Standards Development

Various stakeholder types offer valuable perspectives to standards development activities, and various standards development organizations have different mechanisms for participation and procedures for voting, establishing balance, and ensuring due process.

For example, voting models may allow for one vote per individual (e.g., ASME, SAE International), one vote per organization (e.g., AAMI, Open Geospatial Consortium), or one vote per country (e.g., ISO, IEC). This is illustrated in Figure 3.

Figure 3: Pathways to Globally Relevant Standards



Individuals participate in standards development committees as representatives of their organizations or their individual interests and offer their own technical contributions and experiences. Employers may limit the type of information they can openly share to protect intellectual property, and the SDO does not require that proprietary information be shared.

Balance of representation in standards development helps ensure market relevance of standards as well as market integration of the technologies being standardized. Each type of stakeholder brings strengths to the table and adds value to the discussions and decision making. Here are examples of contributions offered by common stakeholder types:

- **Users/Consumers/Civil Societies**: offer the experience of the direct user of a product or service – a boots on the ground perspective
- **Manufacturer/Developer**: offer the experience of design and testing of parts, components, and systems
- **Consortia/Industry Association/Professional Society**: offer a broader view which represents a consensus of a collection of industry stakeholders, on topics such as challenges, opportunities, or current and future technology trends.
- **Academia/Research Institutions**: offer experiences of trends and needs in the research community, needs of emerging professionals, and bring anonymized data to standards meetings
- **Government (international, federal, state, local, tribal):** offer perspectives about where standards could support current or future regulations and policy, anonymized data, knowledge about trends of technology (based on applications), or safety and compliance issues that incident reporting and tracking bring to light
- **Code Developers or Conformity Assessment Bodies:** offer perspectives about where standards are needed or need revisions based on new technology, safety trends, or common challenges they learn in the application of their codes and programs

1.4 Challenges and Perceptions Related to CETs and Standards

As outlined in both the USSS and USG NSSCET, the broader standardization community recognizes the need for continued education about the role and benefits of voluntary consensus standards. This education is not only beneficial for current standards stakeholders and emerging professionals but also for stakeholders that have not engaged in standard activities previously. Organizations and individuals that have not yet engaged in standards development may

harbor perceptions that standards hinder innovation, that startups will not have the same strength of voice as established or larger organizations, that their intellectual property is at risk, and that the investment of time and resources will not yield any returns.

Individual SDOs offer training for their members about the processes and tools to support standards development activities within their organizations. Additionally, ANSI's Committee on Education works with the standardization community to develop and provide educational programs and resources that raise awareness about the importance of standards and conformity assessment to the academic community, the public, and the future standards workforce. Lastly, USG NSSCET Line of Effort #6 (pg. 11) also commits U.S. government to educate and empower the new standards workforce.

Even with an educated workforce, the question of standards readiness remains. Each technology matures at a different pace, and adoption by the various sectors where technology convergence is a factor is not simultaneous. There is not a one-size-fits-all process for evaluating when stakeholders introducing new technologies should embark on standardization activities. Numerous factors will impact when the timing is right and what the stakeholders will standardize first. Section 3.2 describes the two concepts that were discussed at the ANSI brainstorming sessions and which explore these factors through standards readiness phases (based on the readiness of stakeholders to share information) and standards readiness considerations (considering technology, market, community, and capacity aspects).

2. STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIPS (SD-PPPS)

After examining a rich landscape of literature and speaking to several interviewees about existing public-private partnerships, ANSI has developed a description of standards-driven PPPs (SD-PPPs), five proposed SD-PPP models, and several PPP use cases found in Appendices A and E. The five SD-PPPs models outlined in Section 2.3 were also provided to attendees before the brainstorming sessions and utilized to gather input during event discussions. An analysis of these efforts is found in 2.4 SD-PPP Use Case Analysis

2.1 What is a Public-Private Partnership (PPP)?

While there is a long history of public-private partnership (PPP) utilization around the world, no single widely-adopted definition exists. For the purposes of this project, ANSI has defined PPPs as "collaborations between one or more government agencies and one or more private-sector organizations for the purposes of delivering a project or service, and which involve the sharing of resources, responsibility, risks, and benefits." PPP characteristics and objectives are flexible, may be formal or informal, and vary based on the needs of parties involved. However, the most prevalent use cases are long-term agreements that support infrastructure development where the government funds the private sector to carry out a project.

2.1.1 Ensuring a Successful PPP

There have been several evaluations of PPPs (also abbreviated as P3) carried out by the public and private sectors. Infrastructure development to support transportation is one of the most common and older examples of applications of public-private partnerships. Some models are more widely known and/or evaluated to support U.S. manufacturing (e.g., Manufacturing USA, and Manufacturing Extension Partnership (MEP)), emerging and cross-cutting technologies (e.g., microelectronics) and standards development. Regardless of purpose, there were common threads in the guidance for a successful traditional PPP including alignment on mission, transparency, establishing governance and safeguards, investment of adequate resources, and understanding the needs of all partners and flexibility.

U.S. Department of Transportation (DoT)[4]

The U.S. Department of Transportation (DoT) and State DoTs have entered partnerships with the private sector (e.g., either a single private entity or a consortium of several companies) to deliver, operate, and maintain transportation services. Over decades of experience, these collaborations have culminated into best practices and consolidated into the DoTs Successful Practices for P3s: A review of what works when delivering transportation via public-private partnerships (March 2016). The report resides on the Build America Bureau online P3 Library, and provides guidance to help involved parties from concept to completion including detailing the types of P3 structures, financial mechanisms, legislation, how to approach project definition, evaluation, and metrics, monitoring, and oversight, etc. Each phase has its own needs for success but the DoT recognized four key themes for overall success:

1. Ensure the P3 option creates value for the public.
2. Maintain transparency and conduct outreach throughout the P3 process.
3. Foster fair competition and long-term partnership.
4. Build a strong P3 program with adequate resources.

Additional DoT guidance, Establishing A Public-Private Partnership Program: A Primer, explores key issues related to establishing a P3 program at a public agency for highway infrastructure. Successful partnerships rely on a clear understanding of what the partnership involved wants and needs. The DoT illustrates (in DoT Table 1-1 Public and Private Sector Cultural Perspectives and shown in Table 1) that there are cultural perspectives in play between the partners which impact their view of a project.

[4] Resources referenced in this section (from 2012 and 2016) are still in use and reference last updated in January of 2024.

Table 1: DoT Public and Private Sector Cultural Perspectives

Public Sector	*Private Sector*
Projects – Seeks to address transportation needs by developing "projects" to improve the infrastructure network.	**Deals** – Sees the process in terms of negotiated transactions.
Stakeholders – Seeks to address the concerns of various parties, including local residents, facility users, and political representatives.	**Stockholders** – Seeks to generate dividends for its stockholders.
Process – Applies and complies with prescriptive, standard operating procedures designed to provide uniformity, minimize risk and build consensus among stakeholders.	**Outcome** – Demands greater flexibility and expediency to arrive at final objective.
Policy Goals – Develops projects to achieve policy goals such as improvements to mobility and safety.	**Profits** – Interested in a competitive return on investment
Transparency – Seeks to share information with the public to ensure public participation and accountability.	**Confidentiality** – Protects intellectual property and the competitive advantages derived from innovations.

Lastly, the DoT calls out three elements which help effectively manage the risks that occur during the contract term and allow the private party to meet its contractual obligations while the public agency safeguards the public interest:

1. **Defined Management Systems and Incentives**: designing a contract that aligns private sector incentives with public sector goals and clearly defines performance standards and performance management systems
2. **Effective Contract Governance**: assigning a competent, long-term team to govern the contract
3. **Engaged Parties**: establishing communication processes that facilitate an engaged and adaptive relationship between the public and private parties

Institute for Defense Analyses

In July 2021, the Institute for Defense Analyses (IDA) published a report titled Lessons Learned from Public-Private Partnerships (PPPs) and Options to Establish a New Microelectronics PPP[5]. Under contract with the Defense Advanced Research Projects Agency (DARPA), IDA conducted a study to identify lessons learned related to the design and implementation of PPPs. The study team identified 32 lessons related to eight concepts (governance, funding, operations, intellectual property (IP), security, innovation ecosystems, Federal authorities, and evaluation and success measures). Table ES-1 (page 10) of the IDA report outlines details on all the concepts and related lessons. A high-level summary of IDA's five keys to success are as follows:

1. **Clearly Defined Goals**: The goals must be clearly defined and different visions on topics must be reconciled (e.g., basic research, proof of concept testing, prototyping, and workforce development).
2. **Transparent and Trusted Governance Model**: A transparent governance framework which has the broad confidence and support of the PPP members is critical. It must include the high-level business strategy, the technical agenda and priorities, member engagement, clearly defined success measures, and be consistent with the members' authorities and business models.
3. **Flexible Funding Structure:** It must be flexible to accommodate varied members' expectations and sufficient to support the PPP's mission. Funding structures tied to governance must allow for dispute resolution to ensure that members do not withdraw from the PPP and continuously attract new partners as the PPP evolves.
4. **Adaptable Yet Clearly Defined IP Policies:** IP policies and rules must be defined at the start. This will be challenging given the widely different approaches that exist in industry, university, and government, and the need to harmonize them. These policies must adapt to a range of pre-existing commitments, policy approaches, and perspectives on physical security and export control.

[5] Institute for Defense Analyses. Lessons Learned from Public-Private Partnerships (PPPs) and Options to Establish a New Microelectronics PPP. July 2021. https://www.ida.org/-/media/feature/publications/l/le/lessons-learned-from-ppps-and-options-to-establish-a-new-microelectronics-ppp/d-22782.ashx**.**

5. **Performance Measurement Tied to PPP Goals:** Performance measurement should include technical milestones and economic and social returns (e.g., creation of new businesses, jobs, and social well-being). Financial sustainability is an indicator of success. Timelines for self-sufficiency (from Federal Funds) may vary depending on the PPP's goals and the scale of investments.

The MITRE Corporation

The MITRE Corporation, which operates six Federally Funded Research and Development Centers (FFRDC)[6], highlights best practices[7] based on their experience as:

- **Shared purpose** among partners who expect clear mutual and public benefit under a charter that aligns interests and expectations
- **Trust** among partners built through delivering as expected and communicating proactively
- **Accountability** via data-driven decision making and performance-linked incentives
- **Partner buy-in** based on the value and benefit to stakeholders exceeding cost and risk, as well as the empowerment of partners
- **Value delivery** via responsive operation, where the partners employ the most effective governance and business models, technologies, and protocols

MITRE speaks to PPPs as an opportunity for the government to "harness private sector capabilities, efficiencies, and innovations for public good" and how the model can be applied to other issues beyond their most common use for development of key infrastructure (such as in transportation).

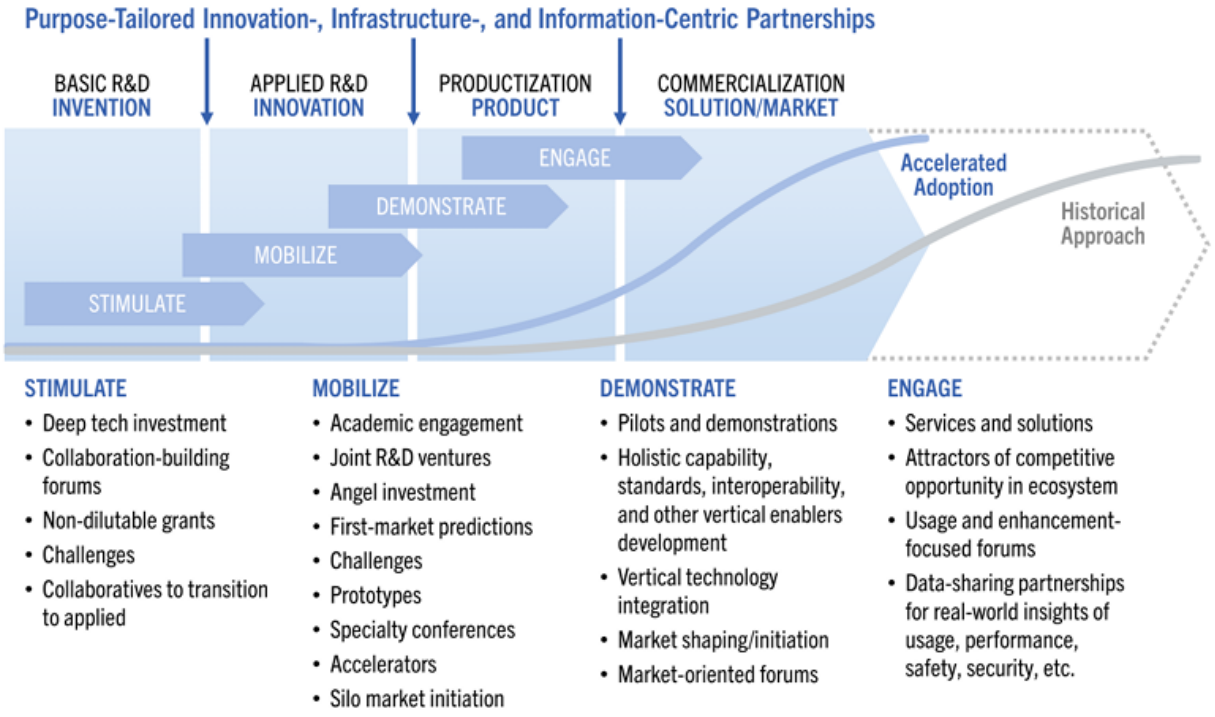
In 2023, MITRE published a report titled *Partnerships to Accelerate Advancement of Priority S&T*,[8] which acknowledges that technology development is at a critical state and delves into the role partnerships play to support such advancements. Simply providing additional resources for a technology development alone will not result in positive impact. Applying resources and establishing specific public-private collaboration at the "right time and with the right focus within the technology lifecycle can rapidly accelerate S&T development and its application across a variety of use cases."

The paper introduces three types of partnerships (innovation-centric, information-centric, and infrastructure-centric) and four levers for supporting technology advancement during the earlier stages of its development. Standards development is considered part of lever three and four. Each of the following four levers also has proposed supporting activities as outlined in Figure 4:

1. **Stimulate**: research and create interest
2. **Mobilize**: a network / active ecosystem
3. **Demonstrate**: impactful solutions
4. **Engage**: increase business/industry engagement (establishing routes to market)

[6] National Science Foundation (NSF). Last accessed August 9, 2024. *Federally Funded Research and Development Centers (FFRDC)*. https://ncses.nsf.gov/resource/master-gov-lists-ffrdc.
[7] The MITRE Corporation. January 10, 2017. *Public-Private Partnerships: Advancing Public Service in Partnership*. https://www.mitre.org/sites/default/files/publications/mitre-public-private-partnerships-advancing-public-service_january-2017.pdf.
[8] The MITRE Corporation. *Partnerships to Accelerate Advancement of Priority S&T*. January 10, 2017. https://www.mitre.org/sites/default/files/2023-09/PR-23-02057-05-Partnerships-to-Accelerate-Advancement-of-Priority-S-T.pdf.

Figure 4: MITRE Examples of Collaborative & Partnership Activities to Support Each Lever in a Technology Lifecycle



As shown in this figure, agnostic of partnership type (and drivers), resources invested along this timeline are expected to accelerate adoption of technology. Investment of resources would come from various stakeholders – including the government. There are different value propositions for each stakeholder to support activities along the lifecycle. The MITRE model of technology evolution does not differ from other recognized lifecycles or maturity levels. Additionally, the phase in which standards development is indicated (Lever 3 and 4) does not differ from what is commonly seen in standards development and proposed in the Standards Readiness Phases (see section 3.2)

2.1.2 PPP Related Regulation and Contractual Agreements

Public-private partnerships may be enabled, guided, or executed through various legislation, guidance, and contracts. A legal analysis of the following examples was not conducted (nor was it in scope of the ANSI project) but are included because they were referred to in presentations during the brainstorming sessions, highlighted in literature review, or discussed in PPP interviews as enabling PPPs.

- Stevenson Wydler Technology Innovation Act of 1980, September 26, 1980: Directs the Secretary of Commerce to establish and maintain an Office of Industrial Technology to improve the economic, environmental, and social well-being of the U.S. by promoting technological development.

- Bayh–Dole Act / Patent and Trademark Law Amendments Act, December 12, 1980: Enables universities, nonprofit research institutions and small businesses to own, patent, and commercialize inventions developed under federally-funded research programs within their organizations.

- Federal Technology Transfer Act of 1986, October 2, 1986: Amends the Stevenson-Wydler Technology Innovation Act of 1980 to authorize Federal agencies, subject to specified conditions, to permit the directors of their Government-operated Federal laboratories to: (1) enter into cooperative research and development agreements (CRADAs) with other Federal agencies, State or local governments, industrial organizations,

industrial development organizations, public and private foundations, nonprofit organizations including universities, licensees of Federal inventions, and other persons; and (2) negotiate patent licensing agreements.

- Cooperative Research and Development Agreements (CRADAs) (15 U.S.C. § 3710a): A CRADA is a formal research contract between a federal entity and a non-Federal organization (industry, universities, nonprofits, small businesses) to advance technologies toward commercial applications. A federal laboratory may provide personnel, services, facilities, and equipment, but no funds, to the joint research and development efforts.

- Other Transaction Agreement (OTA): A flexible, strategic partnership between the government and industry, to foster innovation and promote collaboration.

There are several other types of agreements referred to in the next sections about standards-driven PPPs which are not defined in this report. There are other common definitions publicly and readily accessible.

2.2 What is a Standards-Driven Public-Private Partnership (SD-PPP)?

Standards-driven PPPs (SD-PPPs) are a type of PPP where resources invested are directly impacting consensus-based standards development. SD-PPPs may or may not involve contractual agreements, financial support, or formal relationships between public and private representatives. SD-PPPs may prove more effective when there are synergies between private-sector technology and innovation, and public-sector priorities and incentives. Common work products of SD-PPPs may support:

- **Pre-standardization activities**: development of landscape analyses, roadmaps, gap analysis, research, etc.
- **Standards development**: support for the proposal and/or formation of new committees, identifying and convening technical experts, content development, etc.
- **Implementation**: increasing awareness, technical training, workforce development, conformity assessment, etc.

Typical objectives and characteristics of SD-PPPs have been formulated into models below. The details associated with the models shown should not be perceived with definitive or restrictive boundaries; rather, they support comparison of existing use cases and evaluation of approaches based on the standards readiness of technologies and services. The models outline the potential partners, characteristics, objectives, roles, funding, and contractual considerations typically found in the research and standards community. There are five models proposed in this document:

1. Direct-Participation
2. Standards Acceleration
3. Funded Participation
4. Funded Standards Development
5. Policy and Conformance Driven

Actual SD-PPP use cases often include the characteristics of more than one model. For example, an SD-PPP may be a “standards acceleration” and a “funded participation model.”

2.3 Standards-Driven Public-Private Partnership (SD-PPP) Models

2.3.1 Assumptions

The following terms are used within the SD-PPPs models. To avoid repetitive listings in the tables below, these terms are defined to provide context for these models only and are not considered inclusive.

Public Sector / Entity

- Government: international authority, federal, state, local, military, law enforcement, government laboratories, etc.

Private Sector / Entity

- Industry: manufacturer, developer, service providers, consortia, trade association, professional societies
- Research Institutions: universities, centers of excellence (CoE), think tanks, research firms
- Workforce Development Providers: any organization offering services to provide knowledge, skills, and abilities (KSA) education and training to individuals including academia and other training providers
- Certification Bodies: non-governmental / third-party product or personal certification providers
- Standards Development Organization (SDO): accredited and non-accredited standards and codes development organizations, as well as consortia, professional societies and other groups convening experts to develop consensus standards

Other:

- Agreement: A written agreement which supports the execution of a SD-PPP may be referred to as (but not limited to) a cooperative agreement, award contract, procurement contract, Cooperative Research and Development Agreement (CRADA), memorandum of understanding (MOU)/agreement (MOA), other transactional agreement (OTA), bilateral contract, non-disclosure agreement (NDA), licensing agreement, etc.

2.3.2 Direct-Participation

A direct participation SD-PPP model is when the public sector directly participates in the standards development process alongside any other stakeholder at the table. As with any other participant, they represent their organization and follow any policies set forth by their employer as well as the policies, procedures, and/or bylaws of the SDO supporting the standards development activity. Policies and guidance about federal government participation can be found in Public Law 104-113, National Technology Transfer and Advancement Act of 1995, and OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.

Table 2: Direct Participation SD-PPP Model Characteristics

Partners Involved	- **Government, SDOs and SDO members**
Objectives	- Support the development of standards - Provide insight about what role standards would play in relation to existing or future government regulations/policy - Gather information to inform potential government regulations/policy
Work Products	- Pre-standardization: technical reports, strategic plans - Standardization: standards development - Implementation: increasing awareness, technical training, workforce development on standards
Convening Mechanisms	- Meetings (various forms) of stakeholders through committees, subcommittees, and working/task groups which are organized by SDOs - Collaborative electronic tools used for draft development and approval of work products
Public Sector Role	- Government actively participates in an SDO at varying capacities including contributing technical expertise for draft development, voting on ballots, chairing a committee, participating in short and long-term strategy development, hosting meetings, and providing liaison reports
Private Sector Role	- SDO provides the infrastructure and services to convene, develop and publish the standards - SDO members actively participate in an SDO at varying capacities including contributing technical expertise for draft development, voting on ballots, chairing a committee, participating in short and long-term strategy development, hosting meetings, and providing liaison reports
Funding Considerations	- Funding is not provided by the public or private sector; instead, each organization provides non-financial contributions based on the services an organization normally provides or expertise a representative is permitted to share - SDO membership fees may apply
Agreement Considerations	- No agreements between partners is necessary. - Terms and conditions for SDO membership may apply.

2.3.3 Standards Acceleration

A standards acceleration SD-PPP is primarily focused on convening stakeholders to discuss opportunities, challenges, and needs for a given technology and applicable sectors. The primary objective of SD-PPP activities may not be to develop standards but instead support pre-standardization efforts. Ultimately, the desired outcome is to determine if there is consensus about the need for standards, and to help advance decision-making and therefore accelerate subsequent standards development.

Table 3: Standards Acceleration SD-PPP Model Characteristics

Partners Involved	SDOs, research institutions, industry, workforce development providers, government
Objectives	Accelerate the development of standards by convening experts to increase awareness about existing and needed research and standards
Work Products	Pre-standardization: technical workshop and symposia, standards road mapping (landscaping and gap analyses), and other research and technology reports
Convening Mechanisms	- Meetings (various forms) of stakeholders through committees, subcommittees, and working/task groups which are organized by one of the PPP partners - Collaborative electronic tools used for draft development and approval of work products
Public Sector Role	Government actively participates in the activity at varying capacities including contributing expertise for development of the work products, such as chairing a committee, participating in short and long-term strategy development, hosting meetings, and providing liaison reports
Private Sector Role	Private sector actively participates in the activity at varying capacities including contributing expertise for development of the work products, such as chairing a committee, participating in short and long-term strategy development, hosting meetings, and providing liaison reports
Funding Considerations	- Public and private sectors may provide financial support. If a direct result of a grant, the private sector funding may be matched by public sector funding in whole or in part. - Public and private sectors may proivde in-kind contributions via technical expertise, host events, as in-kind support. - Private sector may offer financial sponsorships. Contributions are typically received from trade associations and consortia to offset costs for roadmapping efforts.
Agreement Considerations	- An agreement, such as a cooperative agreement or MOU, may be unitized to cover roles and responsibilities of activity sponsors - A non-disclosure agreement (NDA) may be utilized and be applicable to all participants. - Terms and conditions for membership may apply depending on which organization is supporting the activity.

2.3.4 Funded Participation

A funded participation SD-PPP is utilized to increase participation of subject matter experts in the standards development process. Often, startups, small or medium-size enterprises in new or niche technology areas, have limited resources to travel and participate in standards, or, the sector has not yet established enough resources to have as many subject matter experts who have longstanding knowledge and experience both in the field and in standards development. Both resource constraints can delay standards development or impact a balance of representation. For this to be a PPP, some funding for individuals to participate would need to come from the government but may also come from the private sector.

Table 4: Funded Participation SD-PPP Model Characteristics

Partners Involved	**Government, industry, research institutions**
Objectives	Support increased participation to balance the representation of stakeholders in an activity including small and medium-size enterprises, startups, or key technical experts without the resources to pay participation (membership/event) fees or travel
Work Products	N/A, this supports standards development but the objective is not a tangible work product.
Convening Mechanisms	- N/A, beyond communications among the government, applicant, and SDOs, no activity is convened as a result of this PPP. - Funding recipient would participate in the SDO activities via their convening mechanisms.
Public Sector Role	- Active communications with SDO and industry about gaps in expertise at the table - Allocate funding in agency budget and have an application process to access funds - Active participation in standards development is necessary from the public sector if policy/regulations implications exist or are anticipated.
Private Sector Role	- Solicit funding from the public sector through the mechanisms offered by the government. - Active communications with the government about gaps in representation - Active participation in standards development is necessary from the private sector.
Funding Considerations	- Funding from public entities may be allocated from a government grant or government project budget. - Funding from the private sector may be allocated as well; however, public funding is required for this to be a PPP.
Agreement Considerations	- The partnership may be formal (with contractual agreement) or informal (without contractual agreement). - The government may have an application process and terms for an applicant to abide by. - Contracts may be utilized to cover roles, responsibilities, and reporting of funding providers and recipients.

2.3.5 Funded Standards Development

A funded standards development SD-PPP is utilized when stakeholders need resources to conduct research, testing, or data gathering to help inform and develop standards. The activities may result in content development (such as test methods, best practices, or design requirements), technical presentations at a SDO meeting, or help with anonymizing information so industry data can be shared without revealing IP. In some cases, funding is allocated to an organization or to an individual with the objective of drafting a standard(s).

Table 5: Funded Standards Development SD-PPP Model Characteristics

Partners Involved	**Government, industry, research institutions, SDOs**
Objectives	Accelerate standards development by funding initial research
Work Products	- Pre-standardization: Research, research reports, databases, statistics - Pre-standardization: Formation of a new standards developing committee or SDO - Standards Development: Draft proposed test methods, design specification, best practices - Implementation: Increasing awareness, technical training, workforce development on standards
Convening Mechanisms	- Structure: A center of excellence (COE) or institute may be formed to carry out the research but this is not always the case. A singular or narrow scope of research may not require a formal structure to be established. - Strategic Planning: Convene Advisory / Steering committee meetings to direct and maintain the mission, goals, and strategic direction of the project - Research Projects: Convene meetings and events to outline project scope, execute project and evaluate results
Public Sector Role	- Active communications with SDO and industry to learn and identify challenges and solutions to standards development obstacles - Allocate funding in agency budget and have an application process to access funds - Active participation in standards development is necessary from the public sector if policy/regulations implications exist or are anticipated
Private Sector Role	- Solicit funding from the public sector through the mechanisms offered by the government - Active communications with the government about challenges and solutions to standards development obstacles - Active participation in standards development is necessary from the private sector
Funding Considerations	- Public and private sectors may provide financial support. If as a direct result of a grant, the private sector funding may be matched by public sector funding in whole or in part. - Public and private sectors may proivde in-kind contributions via technical expertise, host events, as in-kind support. - Private sector may offer financial sponsorships. Contributions are typically received from trade associations and consortia to offset costs for efforts.
Agreement Considerations	- An agreement, such as a cooperative agreement or MOU, may be utilized to cover roles, responsibilities, and reporting of funding providers and recipients. - A non-disclosure agreement (NDA) may be utilized and be applicable to all participants.

2.3.6 Policy and Conformance Driven

A policy and conformance driven SD-PPP is utilized when the public and private sector collaborate to develop standards specifically to meet a new regulation, policy, or conformity assessment requirement. Initiation of this SD-PPP may also be the result of an emergency (e.g., pandemic or incident involving fatalities). This SD-PPP stands out as its own model solely because it requires rapid development of one or more standards and dedicated resources to accomplish this in a specific timeline. This scenario typically involves a combination of characteristics described in the Direct Participation, Standards Acceleration, and Funded Participation SD-PPP models.

Table 6: Policy and Conformance SD-PPP Model Characteristics

Partners Involved	**Government, industry, research institutions, SDOs**
Objectives	Enable or accelerate standards development to support an anticipated new regulation or certification requirement. The standards are expected to be incorporated by reference.
Work Products	- Pre-standardization: Strategic plans and roadmaps - Standards Development: Standards (one or more standards) - Implementation: Increasing awareness, technical training, workforce development on standards
Convening Mechanisms	- Meetings (various forms) of stakeholders through committees, subcommittees, and working/task groups which are organized by one of the PPP partners - Collaborative electronic tools used for draft development and approval of work products - Direct commuication to determine, execute and report milestones
Public Sector Role	- Lead or actively participate in communications with the private sector to jointly develop a strategic plan which sets forth specific needs, timeline with milestones, and other necessary expectations for execution - Allocate funding in agency budget to ensure government staff have support to actively engage in strategic plan development and execution
Private Sector Role	- Lead or actively participate in communications with public sector entities to jointly develop a strategic plan which sets forth specific needs, timeline with milestones, and other necessary expectations for execution - Determine if additional funding is needed and budgeted for to support the private sector if acceleration of deliverable is needed - Allocate funding in organizational budgets to ensure staff have support to actively engage in strategic plan development and execution
Funding Considerations	- Funding is not required by the public or private sector. In some instances, each organization provides non-financial contributions based on the services an organization normally provides or expertise a representative is permitted to share. - To ensure success, all stakeholders will need to allocate additional time and resources for acclerated efforts over longer periods of time. It may require that responsibilities of non-related activities are reallocated to other staff temporarily or permenantly. In addition to time investments, it is likely that travel to events will increase significantly especially as the activity begins. - SDO membership fees may apply
Agreement Considerations	- The partnership may be formal (with contractual agreements) or informal (without contractual agreement). - If funding is part to the partnership, agreements may be utilized to cover roles, responsibilities, and reporting of funding providers and recipients. - A non-disclosure agreement (NDA) may be utilized and be applicable to all participants.

2.4 Standards-Driven Public-Private Partnership (SD-PPP) Use Case Analysis

During literature review and interviews related to numerous public-private partnerships, ANSI was striving to determine whether the PPP activities included pre-standardization, standards development, or standards related implementation activities. In some instances, ANSI concluded that the PPP was not a standards-driven PPP, although it supported technology development. ANSI has retained several examples in Appendix D.

Building on the evaluation of traditional public-private partnerships to support infrastructure development, advance research and development, and spur socio-economic or environmental improvement, ANSI generated five questions to aid in evaluation and comparison of several SD-PPPs. The details included in the SD-PPPs found in Appendix D follow these five areas that were identified through research and direct communications with partners involved in the PPP.

Area 1	**What were the drivers for this public-private partnership (PPP)?**
Request	Describe the drivers for this PPP. Some common drivers include response to draft/published legislation, agency policy, incident response, safety, compliance, efficiency, new technology integration.
Result	There were several drivers for the SD-PPPs including to increase safety and security, increase awareness about standards, support conformity assessment, accelerate integration of a new technology into the market (for one or more use cases/sectors), improve efficiency and reliability, and benchmark technologies. Some of the SD-PPP uses cases were driven by legislative actions and others from environmental or economic studies.

Area 2	**What were the goals and scope of work for the PPP?**
Request	Describe the work product(s) for the PPP as well as any short-term and long-term goals. Some common goals include the development of one or more standards, roadmaps, pre-standards R&D, workforce development, training, etc.
Result	Each SD-PPP was established to support a particular product, technology, or application of technology. The most common goal was to establish industry positions (speak with one voice), increase coordination and awareness, and align standards strategies with policy needs. While there are similarities in the missions, some PPPs were not organized for the purposes of supporting standards development but evolved into addressing the needs (e.g., developing a roadmap).

Area 3	**Role, Responsibilities & Participation:**
Request	Describe the role of the stakeholders (e.g., industry, government, academia) involved in the initiative. Some common roles seen include sponsorship, contractual agreements, strategy development, research, technical or content contributions, leadership, voting/abstaining, monitoring/active participation. Additionally, after initial work program began, how was the relationship maintained?
Result	In several of the use cases, the public sector provided funding and in-kind contributions. The private sector mostly drove the technical discussions with the public sector convening or as active participants. The public and private sector were both part of the strategic/advisory discussions.

Area 4	Implementation Methods:
Request	Describe how the PPP was executed and what tools or resources were leveraged. How were the public and private sector brought together to share information, develop resulting work products, and arrive at consensus? Some examples are utilization of working groups, workshops, mentorship, surveys, training, etc.
Result	Convening experts was the leading implementation method, mostly through committee and working group meetings and workshops. Surveys were not communicated as a common tool, but instead direct engagement between stakeholders in active discussions. Where formal discussions were noted, primarily in standards development activities and roadmapping, consensus was required and formal voting was conducted where needed, but not in all cases. It should be noted that in some instances, the SD-PPP was led and moderated by government and others by the private sector.

Area 5	Measurement of Success:
Request	Describe if and which PPP goals were achieved. Additionally, please describe any perceived or measured benefits. Some anticipated benefits include accelerated standards development, the PPP work products helped inform policy/regulations, standards were incorporated by reference, decreased incidents, etc.
Result	Various uses cases cite specific examples of success, such as completion of a roadmap, development of a standard (industry or government standard), and overall increased awareness about challenges and opportunities. In use cases where standards and roadmaps were not generated, there was an overall perception that standards readiness had not matured to support that result (e.g., research or more discussion needed).

3. BRAINSTORMING SESSIONS FOR CRITICAL AND EMERGING TECHNOLOGIES

3.1 ANSI Methods for Brainstorming Sessions

ANSI hosted two hybrid discussion-based brainstorming sessions to engage stakeholders in July 2024. The sessions explored challenges, opportunities, standards readiness, and the role of PPPs in sharing information and identifying priority standards development activities. The first event covered artificial intelligence and machine learning (AI/ML) with a focus on healthcare and manufacturing, and the second covered automated and connected infrastructure with a focus on transportation (ground vehicles and aircraft). The subtopics of healthcare and manufacturing, as well as ground vehicles and aircraft, were selected because they have different standards and market integration maturity levels.

The use of AI/ML in healthcare versus manufacturing presents different challenges, standards readiness and needs, and regulatory considerations. The use of automation in ground vehicles and aircraft also has different challenges (operational environments), standards readiness, and regulatory considerations. ANSI believed that providing the opportunity for these variabilities to surface would facilitate the evaluation of the role of PPPs for these technologies. Considerations identified could also inform standardization of other CETs.

Discussions in both brainstorming sessions were guided by the same questions and foundational concepts. For example, both sessions included briefings about the technology, the role of standards, standards readiness phases and considerations (see section 3.2), public-private partnership models (specifically Section 2.3), and current information sharing practices and needs reflected by industry through the NIST RFI and listening sessions (see section 1.1.5 and section 4.2.4.1). Overall, each brainstorming session asked specific questions that targeted:

- What is the overall awareness by the public and private sectors of challenges and opportunities where the technologies converge in a sector or industry application?
- What is the maturity of standards development to support one/both technology(ies)?
- Is the pace of standards development on par with the technology maturity level?
- What is the overall awareness of the public and private sectors about: (1) technology-specific standards development; (2) conformity assessment / certification needs; (3) research and development needs?
- What role(s) is the government currently playing in pre-standardization activities and standards development for these technologies?
- What could be done to accelerate standards development and market acceptance?
- What benefits or challenges do you see with a PPP for this/these technologies?
- What type of PPP model could benefit this/these technologies and at what (if any) point would an organized PPP activity be most advantageous?

Attendees provided input in advance of each brainstorming session on the challenges and opportunities associated with the technology, standards, PPPs, and information sharing. During each session, live discussion was augmented by Slido[9] polls providing quantitative and qualitative context from attendees in the room and online. This hybrid engagement was leveraged across all four sections of the events:

- Session 1: Technology Convergence and Standards Readiness Briefings
- Session 2: Challenges, Opportunities and Standards Readiness Discussion
- Session 3: Standards-Driven Public Private Partnerships
- Session 4: Information Sharing Necessary to Support CET Standards Development

3.2 Standards Readiness Briefings

The term standards readiness is not defined. It is proposed as a concept to assist in evaluating when to initiate a standardization activity for a given technology or sector. Various types of standardization activities (e.g., landscape

[9] Interactive online tool which supports participant engagement: www.slido.com

analyses, roadmaps, standards development, conformity assessment) exist and each can support the path to standardization in different ways and at different times.
An established way to evaluate and measure standards readiness is also not defined. Should the evaluation of standards readiness be aligned with Technology Readiness Levels (TRLs), DoD Manufacturing Readiness Levels (MRLs), or developed independently? Does the standardization community need standards readiness "levels," and if so, how can one go about developing such a scale and how could it be measurable? Two standards readiness briefings were offered during Session 1 at both brainstorming events which helped provide context and support event discussions.

NIST Notional Standardization Readiness Considerations

Clare Allocca, NIST, presented NIST's perspective and efforts to evaluate what factors influence standardization readiness and what information is needed to make an informed decision to engage in standards development activities. NIST drafted notional considerations[10] of standardization readiness, which inform a standardization strategy which are included in Ms. Allocca's presentation and are briefly highlighted as follows:

- **Technology**: Has it been proven, it is part of a broader system of technologies, or can it be measured?
- **Market**: Are there multiple players in the market, defined use cases, policy considerations, or an effective supply chain?
- **Community**: Standards should be informed by and support the diverse perspectives including producers, users, government, academia, etc. Is there broad-based benefit for this diverse community?
- **Capacity**: Is the community willing to come to the table and include balanced representation and participation?

These notional considerations were explored during a recent NIST CHIPS Research and Development Office's Standardization Readiness Level (StRL) Workshop (June 2024) to consider community perspectives on metrics for standardization readiness. NIST has been working with international standards working groups to further the concept of standardization readiness and apply it to other critical and emerging technology areas.

ANSI Notional Standards Readiness Phases

Christine DeJong Bernat, ANSI, presented notional standards readiness phases which evolve based on private sector's (industry's) willingness to share information. The willingness is evidenced by the level of information shared by stakeholders in various forums (e.g., consortia/associations, standards organizations, research institutions, regulators). ANSI mapped standardization activities across three phases – pre-standardization, standardization, and implementation. The pre-standardization phase comprises two sub-phases – premature and exploratory. The standardization phase comprises both planning and development sub-phases.

These sub-phases are outlined in Table 7 (white rows) of Ms. Bernat's presentation and are briefly highlighted as follows:

- **Premature:** At this phase, there are not enough stakeholders or consistency in technology to evaluate design and performance. Additionally, if there is more customization of technology rather than stabilized and consistent designs, it is less likely that industry will wish to standardize. The sector is looking towards existing standards to evaluate their technology internally and assess where it could fit in the market.
- **Exploratory:** Stakeholders have entered the exploratory phase of standards development if they have begun finding synergies with other technology in the marketplace. They know better who to engage within the supply chain, are using related standards more consistently, and have begun exploring regulatory or compliance considerations. More organizations are publicly speaking about their technology development or identifying as a player in the market.

[10] NIST draft notional considerations were shared with brainstorming session attendees and should not be regarded as final. The version linked to this report was last updated in January 2024.

- **Planning:** This phase begins when industry starts to identify existing standards which apply broadly or specifically to their technology. This landscape review will aid stakeholders in the identification of gaps. Terminology becomes increasingly critical so stakeholders may begin to convene to gain consensus on this front. Lastly, during this phase, industry agrees that standards are needed and begins to engage SDOs.
- **Development:** During this phase, a balanced representation of stakeholders exists and engages with one or more SDOs (through existing committee(s) or by forming new ones). Development of standards begins and may be done with or without a strategic plan. The pace of standards development varies and is dependent upon several factors. This stage will repeat indefinitely as new standards are developed, and existing standards are revised, stabilized, or withdrawn.
- **Implementation:** The implementation phase is where standards are effectively used by industry in contracts, certification programs or regulation and policy. Feedback on standards content is redirected to SDOs and updates are made as needed.

Table 7 shows the connectivity among the activities (blue rows) associated with the five SD-PPPs models and the activities outlined in the standard readiness phases. Similar to the SD-PPP models, phases of standards development do not have hard start and stop points. Activities throughout these phases may overlap, be revisited or re-strategized, or sunset throughout the lifecycle (entry, maturity, innovation, or retirement) of a product in the marketplace.

Table 7: Crosswalk Between SD-PPP and Standards Readiness Phase Activities[11]

	PRE-STANDARDIZATION		STANDARDS DEVELOPMENT		IMPLEMENTATION
	STANDARDS READINESS PHASES				
	PREMATURE	EXPLORATORY	PLANNING	DEVELOPMENT	IMPLEMENTATION
Standardization Activity	- No discussions/interest in standardization	- Identification & evaluation of existing related standards & conformity assessment programs of similar technologies - Benchmarking	- Landscape & gap analysis - Roadmapping - Terminology development - Soliciting stakeholder engagement	- Standards committee(s) formed - Soliciting leadership and stakeholder engagement - Standards drafted, approved & maintained	- Standards approved, **maintained** & utilized - Conformity assessments - Referenced in law or regulation, as applicable
Potential SD-PPP Model(s)	- No drivers for SD-PPP exist yet	- Standards Acceleration - Policy & Conformance Driven	- Standards Acceleration - Funded Standards Development - Policy & Conformance Driven	- Direct Participation - Funded Standards Development - Funded Participation - Policy & Conformance Driven	- Direct Participation - Funded Standards Development - Funded Participation - Policy & Conformance Driven
Potential SD-PPP Activities	- N/A	- Focus Groups - Technical Workshops - Landscape Analyses - Regulatory/Conformity assessment review	- Gathering critical mass & establishing balance of experts - Focus Groups - Technical Workshops - Technical/Research Reports - Landscape Analyses - Standards Roadmaps - Strategic Plans (R&D/Standards) - Regulatory gap assessments	- Sustain balance of experts & critical mass - Technical workshops - Technical/Research Reports - Continued R&D - Coordination on standards & policy development priorities - Continued strategic planning - Workforce development	- Sustain balance of experts & critical mass - Technical training / workshops to increase awareness & adoption - Workforce development - Continued R&D - Evaluation of standards impact along with refinements and expanding on portfolios
Information Sharing & Awareness	- Internal prototyping/research has begun - Stakeholders working independently - Consortia/Association discussions not taking place, or do not exist for a particular technology	- Collaborative research takes place - Like-minded stakeholders sharing minimal information - Consortia/Association discussions & evaluation begin	- Research is being strategized - Like-minded stakeholders collaborating & sharing minimal information more broadly - Consortia/Association position/issue papers developed	- Research is ongoing - Balanced representation of stakeholders collaborating - Stakeholders investing resources to draft & vote on standards - Consortia/Association recommendations issued	- Research is ongoing - Balanced representation of stakeholders collaborating & doing business - Stakeholders investing resources to draft & vote on standards - Consortia/Association advocating for standards adoption

[11] Appendix C includes a table with Standards Readiness Phases table and the crosswalk to SD-PPPs table for ease of reference.

4. ARTIFICIAL INTELLIGENCE (AI) AND MACHINE LEARNING (ML) BRAINSTORMING SESSION

The final agenda for the event is found in Appendix C.1.

4.1 Background

What is artificial intelligence (AI)? How can the USG, industry, and standardization community better understand its role and impact?

AI is not just one technology, but a variety of software and hardware enabling technologies (machine learning, deep learning, knowledge representation) that can be applied in various ways in a potentially unlimited number of applications, ranging from manufacturing to financial services, and health care to transportation. As recognized in Driving U.S. Innovation in Artificial Intelligence: A Roadmap for Artificial Intelligence Policy in the United States Senate:

> *AI's [has the] capacity to revolutionize the realms of science, medicine, agriculture, and beyond; the exceptional benefits that a flourishing AI ecosystem could offer our economy and our productivity; and AI's ability to radically alter human capacity and knowledge. At the same time, we each recognized the potential risks AI could present, including altering our workforce in the short-term and long-term, raising questions about the application of existing laws in an AI-enabled world, changing the dynamics of our national security, and raising the threat of potential doomsday scenarios.*

The May 2024 Roadmap was developed by the Bipartisan Senate AI Working Group and includes several recommendations about legislation, appropriations, research, continual assessments, and more. The recommendations were influenced by discussions with stakeholders at nine Insight Forums and several recommendations touched on standards and PPPs, specifically:

- Encourages the relevant committees to develop legislation to leverage **public-private partnerships** across the federal government to support AI advancements and minimize potential risks from AI (pg. 8)
- Explore mechanisms, including through the use of **public-private partnerships**, to deter the use of AI to perpetrate fraud and deception, particularly for vulnerable populations such as the elderly and veterans (pg. 12)
- Supports the development of **standards** for use of AI in our critical infrastructure and encourages the relevant committees to develop legislation to advance this effort (pg. 11).
- Believes the federal government must ensure appropriate testing and evaluation of AI systems in the federal procurement process that meets the **relevant standards**, and supports streamlining the federal procurement process for AI systems and other software that have met those standards (pg. 12).
- Encourages the relevant committees to consider whether there is a need for additional standards, or clarity around existing **standards**, to hold AI developers and deployers accountable if their products or actions cause harm to consumers, or to hold end users accountable if their actions cause harm, as well as how to enforce any such liability **standards** (pg. 14).
- Encourages companies to perform detailed testing and evaluation to understand the landscape of potential harms and not to release AI systems that cannot meet industry **standards** (pg. 12).
- Support efforts related to the development of a capabilities-focused risk-based approach, particularly the development and **standardization of risk testing and evaluation** methodologies and mechanisms, including red-teaming, sandboxes and testbeds, commercial AI **auditing standards**, bug bounty programs, as well as physical and cyber security standards. The AI Working Group encourages committees to consider ways to support these types of efforts, including through the federal procurement system (pg. 16).

President Biden's Executive Order on the *Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence* (EO 14110 Sec 11. Ii(b)) directed the Secretary of Commerce to "establish a plan for global engagement on promoting and developing AI standards." With input from the private and public sectors, NIST developed NIST AI 100-5: A Plan for Global Engagement on AI Standards (hereafter Plan) in July 2024. The Plan broadly summarizes priority topics for and

desired outcomes from standardization work, global engagement activities, the importance of standards for AI, a landscape of AI standardization activities.
NIST AI 100-5 provides a list of high priority standards activities which either serve as foundational standards, increase trustworthiness, or increase adoption of AI. Additional details on each of the following are included in the report:

- Terminology and taxonomy
- Measurement methods and metrics
- Mechanisms for enhancing awareness and transparency about the origins of digital content
- Risk-based management of AI systems
- Security and privacy
- Transparency among AI actors about system and data characteristics
- Training data practices
- Incident response and recovery plans

Recommended actions for U.S. public and private stakeholder engagement in global standards include direct engagement in standards activities (including pre-standardization), support for horizontal (across sectors) standards, assistance with implementation of resulting standards and guidelines, and ensuring that continued information sharing is enabled. NIST also highlights the importance of the USG to "leverage opportunities to align and collaborate on standards such as Joint Committee Meetings, AI working groups, public-private partnerships."

The Plan is guided by principles set out in the National Institute of Standards and Technology (NIST) AI Risk Management Framework (AI RMF) published in January 2023 and the USG NSSCET. This framework helps better manage risks to individuals, organizations, and society associated with AI and supports the fourth priority standards area listed above.

AI Standards Development Activities

An AI standards landscape was not part of ANSI's project objectives. Readers are encouraged to review NIST AI 100-5 Appendix B which provides a detailed summary of activities. From a high-level, it is beneficial to recognize that there are ongoing vertical (AI technology-specific) and horizontal (sector-specific) standard efforts. Brainstorming session discussions explored the needs and awareness along these fronts.

As communicated during ANSI event planning discussions, and as emphasized in the event, the ISO/IEC JTC 1 SC 42 Artificial Intelligence has been developing vertical / technology-specific standards and coordinating with outside entities to offer guidance related to sector-specific applications of their work. The SC42 was created in 2017 and ANSI is the Secretariat. Their work programme includes numerous published and in-development standards. Various standards organizations are working to identify how AI will impact their members and standards activities, some of which have formed working/task groups to coordinate their initiatives.

4.2 AI/ML Brainstorming Session Summary

This event took place on July 17, 2024. Approximately 150 individuals attended from over 90 organizations. Organizations included academia, AI developers and deployers, consortia, research institutions, standards and code developers, U.S. government, and trade associations.

ANSI issued various Slido polls throughout the event. Responses (mostly anonymous) were received from in-person and online attendees and the level of participation varied throughout the event. The Slido polls and results supplemented live discussion. Some Slido feedback is incorporated into written summaries and some polls are shown graphically. The Slido results should not be regarded as an industry position as this was not a formal targeted survey effort.

4.2.1 Understanding Technology Convergence and Standards Readiness

The methods used to evaluate and regulate tangible products is different from those used for digital products. Digital products and services are complex and no ecosystem for their conformity assessment has been established. Laura

Lindsey, Microsoft, opened the technical discussion, speaking to the need for standards to help enable trust, accountability, transparency, and global coherence, and to support market adoption and regulatory outcomes. Lindsey detailed standards activity within ISO/IEC that aims to establish that foundational AI ecosystem, including ISO/IEC 42001 Information technology - Artificial intelligence - Management system. She also spoke on the role and challenges of conformity assessment schemes with management system standards (also referred to as "joint certification"). See Ms. Lindsey's presentation here.

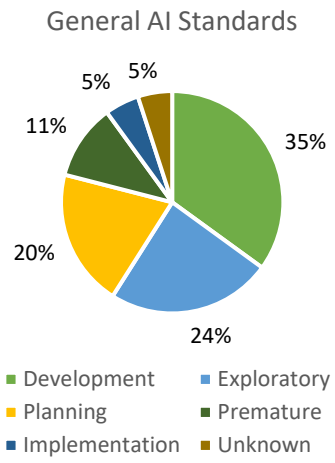
Following Ms. Lindsey's briefing, Clare Allocca (NIST) presented standards readiness considerations and Christine Bernat (ANSI) presented about standards readiness phases. A summary of both briefings is found in section 3.2).

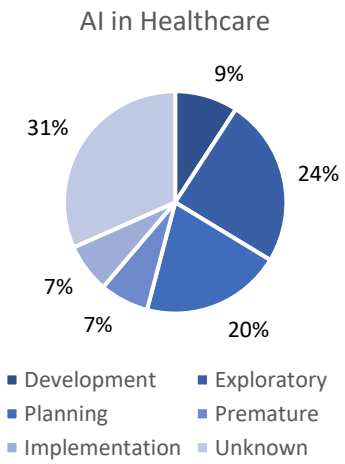
4.2.2 Challenges and Opportunities and Standards Readiness Discussion Goals

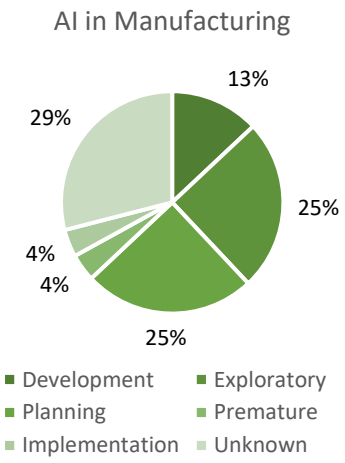
Various factors come into play when evaluating whether conditions are right to embark on a standardization activity for a given technology, and to help predict development needs and timing of a standardization strategy. Attendees were asked the following questions to support the healthcare and Manufacturing discussions:

- What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?
- What role do stakeholders see standards playing in overcoming challenges?
- What is the role of industry vs government to maximize opportunities?
- What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?
- What is the role of government to maximize opportunities? To support standards development?

Before conversations began, attendees were asked in what phase of standards readiness are general AI standards, AI standard for healthcare, and AI standards for manufacturing. One possible interpretation of these results is that there is more awareness about general AI standards than vertical standards supporting healthcare and manufacturing. This interpretation is supported because standards development on AI in healthcare is in development. Additionally, the subsequent poll resulted in a low rating of perceived awareness about standards activities.



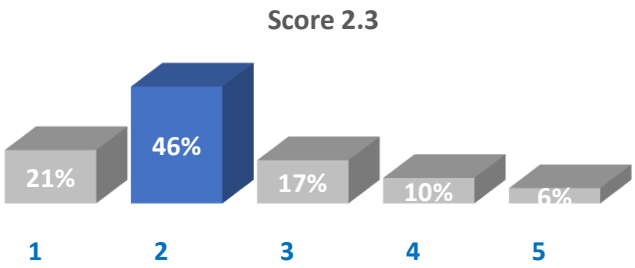




What is the overall awareness of AI standards activities?

Polling:

Attendees were polled to rate the perceived overall awareness of AI standards activities today. The score was a 2.3 out of 5, with 1 being low and 5 being high.



4.2.2.1 AI / ML in Healthcare

Moderator: Shawn Forrest, Digital Health Center of Excellence (DHCoE), U.S. Food and Drug Administration (FDA)

Opening Remarks: Mr. Forrest is part of a task force at the Center for Devices and Radiological Health (CDRH) which looks at which standards would support FDA in regulating devices and also participates in ISO/IEC SC42. The FDA has been examining AI (including standardization) over the last few years. For example, the role of standards to enable the use of AI by quality assurance labs and in certification is under consideration. The FDA published a list of submissions[12] which highlight AI technologies which enable them. The trend is showing a sharp increase of AI use. In advance of the session, attendees provided feedback about the opportunities and challenges with AI which apply to multiple industries and are not necessarily specific to healthcare alone. As acknowledged in this feedback, AI provides efficiencies and may highlight findings that healthcare professionals could miss. The healthcare industry has workforce shortages and AI is a timely tool to support this sector.

What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?

Discussion:

Attendees reviewed the feedback submitted prior to the event. Discussion focused on the following areas as summarized below:

1. **Information modeling improvements:** Is this an opportunity or a challenge? Reducing repetitive work to support clinical workflows is an opportunity. However, information, technologies, people, and workflows are always interacting in a healthcare setting. The information flows from one place to another, from one collaborator to another, however, the U.S. does not have interoperable healthcare system. Is a lack of interoperability a barrier to leveraging AI in healthcare?

   Currently mapping between systems and sources is done manually. If we have trained AI models which understand the mapping from different sources, where AI interprets the data it receives, it could enable interoperability. When do we trust AI enough to do that translation? Large language models (LLMs) had the

[12] U.S. Food and Drug Administration. Accessed August 15, 2024. *Harnessing the Potential of Artificial Intelligence*. https://www.fda.gov/news-events/fda-voices/harnessing-potential-artificial-intelligence#:~:text=To%20give%20you%20an%20idea,submissions%20for%20AI%2Denabled%20devices.

ability to learn new languages without training. If AI can get there, it will help make information from different sources more cross-functional.

The timing for implementation of this seems far off because it unlikely that the healthcare industry will share its data models and electronic health records (EHRs). It may necessitate federal requirements, akin to what exists in Canada and the U.K. However, for example, in cardiology, the users demanded interoperability which encouraged the cardiologists and the manufacturers (National Electrical Manufacturing Association - NEMA) to collaborate and overcome challenges to achieve this.

2. **Ecosystem Awareness:** Education about the landscape of standards, such as increasing the awareness about horizontal standards and how they can be applied to various sectors, how they can be integrated into vertical standards. Exploration and education about the commonalities within healthcare (e.g., pharmaceuticals, hospitals, research, laboratories). Once commonalities are identified, then developing solutions to challenges (such as terminology) and identification of standards applications and needs are easier to tackle.

   There may be risks of having too many people at the table to focus on a singular solution; however, it may be helpful to organize experts from like-minded industries, with similar use cases, or similar risk profiles, to establish common challenges and solutions. There will likely be some alignment on topics such as data management and evaluation of the robustness of a model.

3. **Trust and Governance:** Standards alone may solve the challenge of trust but governance may help improve transparency and bias mitigation, or other problems that may arise from technology. Some additional challenges are:
   - ownership of AI generated data related to specific patient conditions
   - communications with the public and the patients on the benefits and risks of AI enabled medical devices
   - transparency and explainability, particularly for generative AI, especially in healthcare

   Established in 2020, the Data and Trust Alliance has developed three data provenance standards, which will be hosted by OASIS (consortia standards body). If, when, and how would these types of standards need to transition into the broader international standards?

Polling:

Additional challenges and opportunities were provided via Slido during the event, in addition to those collected prior to the event. Below is a list of the feedback ANSI received, which is organized by subject area:

Opportunities	***Challenges***
Information modeling improvements	Standardizing practices for patients and providers
Revalidation processes (for healthcare models)	Privacy of health data (especially in use of data for training)
Address workforce shortage via AI supported workflows and EHR platforms	Ownership of AI-generated data related to specific patient conditions.
Reduce repetitive work / human errors	Communications with the public and the patients on the benefits and risks of AI enabled medical devices
Clinical decision support	Determination of liability
Assist pattern analysis in medical images	Trust
Precision health, algorithmic medicine, virtual health assistants, digital clinical encounter precision medicine, digital speech analysis for clinical diagnosis, automated patient decision aids, ambient digital scribes, AI enabled diagnostic image interpretations, computer assisted coding and documentation	Premature deployment without testing in real-world
Support public health emergency preparedness & response	Data/algorithmic bias

Link with interdisciplinary teams to exchange best practices.	Data governance, data sharing vs privacy & security
Equal access to healthcare (e.g., low-income families / low-resource areas)	Transparency in AI decision-making
Integration of nanotechnology	Cost and outcomes: Who will pay for AI?
Faster development of QA/QC testing methods to ensure product quality	Workforce Development: Risk and benefits training as well as erosion of skill.
Potential for innovative solutions for unmet medical needs that were not possible with existing technologies	Capacity Building
Rapidly accelerate to allow personalized medicine	Integration with the third-party service providers
	The speed of development international standards / Standardization keeping pace with the technology

What role do stakeholders see standards playing in overcoming challenges?

Discussion:

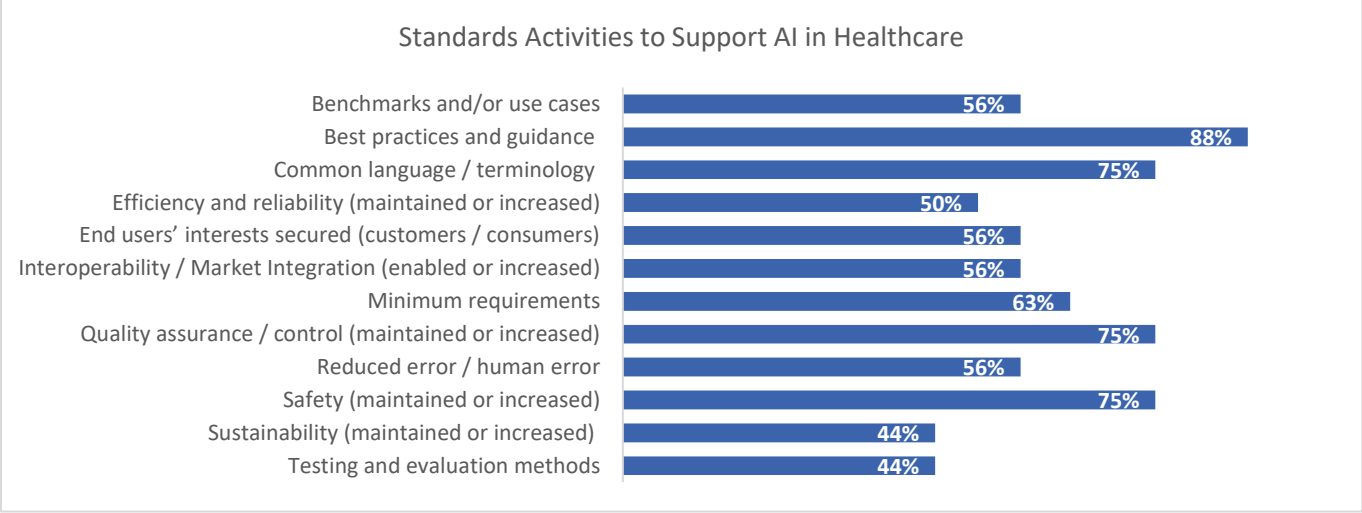
The role of standards as they relate to the specific challenges was discussed under the prior question. Building on that discussion, two new areas were highlighted:

1. **Supporting Regulation --** Standards will be needed to help the regulatory structure because the pace of regulations is not able to keep up with the pace of innovation. The pace of standards will still be challenging but progress could be made if done incrementally. Standards can be a tool to help all stakeholders, including regulators like the FDA.

2. **Supporting Conformity Assessment –** Criteria is needed to assess against. Variances (or broader allowances) in the criteria against which conformity is measured will result in different assessment outcomes. Standards need to be evolving to the point where they get to a level of specificity that the conformity assessment gives applicants and users what they would expect when something else gets certified, tested, or inspected. For example, the ISO/IEC 42001 AI management system standard is high-level. If two systems certified as meeting 42001 have different outcomes (i.e., different AI systems given the same information result in different answers), it will create confusion in the marketplace. The next step for addressing this challenge is to identify or develop those other standards which fill that gap (on trustworthiness, explainability).

Polling:

Standards offer many benefits. Attendees were asked to select which of the following standard work products or results would help enable AI in **healthcare**. Best practices and guidance were identified as the top need. The results are as follows:



What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?

Discussion:

- **Guidance about Regulator Needs:** The private sector needs guidance from the regulators about what standards they need in order to support the regulatory infrastructure. This would better direct industry on what to expend their time and resources to develop. The approach emphasizes less that industry tells regulators what regulations industry needs and more that the regulators tell industry where there are gaps and needs the standards can help fill to support their overarching framework and infrastructure.

- **U.S. Legislation:** The European Commission has the AI Act (Regulation (EU) 2024/1689) which provides AI developers and deployers with requirements regarding specific uses of AI. It would be helpful if the U.S. had something similar, a federal AI policy, which industry could then supplement with standards.

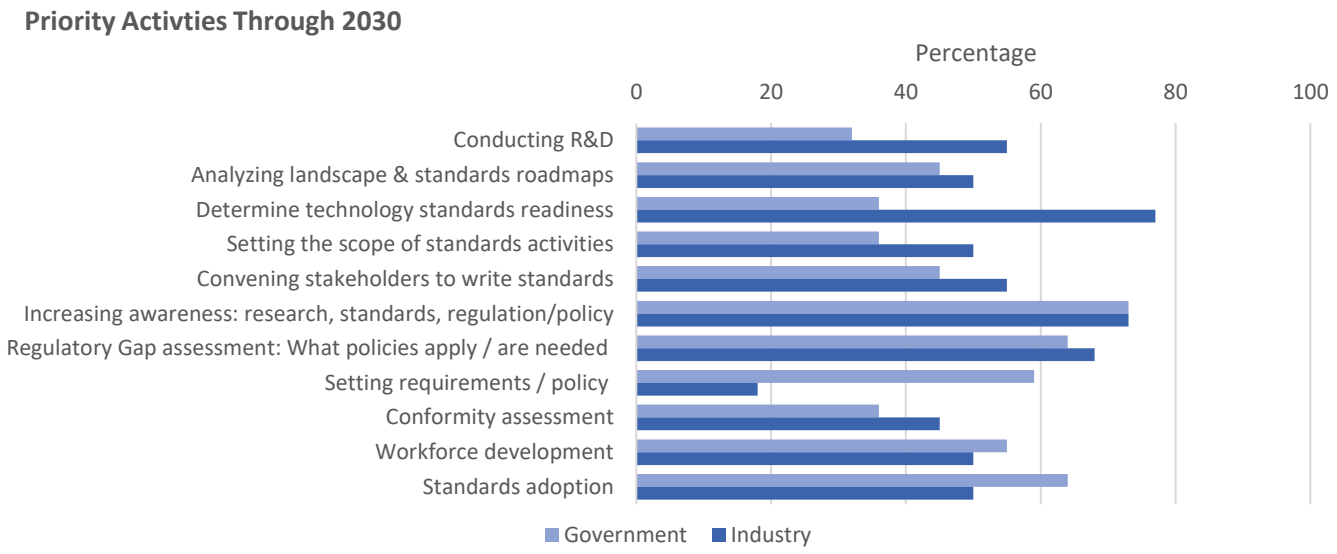
- **Other Healthcare Specific Feedback:** In addition to the two high-level suggestions above, attendees also suggested the following:

    - Multiple frameworks would be needed, or branch off a main framework. Healthcare, med devices, pharma, biologics. All have similar yet different needs. Some of these will have more cross-over than others.
    - AI framework for public health & healthcare emergency preparedness/surveillance.
    - Health data privacy rules to protect patients
    - Regulation that clarifies the role of medical practitioners and of support they receive from AI. If this is not clear, AI may have many patients thinking they do not need healthcare professionals and run the risk of malpractice.

What is the role of industry vs government to maximize opportunities? To support standards development?

Polling:

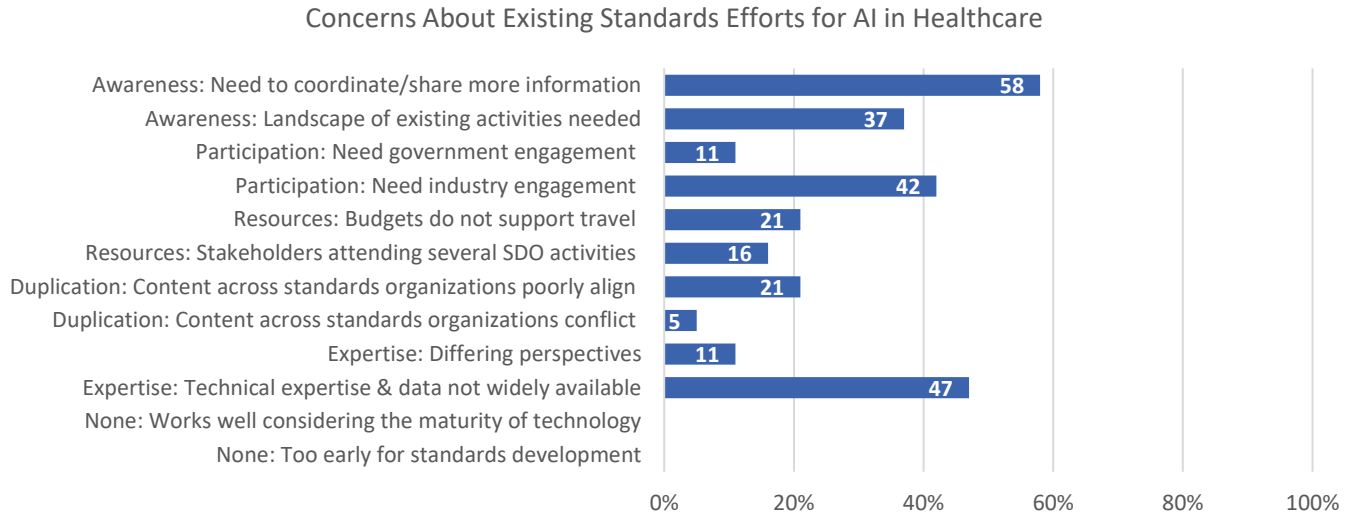
Attendees were provided a list of activities which could potentially enable AI in healthcare. They were asked to identify which the industry and government should prioritize over the next five years. The results are as follows:



What concerns have been raised about existing standards efforts?

Polling:

Attendees were provided a list of common concerns which could potentially slow or hinder standards development. They were asked to identify which three have been raised from their perspective. The results are as follows:



4.2.2.2 AI / ML in Manufacturing

Moderator: Franck Journoud, National Association of Manufacturers (NAM)

Opening Remarks: NAM sees applications of AI in the "shop floor" both upstream and downstream. Upstream manufacturing in design of products (market and production data, mechanical and chemical properties) over the last 15 years. There has been an evolution of manufacturing over the last 20 years towards increased digitalization – sensor technologies, automation, and implementation of AI to optimize the manufacturing process itself. The operation of manufacturing equipment has seen benefits of using AI to support predictive maintenance rather than corrective repairs, gains in efficiency, and assure quality of product output. These benefits also have positive impacts on worker safety as well. Downstream from the shop floor (management of the supply chain), AI helps predict, prevent, and mitigate disruption both for components and logistics management.

Company decision makers wanted their data to remain closely guarded so significant trust is required. Data is shared with vendors, suppliers, and consultants. Data quality is an important issue to manufacturing regardless of AI, and does impact the data output from AI (i.e., garbage in, garbage out). In a manufacturing process, many aspects are governed by either standards or regulatory requirements (safety, emissions, energy use); therefore, the AI systems need to support conformance to these requirements. Manufacturing uses for AI do not often raise public policy concerns beyond common implications of bias, equity, and privacy.

What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?

Discussion:

- **Standardizing AI:** Standardizing AI could be broken down into four parts**:** What information goes into the model, the model[13] itself, the information that comes out of the model and maintaining the model. Standardizing the

[13] Thieme, Anja, and Cicely Morrisson. September 19, 2022. Microsoft Research Blog. *AI Models vs. AI Systems: Understanding Units of Performance Assessment*. https://www.microsoft.com/en-us/research/blog/ai-models-vs-ai-systems-understanding-units-of-performance-assessment/.

model or systems is challenging at this stage; however, it is feasible to standardize what information goes in and comes out. There are many data standards available (e.g., data provenance, security) and under development today. There is a rapid shift in how AI is being used and applied, and therefore not all AI is ready for standardization, especially in manufacturing (where quantifiable results are desired). It is more important that the outputs are working, and are based on the inputs. However, there is interest in the model/systems being explainable.

- **Explainable AI:** What "explainable" is and what it should be are not the same. Explaining the mathematical process by which the model arrives at a decision would not be helpful. However, trust is built if we understand "why" it made a specific decision and that the decision is reproducible. Regulating the mechanics of the model/system is not beneficial. The need for standardizing "explainability" may not be critical, even if it is even possible to produce the types of explanations stakeholders are seeking. AI is used to guide users, for example, leading them to an issue in a manufacturing system, but there are multiple factors that impact what decisions should be made after identifying an issue. The manufacturer remains the decision-maker. Human-in-the-loop (intelligent automation vs AI), human-centered design, human-expectations, and usability should be the focus.

- **Replacing Workforce:** The use of AI in the workplace has raised the question about whether AI would replace humans in the workforce. However, no, AI would not replace a human because humans process a wider amount of data than AI. AI view is limited to that of data from sensors and the inputs humans give it. For example, it would detect an anomaly and then shuts down the system. However, the anomaly may be something very simple which should not require system shut-down. Only a human would be able to evaluate that and make informed decisions.

- **Horizontal vs Vertical Standards:** How are horizonal standards efforts applicable to manufacturing? Horizontal standards should be applicable to manufacturing but some additional guidance may be needed. For example, the risk management standards (ISO/IEC 42001) could be leveraged with some additional unique manufacturing guidance. ISO/IEC 42001 may help characterize risks of using AI in the manufacturing process, but there are several other standards and tools used more broadly for manufacturing today. It is important for the standards community to not reinvent the wheel and to leverage the work already done.

- **Automotive:** AI and ML are critical for manufacturing. Uptime is one of the most important functions for a manufacturing facility because products and parts cannot be delivered without it. AI helps staff monitor all their technology and enables predictive maintenance so downtime is minimized. Standards enable and secure this. SAE International has standards activities for AI in manufacturing in development.

- **How are the standards quantified?** Key performance indicators (KPIs) need to be established. Different manufacturing types and classes have different KPIs so identifying agnostic KPIs would be more advantageous.

- **Standards vs Proprietary Application Programming Interface (API) and Guidance:** As regulations are issued calling out what needs to be shown, standards can help do that in a broader fashion – addressing various global regulations – and a framework for demonstrating conformance and improving interoperability. Horizontal standards in AI, versus other domains, are trailing the technology. For example, 5G will not work without standards because the systems will not talk to each other. AI standards serve more as a governance function because AI systems do not have to perform the same ways or be technically interoperable. Methodologies for management, oversight, and data quality are still needed and cannot be captured in APIs. Lastly, APIs do not help the broader market, nor small and medium-size enterprises, but voluntary and government standards do.

Polling:

Additional challenges and opportunities were provided via Slido during the event, as well as collected prior to the event. Below is a list of the feedback ANSI received:

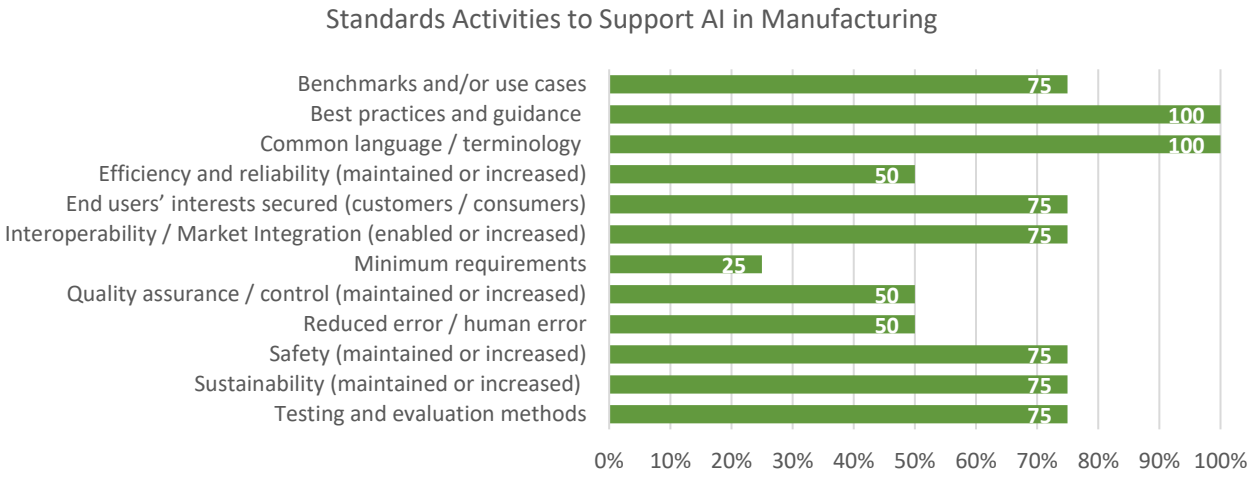
Opportunities	***Challenges***
Novel redesigns of conventional parts	IP protection
Restoring workflows or production lines	Trust
Asset, process & system monitoring and/or oversight	Data quality
Maintenance prediction & reporting	Risk analysis / ROI practices
Quality control	Integrating into safety standards / functions
Fraud detection & prevention	Data / algorithmic bias
Increase data collection	Training
Create benchmarks & testing protocols to assess safety, performance, etc.	Monitoring effects of AI decision-making
Information retrieval for reporting	Not meeting safety standards but deploying anyway

What role do stakeholders see standards playing in overcoming challenges?

The role of standards as they related to the specific challenges was discussed under the prior question.

Polling:

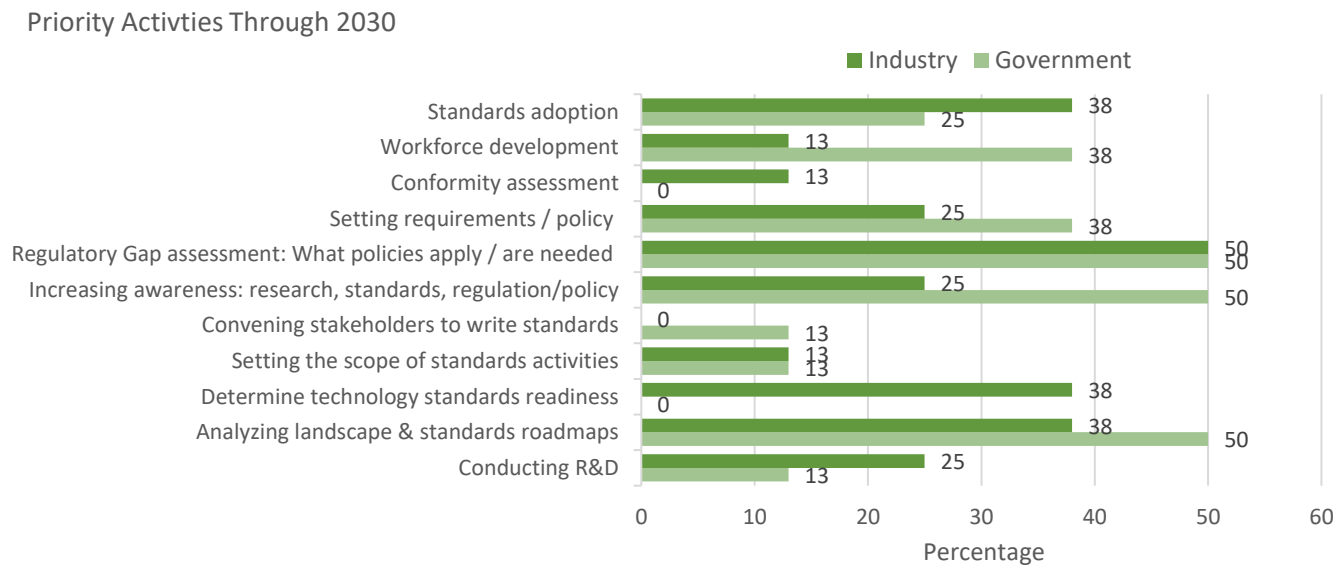
Standards offer many benefits. Attendees were asked to the select which of the following standard work products or results would help enable AI in **manufacturing**. Best practices and guidance were identified as the top need. The results are as follows:



What is the role of industry vs government to maximize opportunities? To support standards development?

Polling:

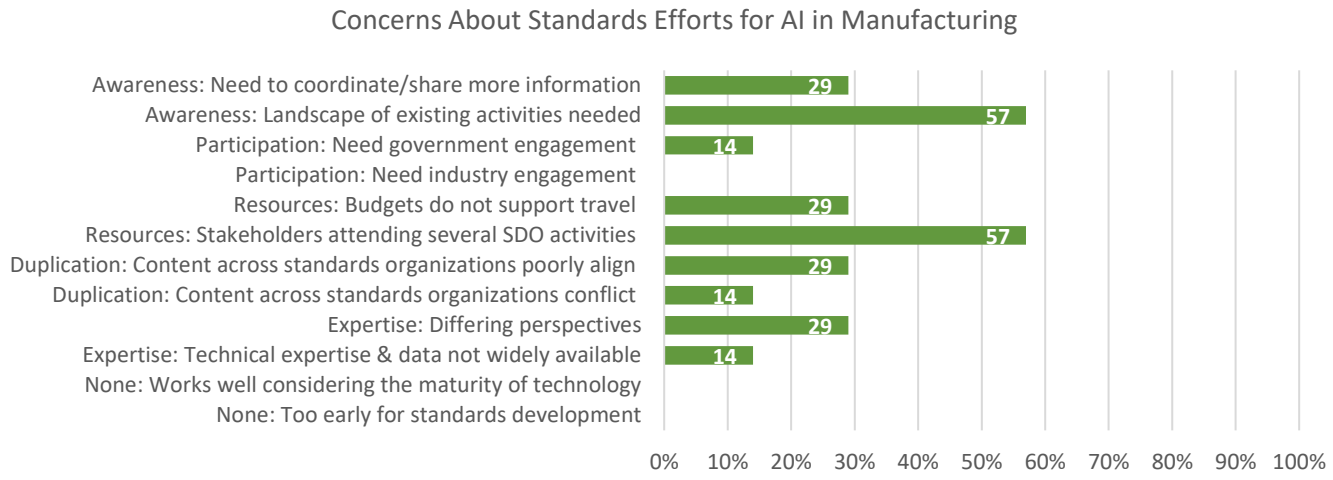
Attendees were provided a list of activities which could potentially enable AI in **manufacturing**. They were asked to identify which the industry and government should prioritize over the next five years. The results are as follows:



What concerns have been raised about existing standards efforts?

Polling:

Attendees were provided a list of common concerns which could potentially slow or hinder standards development. They were asked to identify which three have been raised from their perspective. The results are as follows:



4.2.2.3 Suggested AI Related Regulation, Policy and/or Conformity Assessment Frameworks

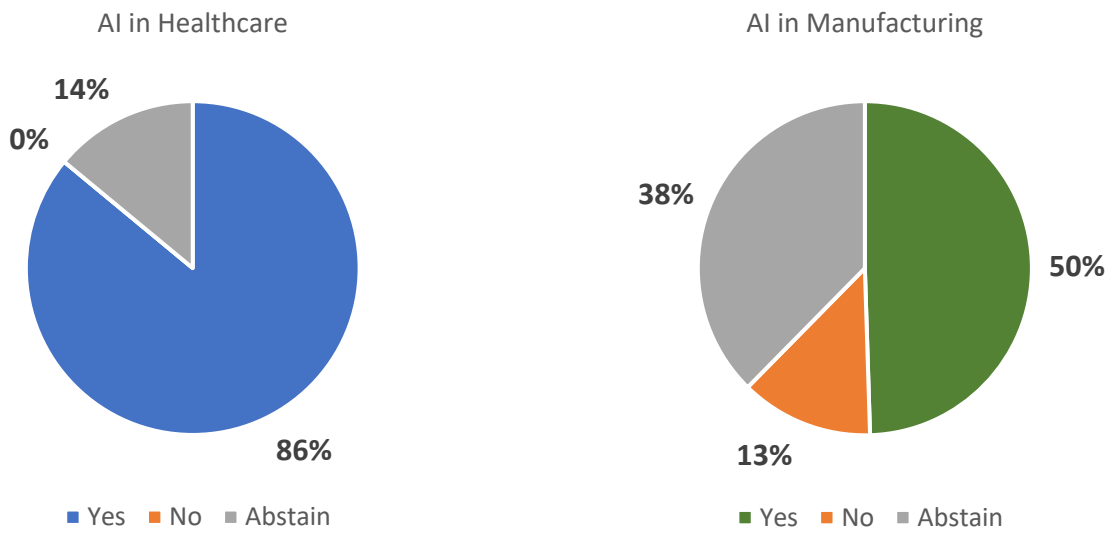
In both the healthcare and manufacturing discussions, as well as the data collected prior to the event, there were more general regulation, policy and conformity assessment needs identified than specific sector needs. Below is a list of the recommendations, which is organized by topic area:

- Uniform standard essential patent (SEP) policy statement to mitigate abusive SEP licensing conduct
- All three are needed - regulation, policy and/or conformity assessment frameworks
- Technology Readiness Level assessment
- Legislation on transparency of use
- Indication and limitations of use via labeling
- Regulation on water-marking AI generated contents

- Requirements to explanation of how the AI arrived at an "answer"
- Requirements to disclose what data was used to train the AI
- Alignment on core safety and security needs
- AI risk controls (ISO/IEC 42001)
- Assessments to determine ethical/bias/fairness/equity in AI models
- Ranking systems for large language model (LLM) platforms
- Defining what is proprietary data
- Data protection limitations
- Data protection principles – ways to share data without legal issues
- How do we determine liability when something bad happens, who's at fault/risk?
- Instead of enabling or accelerating the introduction of AI technologies, regulations should “protect” against potential harm from the introduction of AI (or other technologies).
- Regulation should follow technology development, not come before it
- Conformity assessment frameworks (schemes) are so heavily dependent on the specified requirements to which fulfillment is demonstrated that it would be counter-productive to invest significantly in conformity assessment frameworks before the underlying specified requirements (regulations, standards, etc.) begin to come in to focus.
- Regulation of third-party AI certification organizations

4.2.2.4 Should AI Standards Development be Accelerated?

Attendees were asked if standards development for AI in healthcare and AI in manufacturing needs to be accelerated. The results are as follows:



4.2.3 Role of Standards-Driven PPPs for AI

Standards-Driven Public Private Partnerships (SD-PPPs) Models

Christine Bernat, ANSI, presented five proposed SD-PPPs. Ms. Bernat’s presentation can be found here. A summary of those models is found in Section 2.3.

4.2.3.1 Perspectives on Public-Private Partnerships Briefings

Government Perspective: Natalia Globus Martin, National Institute of Standards and Technology (NIST)

Ms. Globus Martin's presentation can be found here.

Summary:

The U.S. standardization system is unique compared to other countries and is built upon a voluntary, decentralized, and private sector-led, open standards development process. The U.S. government engagement in the U.S. standards system varies widely depending upon individual agencies' missions and functions. Federal agencies at every level of government use standards to support regulation, procurement, and policy activities, as well as incorporate standards into voluntary programs. NIST serves as a point of engagement and entry, and plays a leadership role in facilitating strong interagency coordination and support of the private sector-led standards developing organizations.

U.S. law and policy requires federal agencies to use international, voluntary consensus standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. This includes:

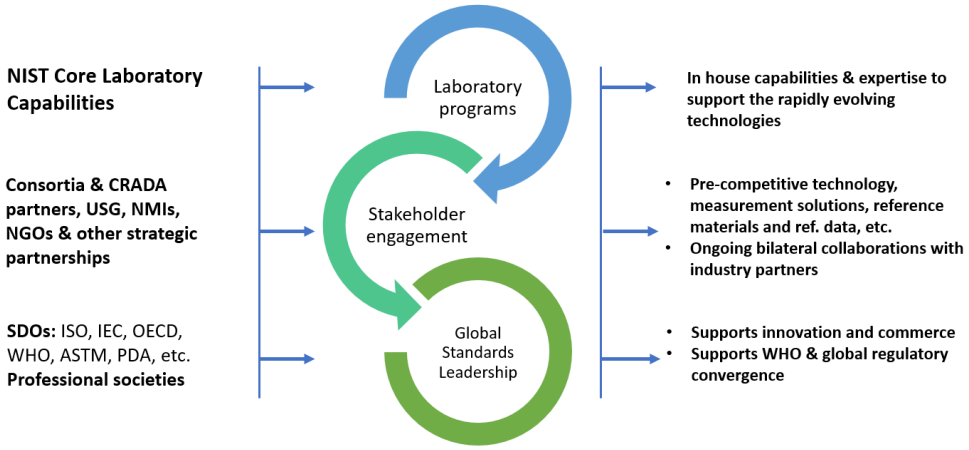
- National Technology Transfer and Advancement Act (NTTAA)
- OMB Circular A-119
- Trade Agreements Act (TTA) of 1979
- M-12-08, Principles for Federal Engagement in Standards Activities to Address National Priorities

Technology Transfer mandate refers to the transfer of technology knowledge from one organization to another to develop new products and services that benefit society. Federal Technology Transfer refers to technology transfer from federal laboratories (e.g., NIST) to non-federal entities (e.g., industry, universities, and state/local governments). Here are some related legislations:

- Stevenson-Wydler Technology Transfer Act of 1980
- Bayh–Dole Act or Patent and Trademark Law Amendments Act, December 12, 1980
- CRADA Statute 15 USC 3710a (tech transfer)

Accelerating fundamental research and measurement science to drive international standards development is foundational to the discussion especially around CETs where we have a unique understanding for many of these technologies. We also have a unique relationship with industry and academia that benefits advancement in these areas. Consortia Cooperative Research and Development Agreements (CRADAs) are one of the primary tools by which technology and technical expertise can be transferred from federal laboratories to non-federal partners. CRADAs are especially valuable to small, high-tech companies, which often struggle with developing contacts inside federal laboratories. A CRADA offers a low-risk opportunity to collaborate and build valuable relationships. A consortia CRADA allows government partners to work with multiple industry partners at once on a single project with benefit to all parties. Consortia are particularly useful for developing standards/references and addressing issues that affect an entire industry sector (see Figure 5).

Figure 5: NIST From Laboratory to Standards



Lastly, some examples of PPPs which have enable standards development were offered, some of which are included in the Appendix D.

Title	Mechanism	Stakeholders	Drivers for partnering
Quantum Economic Development Consortium (QED-C)	Consortium under Other Transaction Authority	SRI International, DOE, 180 companies	Support the emerging quantum-based industry
National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)	Cooperative Agreement	USA Bio Consortium (150 members), University of Delaware	Accelerating innovation in biopharmaceutical manufacturing industry sector
National Cybersecurity Center of Excellence (NCCoE)	FFRDC + CRADA + MOU	MITRE, industry and academia participants in projects, corporation of technology partners	Address industry's most pressing cybersecurity issues
The Center for Statistics and Applications in Forensic Evidence (CSAFE)	Cooperative Agreement	Led by Iowa State University with partners Carnegie Mellon University, University of Virginia, and University of California-Irvine.	Establish scientific foundation for analytical techniques used in forensics
IBBR	Cooperative Agreement, MOU	University of Maryland, College Park; and University of Maryland, Baltimore	Advance measurement science in biotechnology

Industry Perspective: Rohit Israni, CertientAI

Mr. Rohit Israni's presentation can be found here.

Summary:

ISO/IEC SC 42 is an example of a direct-participation SD-PPP model. The U.S. played a vital role in the early stages of the committee, formed in 2017. The DoD, FDA, NSA, NIST and industry played a critical role in its formation. The program has been very successful because of this collaboration. The race for standards, especially in vertical areas (healthcare), is ongoing. In addition to the direct-participation example that ISO/IEC SC 42 serves, industry and NIST also developed the *NIST AI Risk Management Framework to ISO-IEC-42001 Crosswalk* in 2013. This collaboration has benefited the AI standards efforts.

SDO Perspective: Kerri Haresign, Consumer Technology Association (CTA)

Ms. Haresign's presentation can be found here.

Summary:

CTA is the trade association representing over 1,300 member companies with over 20 special focus divisions, councils, and working groups. CTA also manages over 130 standards. CTA facilitates AI advocacy and has developed horizontal and vertical AI standards such as:

Horizontal
- Definitions and Characteristics of Artificial Intelligence (CTA-2089-A)
- Cybersecurity Threats and Security Controls for Machine Learning Based Systems (CTA-5203)
- Guidelines for Developing Trustworthy Artificial Intelligence Systems (ANSI/CTA-2096)

Healthcare
- Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias (ANSI/CTA-2116)
- The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data (ANSI/CTA-2107-A)
- Definitions/Characteristics of Artificial Intelligence in Health Care (ANSI/CTA-2089.1)
- The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)

Ms. Haresign provided three examples of PPPs in which CTA is engaged:

1. **Over-the-Counter (OTC) Hearing Aids with the U.S. FDA:** This is an example of an incorporation by reference. It began with advocacy and standards development which resulted in new legislation, FDA regulation and the CTA standards being incorporated by reference.
2. **U.S. Cyber Trust Mark Program with the White House, FCC and NIST:** This is an example of direct collaboration on the development of technical specification and advocacy for getting the program established. This public-private sector effort resulted in the development of a voluntary cybersecurity label program for consumer connected devices (consumer IoT). The effort is led by the White House and FCC, with input from CTA, the National Institute of Standards and Technology (NIST) and other government and private sector stakeholders. The following draft standards are being proposed for incorporation by reference, and CTA is closely coordinating with FCC on details.
    - ANSI/CTA-2119, Framework for Evaluation of a Cybersecurity Scheme
    - CTA-2120, Design Requirements for a Label for IoT Device Cybersecurity
    - CTA-2126, Guidelines for the National Cybersecurity Label Conformity and Trust Programs
3. **Energy Efficiency of TVs:** CTA developed the Determination of Televisions Set Power Consumption (ANSI/CTA-2037-D). CTA worked with EPA to provide companies the ability to mark their product (TVs) as energy efficient. It is a voluntary program.

4.2.3.2 Role of Standards-Driven Public Private Partnerships for AI Discussion

Moderator: Amanda Benedict, Association for Advancement of Medical Instrumentation (AAMI)

Opening Remarks: Broadly, AAMI's scope is health technology and the U.S. FDA CDRH is the federal agency responsible for regulating medical devices. AAMI partners with FDA formally and informally and is well integrated into AAMI's health related initiatives. The relationship fits into several of the SD-PPP models presented. For example, FDA is a direct participant in all AAMI's consensus bodies (170 focused domestically or about 230 with international focuses combined), advisory and governance groups. FDA serves as chairs and conveners of these activities, supports education and training, and participates in AAMI collaborative activities. AAMI helps resurface FDA news to industry to increase awareness.

FDA has been regulating drugs since 1906. In the 1960's, there were concerns about safety of medical devices and the need for more regulatory oversight, leading President Nixon to call for device regulation. The FDA was also seeking authority to regulate medical devices based on other issues they were seeing through their work. AAMI was a member organization already working on standards for the medical instrumentation community and advocating for constructive legislation. In 1969, AAMI organized a "National Conference on Medical Devices" conference with industry and government to address safety concerns in the medical community. The conference report (Cooper Report) serves as a framework for the Medical Device Regulation Act of 1976. This Act gave the FDA authority to regulate medical devices sold in the U.S.

The relationship has sustained and evolved over time. There have been several benefits of this relationship:

- Insight into FDA needs
- Identification of gaps in standards or need for revisions
- Increased understanding about whether AAMI standards have 'regulatory readiness'
- Increased broader stakeholder engagement when regulators are present
- Increased bilateral public-private communication
- FDA has increased awareness of standard and insight into the content
- Increased FDA awareness accelerates / strengthens chances of adoption

The FDA is involved in several standards organizations and it is important to ensure the private sector is engaging with the correct offices and representatives. It is helpful to have a central point of contact to help coordinate on specific

activities and be specific about what requests industry has for the regulator. Lastly, the federal employees have to go through several layers of approval processes. Keeping participation modes flexible (e.g., online meetings) can help allow for their continued engagement.

What benefits or challenges do you see with a PPP for these technologies?

Discussion:

- **PPPs Outside the Standards Organization:** How do we ensure the PPP activities integrate successfully into an SDO? A collaborative effort with a good mission could be a path to nowhere if there is not an implementation strategy which address how to transition efforts to the SDO, maintain it, and ensure it is working effectively. In some of the use cases, SDOs were partners or members of the PPP. In other cases, member organizations serve as liaisons between the PPP and the SDO.

- **Sunsetting PPP and Migration of Efforts:** When the PPP is formed, it is important to consider what needs to happen with their effort. Standards development would continue even if a formal PPP is no longer needed.

- **No Forced Outcomes:** If the PPP efforts conclude that standards are not needed after all, it is better not to force standards development because no one benefits from unnecessary standards in the marketplace.

- **Governance:** There is a need for governance as in with any organization. The PPP should not define its own priorities. An impartial governance board should be advising how to move forward.

- **Use Cases:** PPPs can help develop use cases which are very beneficial. SAE ITC sets up consortia to identify concerns and opportunities to develop standards (e.g., Think Tanks). They liaise with SAE International for standards development.

- **Balanced Interest:** If SDO participants are not bringing forward a balance of interest, including both public and private sector needs, a PPP could help with this.

- **Secure Forums/Environments:** An example of a public need are matters of national security. Standards play an important role. There are instances where government needs cannot be communicated at an open standards development meeting. A PPP can offer a closed forum (e.g., through a consortia) where parties can more openly discuss issues, after which some aspects of the needs can be brought into the SDO.
    - There are USG interests that the business sector or development pipeline may not see. It is important to provide a process for how to address this.
    - Consensus Standards Forums – These are by nature open and are not an appropriate venue for national security issues. Those topics would be challenging to discuss in an open standards forum. A separate forum should be established.
    - During early homeland security days, closed processes were established to develop a standard for a specific classified need. Representatives from national security agencies participate in global consensus processes and see issues through a different lens, just as any stakeholder would. National security agencies are trying to determine how to share information in a non-classified manner.

- **Draft Development Outside SDO:** Stakeholders can develop a draft standard prior to bringing it to an SDO. It is not uncommon that an established draft, developed in a closed forum, is introduced into the open SDO process. This is done irrespective of national security issues, but it is an option which can be utilized for that use case. Could this possibly solve some of the concerns around speed of standards development?

Benefits	Challenges
Increase investment & resource allocation	Differing objectives & priorities
Improve standards & regulatory alignment	Complex governance & management
Develop trust & integrity in tools	Data sharing / privacy concerns
Foster transparency & accountability	Information sharing (fear of losing IP, fear of sharing with government)
Diverse perspectives come together	Bureaucratic hurdles of partnership
Increased coordination on standards, policy, training, etc.	Ensuring adequate & balanced representation of stakeholders
Accelerated R&D, standards, and resource integration	Conflict between short-term profit and long-term technical goals
Avoiding duplication	Speed
Establishes platform for testing innovation	Obtaining funding & resources
Accelerate adoption	Competition between public and private sectors
Parallel development of safety standards and initial introductory use cases.	Getting executive leadership sees the value of PPP
Roadmapping - strategy to execution	Changes in legislative or executive agendas
Coordination of roadmapping around pre-standardization prioritization and preparation for standardization.	Competition among different standardization efforts - where to allocate resources, how to align PPP towards (and how to decide on) the most important efforts
Improve interoperability, expands ability to sell a product	Ensuring the output of a PPP outside an SDO is successfully integrated into the workflow and business of an SDO
Support administrative costs of attracting, training, and managing SMEs / Ensure balance	Need delineated agreement as to mutual obligations, attendance requirements, response time to requests

What role can various types of stakeholder organizations play in PPPs for these technologies? E.g., consortia, trade associations, academia, standards organizations, centers of excellence

Discussion:

- **Various Stakeholders:** A PPP which would influence standards should have a balanced representation of all the stakeholders.
- **Role of SDO:** How should an SDO look at engaging in a PPP beyond enabling direct-participation? SDOs should provide insight into what standards exist and what is in development. SDOs can help with communications and act as a bridge.
- **Organization Exists:** There are plenty of organizations already working in this area which could take on these activities and should be part of a PPP. A type of PPP that does not yet exist is one that brings together government, industry, and academia to identify issues and support communications among them.
- **CETs Widening the Scope of Traditional Technologies:** For example, in the automotive sector, the focus was solely on the car. Now with electrification and automation, the focus is outside the vehicle. CETs are similarly impacting other sectors. The ecosystem of organizations is vast and these organizations can help coordinate these discussions and communicate needs to SDOs.

What PPP short-term and long-term goals would have the broadest impact on success? E.g., standards focused R&D, workforce development, research and standards roadmaps, strategic planning

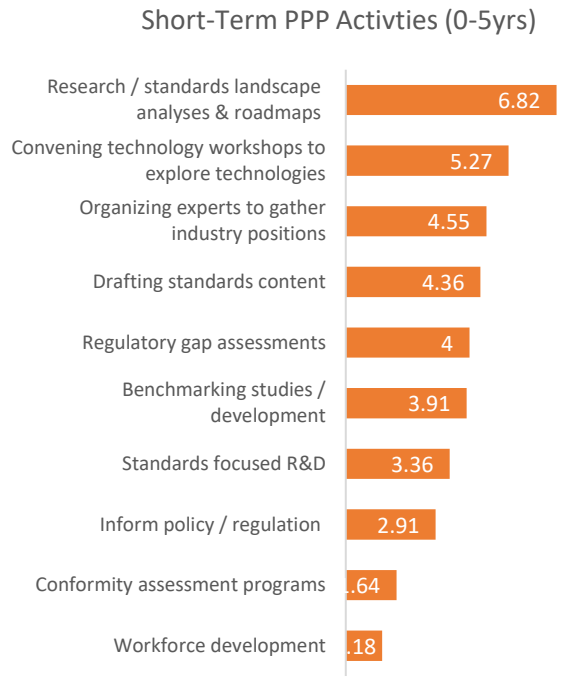
Attendees were to prioritize common PPP activities based on short-term (0-5 yrs) and long-term (5-10 yrs) needs for AI standards development, agnostic of sector. The selections and results were as follows:

Selections:

- Benchmarking studies / development
- Conformity assessment programs
- Convening technology workshops to explore technologies
- Drafting standards content
- Inform policy / regulation
- Organizing experts to gather industry positions
- Regulatory gap assessments
- Research and standards landscape analyses and roadmaps
- Standards focused R&D
- Workforce development

Results:

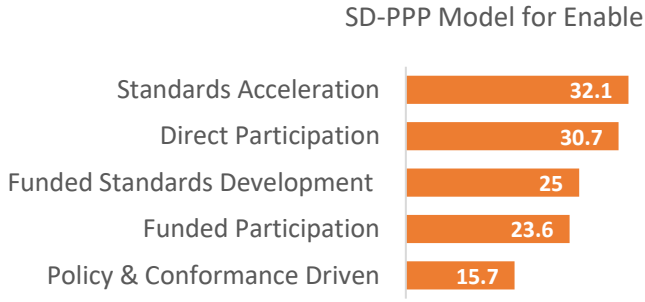
The order represents the ranking and the bar represents the average ranking score.



What type of PPP model or models could benefit these technologies?

Polling:

The results are shown in ranking order and the bar represents the average ranking score shown via percentage.



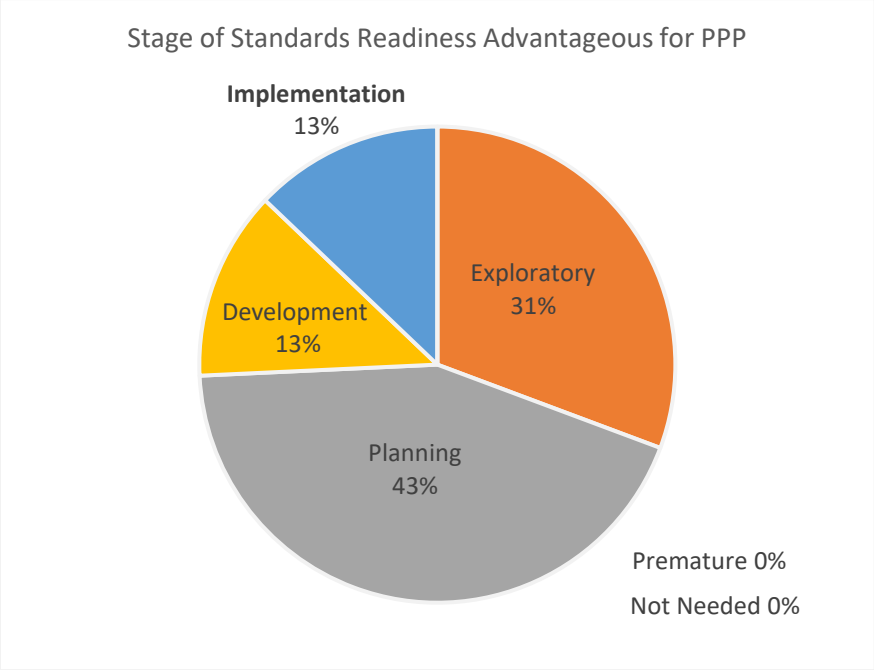
Discussion:

Every one of the models serves a different role in AI standardization (and has advantages and disadvantages). Whether funding comes from private or public sector grants, how do stakeholders coordinate these efforts and determine what is needed? Standards roadmapping seems to be the primary need for the phase that this sector is in because many questions (in various forums) center around 'where are our gaps?' and 'how do we prioritize?'

During which phase of standards readiness (if any) would an organized PPP activity be most advantageous?

Polling:

The results are shown in ranking order and the bar represents the average ranking score shown via percentage:



Does a PPP require a formal agreement to be able to realize its purpose?

Discussion:

- **Roles and Responsibilities –** It can be helpful to have a term of reference (TOR) or clearly defined expectations from various stakeholders to ensure commitments are fulfilled.
- **Flexibility over Formality** - Sometimes formalities get in the way of success, especially in a fast-moving area. PPPs need to be very nimble at this stage.

4.2.4 Current and Future State of Information Sharing

4.2.4.1 Current State of Information Sharing Briefings

To establish an understanding about existing information-sharing approaches in the standardization community today (tracking tools, standards roadmaps, workshops/webinars, etc.) as well as feedback the private sector has shared to-date.

Mary Saunders, American National Standards Institute (ANSI): What information is being shared today?

Ms. Saunders' presentation can be found here.

Summary:

There are several ways that the standards community communicates about existing activities and their value add to stakeholders.

- SDOs provide **overviews by technology areas** (existing and planned activities) as well as how to participate in their activities (e.g., procedures and tools)

- **Standards Landscapes** are produced by the private sector and government agencies and include a compilation of current activities in a particular technology area
- **Assessments and studies** include a collection or synthesis of standards-related data
- **Standards roadmaps** which identify existing standards activities and define gaps for a particular industry or technology area with the objective of information resource allocation, avoiding duplication of efforts and increasing coordination (see also ANSI standards collaboratives)

ANSI *Standards Action* provides timely, accurate information about current standards development work in which ANSI plays a role. The publication is designed to facilitate participation in the American National Standards (ANS) development process as well as other domestic, regional, and international standardization activities advanced by ANSI. Includes current work underway at the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and ISO/IEC Joint Technical Committee (JTC) 1, through U.S. Technical Advisory Groups (TAGs). Each weekly edition comprises a round-up of the latest information available to help all interested parties get informed and engaged in standards.

Sector specific AI standards are beginning to emerge in ISO and IEC (e.g., ISO/IEC JTC 1/SC 42), especially in industries which are beginning to rely on AI including:

- Automotive/aerospace: *SAE International, ULSE*
- Financial Services: *Accredited Standards Committee X9*
- Healthcare*: AAMI, ADA, CTA, DICOM, etc.*
- Consumer IoT: *CTA, etc.*
- Biotechnology: *American Type Culture Collection*

The private sector has expressed priorities for supporting AI standardization including:

- Regular government engagement with private sector stakeholders on both AI-related technical issues and broader AI standards and policy discussions
- Government recognition that many priority interactions will depend on private-sector leadership and joint efforts from the global AI and standards communities
- Consideration of the full standards lifecycle—including research and related technical activities—as well as the full range of issues, both technical and societal, associated with standards for AI applications

Natalia Globus Martin, National Institute of Standards and Technology (NIST): What did industry suggest in RFI responses and past listening sessions?

Ms. Globus Martin's presentation can be found here.

Summary:

An introduction to the USG NSSCET was provided (see slides and section 1.1.4) and a summary of NIST's efforts to solicit input from the private sector (i.e., RFI and listening sessions). The key findings reported from a combination of those efforts were as follows (taken directly from the presentation):

1. Public-private sector coordination:
   - work effectively in consortia and communities of practice
   - develop and promote adoption of sector-specific standards including those critical to national security, public safety, security, health and environmental health and resilience
2. Federal government coordination:
   - coordinate pre-standardization R&D investments
   - coordinate activities, proposals, leadership opportunities, and engagement
   - support the integrity of the international standards system
   - promote WTO TBT Committee principles
3. Foreign government coordination

- work with likeminded partners and allies to ensure CET standards are developed to support U.S. interests
- advocate for a commitment to free and fair market competition
- advance trade policy and agreements that are technology neutrality and promote technology adoption

4. Standards funding opportunities
   - target academia and small- and medium-sized enterprises (SMEs)
5. Standards education
   - enhance educational efforts and leverage academia as a critical partner to increasing U.S. engagement and training the next generation of standards professionals
   - renew a commitment by academia to teaching the value and use of standards in a range of career fields
6. Standards communications
   - explain the role of U.S. government and academia in our system
   - provide education and awareness for senior leaders in industry, government, and academia
   - understand the value of our system with regards to competitiveness and innovation in a range of career fields
   - engage a wide range of market participants in standards efforts
   - engage Congress to bolster support for R&D in CET and increase investment in pre-standardization research
7. Real and perceived barriers
   - reduce visa wait times
   - identify and eliminate knowledge gaps between U.S. policymakers and technical program leaders
   - enhance government participation where government is the member (e.g., ITU)
   - facilitate engagement by providing standards information, education, and to raise awareness among underrepresented stakeholders

Lastly, NIST recently announced a Notice of Funding Opportunity (NOFO) for a Standardization Center of Excellence. A virtual event was hosted on July 11, 2024 and the recording can be found on the NIST website.

4.2.4.2 Future State of Information Sharing

Moderator: Muhammad Ali, HP, Inc.

Opening Remarks: A sustainable standards systems operates off a "three C's" approach:

- **C**ollaboration: This is executed through PPPs, internal and external coordination as organizations, or through forums like ANSI collaboratives
- **C**oordination: This is executed in standards committee efforts, through partnerships in standards development (PSDOs) agreements such as between ASTM/ISO and IEEE/ISO, as well as through joint certification concepts
- **C**onnection: Examples of connectivity of standards with business outcomes and between the horizontal and vertical standards.

The future state of information sharing discussion is broken down into the three phases of standards development (pre-standardization, standards development, and implementation).

What communication standards challenges does this sector face? What could be done to improve it?

Discussion:

- **AI Standards Sector is Noisy:** With so many forums discussing AI, it is hard to identify what to focus on and what is really needed versus what is perceived as needed. Currently in healthcare, there are several organizations racing towards standards development and it is confusing. This has a negative effect on the end user – the patient. Various individual organizations are creating their own AI activities, governing boards, and strategies. It is difficult to not only follow them but productively engage in them.

Polling:

- Several organizations addressing AI

- Different organizations have different goals & scales of efforts
- Space and technology are evolving rapidly, it is hard to stay informed
- AI conversation is "noisy" & information gets diluted
- Communication is fragmented
- Protectionist approaches leading to decreased sharing
- No central repository of information
- Varying terminology & definitions on AI concepts and standards
- Government(s) developing their own standards instead of collaborating with standards groups
- Government not disclosing use of AI
- Startups lack resources, networks, experience w/SDOs, and/or voice in the process in contrary to larger organizations
- Groups are developing standards end-end instead of what is needed for their domain.
- Non-standards forums for discussing standards issues within in the US

During the pre-standardization phases of technology, it is important to begin educating about the value and benefits of standards. How can we amplify this messaging to ensure it reaches the appropriate stakeholders?

Discussion:

- **Go Where the Sector Is:** Meeting stakeholders where they are, do not expect them to come to you. For example, go to conferences where stakeholders already meet. Inviting them to standards meetings may not be successful.
- **Academia:** A lot of AI work is being done in the academic community, which does not always have the same awareness and education about standards. Education is needed on this front and it is another example of meeting stakeholders where they are – go to the academic community. Informing how to translate their research into a standard would be helpful. SDOs can communicate to academia what is needed and they can help fill that gap (e.g., through their PhD programs).
- **Value of PPP:** Small companies and startups, as well as academia, add immense value. Bringing them into the fold of a PPP will be advantageous.
- **Diversity is Needed:** Making a specific effort to engage all the stakeholders, especially those not typically involved should be a strong focus during this phase.

Polling:

- We should individually mentor and educate motivated SMEs to make them productive in the standards development space and reduce frustration.
- Reaching out to academia would be helpful, since many of the core technology developments are being fostered in a standards vacuum.

During the standards development phases, it is important to get the right information in front of the broadest group of stakeholders. How can stakeholders best socialize the standards development activity to get diverse and targeted stakeholders?

Discussion:

- **One-pagers:** Developing concise ways to communicate what is out there or even the value add of a specific standard. It needs to be brief and easily digestible. The title and scope of a standard alone is not helpful. Communicate what participation means.
- **Awareness of Stakeholders at the Table:** Share this information publicly.
- **Mentorship:** Mentoring new participants is key for their effective participation and long-term engagement.
- **Think Global:** Especially for international standards development. This education, training or mentorship needs to be executed globally.

Polling:

- Provide more comprehensive details about standards projects (title, scope, and outline)
- Communicating not only the work being done but the intended value of activities as a whole and individually
- Online collaboration tools for content development
- Leverage online meetings, hybrid, to maximize participation
- Communicate who is and is not at the table so participants know who they can work with and who needs to be recruited

During the implementation phases, how can we increase the adoption of a standard once published? Think about this from a market adoption, regulatory acceptance, and/or conformity assessment standpoint.

Discussion:

- **Communication Strategy:** Publishing the standard is not the end. Plan to promote the impact in advance so it can be promoted shortly after publication. Leverage SDO staff to help you increase awareness.

Polling:

- Communicate the value add as part of publication announcement
- Educational materials to support implementation of a standard, made available close to its publication
- Develop implementation guides for users and lessons learned analyses communicated back to the committee
- Advocate for the inclusion of the standard in relevant regulations and policies
- Establish and leverage early adoption programs (e.g., incentive)
- Create marketing plan for members and increase awareness about the support and use the standard
- Establish user groups or forums where early adopters can share experiences and best practices

What information is critical to support effective bilateral communications between the public and private sector?

Discussion:

- **Value of the Standards:** Communicating the value of standards through innovative ways, such as short videos is critical. Make it easy for them to understand how standards helps their missions.
- **Building Trust:** Industry should be building trust with the government and their customers, regardless of the end objective (for healthcare compliance or manufacturing for customer needs). Taking the time to communicate value over time.
- **Variety of Communication Approaches:** Direct outreach may be better suited to reach each other. Sometimes an open forum is not the best for sharing or allowing for more open dialog.
- **SDO Meetings:** SDO committee meetings themselves provide an effective forum for bilateral communications. It is a forum where all stakeholders can communicate if what they are working on will be useful for all parties, especially where there is a mutual commitment to the mission.

Polling:

- Make communications user friendly and accessible, create the ability to follow information and personalize engagement.
- Public sector (incl. PPPs) can create testing tooling for private sector users, who also complete the loop by providing feedback experiences and errors.
- Communicate the purpose of the standard, including example implementations.
- Share success stories and case studies of effective public-private collaborations to provide models for future initiatives.
- Simplify communications - do not rely on acronyms or numbers

This concludes the summary of the July 17th AI/ML event. All the meeting materials and presentations are online. A summary of recommendations as it relates to the project and the event discussions is included in Section 6.

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5. AUTOMATED AND CONNECTED INFRASTRUCTURE BRAINSTORMING SESSION

5.1 Background

An automated and connected infrastructure is a complex system where multiple technologies converge. Various forms of connectivity and automation are currently being utilized in infrastructure around the world. However, several factors need to be considered such as how the technologies scale, operations increase, and services interoperate safely, cost-effectively, and sustainably. This effort focused on automated and connected transportation.

U.S. Department of Transportation (DoT)

In January 2020, the National Science and Technology Council (NSTC) and the U.S. Department of Transportation (DoT) published a report on *Ensuring American Leadership in Automated Vehicle Technologies, Autonomous Vehicles 4.0* (AV 4.0). The report details ten USG principles to protect users and communities, promote efficient markets, and to facilitate coordinated efforts to ensure a standardized Federal approach to American leadership in automated vehicles (AVs). One of the principles is to "promote consistent standard and policies" citing specifically that:

> *the U.S. government will prioritize participation in and advocate abroad for voluntary consensus standards and evidence based and data driven regulations. The U.S. government will engage State, local, tribal and territorial authorities as well as industry to promote the development and implementation of voluntary consensus standards, advance policies supporting the integration of AVs throughout the transportation system, and seek harmonized technical standards and regulatory policies with international partners.*

AV 4.0 also highlights various federal government efforts in standards and partnerships with industry to advance the discussions.

U.S. Department of Energy (DoE)

One PPP highlighted in AV 4.0 is the 21st Century Truck Partnership (21CTP) which is led by the Department of Energy (DoE) and support by DoD, DoT, and the Environmental Protection Agency (EPA), along with industry partners. This non-funded research program focuses on pre-competitive information exchange across four technical focus areas: internal combustion engines powertrains, electrification technologies, freight operational efficiency, and safety. The program includes AVs as one of the Freight Operational Efficiency and Safety efforts. In October 2023, the *21st Century Truck Partnership Freight Operational Efficiency Technical Sector Team Roadmap* was published.

The roadmap recognizes that connected automated vehicle (CAV) technology can potentially improve freight efficiency and decrease costs. 21CTP anticipates that CAV technology adoption will:

- Reduce traffic accidents due to fewer human errors (94% of traffic crashes according to the National Highway Traffic Safety Administration 2017)
- Reduce travel cost (recovering personnel time while riding and eliminating the need to search for parking)
- Increase in frequency of delivered goods due to per-mile cost reduction, specifically in "last-mile" operations
- Increase in vehicle efficiency due to driving automation, and vehicle energy optimization and planning

Lastly, in addition to addressing perceived technical challenges, the roadmap cites three barriers (pg. 26) for technology development and deployment including:

- Cost: Development and evaluation of technology options for improving freight efficiency can be costly, particularly those involving multiple vehicles and infrastructure elements in a test system.
- Infrastructure: Infrastructure and vehicles for connected and automated vehicle solutions must be developed in parallel. There is a need for reliable and accurate infrastructure that generates stable data streams, particularly to facilitate connectivity and automation. Robust cybersecurity protocols and practices are also needed to ensure safe and secure operation of new technologies.

- Standards: Robust and consistent standards for technologies and practices to improve freight efficiency will help ensure wide acceptance.

Advanced Air Mobility

Automation in aviation is not a new concept. Many systems have been certified into various types of aircrafts today, including commercial (e.g., business aviation) and transport aircraft (e.g., airlines). A pilot is responsible for managing several tasks during pre-flight, in-flight and after landing. Automation of flight controls, or simplified vehicle operations[14], helps alleviate the task load on a pilot. Simplified Vehicle Operations and electric propulsion have paved the way for new aircraft designs and concepts of operations. The new aircraft designs and concepts of operations are part of a concept called advanced air mobility (AAM). As we consider the role of PPPs for CETs, discussions for this brainstorming centered around AAM and not necessarily around broader aviation. It should be noted that unmanned aircraft system (UAS) operations are also considered part of the AAM concept.

Several SDOs (e.g., ASTM International, EUROCAE, RTCA, and SAE International) and federal agencies and departments are exploring how to best enable AAM, including the U.S. Federal Aviation Administration (FAA), DoE, DoD, Federal Communications Commission (FCC), International Civil Aviation Organization (ICAO), National Aeronautics and Space Administration (NASA) and more. AAM can be broken down into three areas, each of which has multiple layers of regulatory and standards considerations:

- **Aircraft and aircraft systems**: Depending on the aircraft size and onboard technologies, different rules or standards would be leveraged.
- **Aircraft operations**: Depending on the type of operations (commercial, pilot training, or personal use), different regulations and training apply.
- **Infrastructure**: Depending on what types of operations and landing facility are utilized, there are different operational considerations including ground crew and equipment, maintenance, and telecommunications support.

There are many factors that come into play to enable AAM and the role of this report will not delve into all the challenges and opportunities presented by AAM; however, various professional organizations supporting these efforts including Aerospace Industries Association (AIA), General Aviation Manufacturers Association (GAMA), National Business Aviation Association (NBAA), Vertical Aviation International (VAI), the Vertical Flight Society (VFS), and others provide helpful technical and sector related resources such as:

- AIA: Metropolitan Airspace Strategy: Initial Advanced Air Mobility Operations (May 2023)
- Black & Veatch: NIA-NASA Urban Air Mobility Electric Infrastructure Study
- Deloitte: Advanced air mobility: Achieving scale for value realization
- GAMA: EPIC Resource Paper – Advanced Air Mobility Aircraft Entry into Service (EIS) Communication, Navigation, and Surveillance (CNS) Typical Capabilities List (TCL) (Version 1.0; September 1, 2023)
- GAMA: Vehicle to Vehicle (V2V) Datalink Communications: Enabling Highly Automated Aircraft and High-Density Operations in the National Airspace Concept Paper (Version 1.0 December 2021)
- GAMA: Data Communications Considerations and Approaches for the Future (Version 1.0, April 2021) Whitepaper
- GAMA: A Rationale Construct for Simplified Vehicle Operations (SVO); Whitepaper Version 1.0 (May 2019)
- NBAA: AAM Roundtable
- VAI: Roadmap of Advanced Air Mobility Operations

[14] U.S. Department of Transportation Whitepaper. Accessed August 19, 2024. *Simplified Vehicle Operations*. https://www.transportation.gov/sites/dot.gov/files/2024-03/HASS%20COE_SVO%20Whitepaper_March%202024.pdf.

Lastly, the Advanced Air Mobility Coordination and Leadership Act (October 2022) defines Advanced Air Mobility as "an air transportation system that moves people and cargo between places using new aircraft designs that are integrated into existing airspace operations as well as operated in local, regional, intraregional, rural, and urban environments." The Act directs the DoT to establish an Advanced Air Mobility (AAM) interagency working group (IWG) to plan and coordinate efforts related to the safety, infrastructure, physical security, cybersecurity, and federal investment necessary to bolster the AAM ecosystem, particularly passenger-carrying aircrafts, in the United States. The IWG is broken down into five subgroups[15] and work is underway:

- Automation Strategy (led by NASA): focused on understanding the acceleration of the desired transition from initial AAM operations with conventionally qualified, onboard pilots through advanced capabilities proposed by the AAM industry, such as simplified vehicle operations, remotely piloted operations, autonomous operations, and remotely supervised flight operations. This group is considering an automation strategy with a comprehensive view related to vehicle, airspace, and enabling communication, navigation, and surveillance (CNS) capabilities to enable various automation/autonomy stages.
- Security Requirements (led by the Transportation Security Administration (TSA)): focused on resolving security concerns related to the introduction and expansion of AAM operations into the existing interconnected transportation domain, preventing the errant or malicious use of AAM systems, and identifying and mitigating potential security risks to AAM aircraft, operations, ground support systems, and other critical infrastructure
- Air Traffic Federation (led by FAA): focused on identifying the requirements and operations management needed to ensure continued safety of the national airspace system (NAS)
- Infrastructure Development (led by FCC and FAA): focused on understanding the aviation facilities needed to support AAM operations, including ground infrastructure; services, including emergency services; accessibility and competition; telecommunications; weather observation and prediction; utility resources; maintenance of vertiports; sensory systems needed for communications, navigation, and surveillance; and multimodal compatibility
- Community Roles (led by NASA and FAA): focused on understanding the need for good public planning for these new technologies and issues such as land governance, transportation equity and accessibility, economic impacts, environmental issues, and workforce development

Lastly, the Government Accountability Office (GAO) must study and report to Congress on the interests, roles, and responsibilities of federal, state, local, and tribal governments affected by AAM aircraft and operations.

5.2 Automated and Connected Infrastructure Brainstorming Session Summary

ANSI's brainstorming session took place on July 30, 2024. Approximately 127 individuals attended from over 94 organizations. Organizations included academia, manufacturers, suppliers, consortia, research institutions, standards and code developers, U.S. government, and trade associations.

ANSI issued various Slido polls throughout the event. Responses (mostly anonymous) were received from in-person and online attendees and the level of participation varied throughout the event. The Slido polls and results supplemented live discussion. Some Slido feedback is incorporated into written summaries and some polls are shown graphically. The Slido results should not be regarded as an industry position as this was not a formal targeted survey effort.

5.2.1 Understanding Technology Convergence and Standards Readiness

Presenter: Timothy Klein, U.S. Department of Transportation

Every U.S. federal government agency has a Standards Executive responsible for ensuring the agency is engaged with standards organizations and leverages the benefits of standards related initiatives into the programs of their agency. As

[15]U.S. Department of Transportation. May 17, 2023. "Request for Information on Advanced Air Mobility." https://www.federalregister.gov/d/2023-10448/p-21.

part of the Office of Assistant Secretary for Research and Technology, Mr. Klein is responsible for the DoT's standards portfolio and seeks to ensure effective technology transfer and increased utilization of DoT research results. Engagement with the standards has shown to help advance these goals.

From a high-level perspective, DoT is an infrastructure and safety regulatory department which provides funding and guidance to build transportation infrastructure and regulate the safety of operations (except maritime). The annual research budget of approximately $1.0 billion is allocated towards meeting regulatory requirements and advancing the safety and efficiency of the national airspace (NAS). Research conducted for ground vehicles, aircraft, and infrastructure is focused specifically on safety and not, for example, broader vehicle research. For the NAS, the DoT is the operator of the airspace; however, the DoT is not the operator of other modes of transportation.

The DoT research efforts are in early stages for supporting CET areas (as identified by NSTC) such as automation, position, navigation, and timing (PNT) technologies. The DoT works very closely with other agencies to support (DoD, DoE, NSF, etc.). Historically, DoT research has not focused on pre-standardization activities, but mostly on applied engineer research. There is now a shift in DoT research to also cover advanced materials, AI in transportation, cybersecurity, quantum, electrification, and new modes of transportation. These changes are driven by the market and societal demands.

Even at a leadership level, for example, for Transportation Secretary Pete Buttigieg, there is an increased recognition of engaging earlier in the standardization process. In July 2024, Secretary Buttigieg emphasized the urgency of electrification of transportation during an interview at Axios.

New entrants into transportation infrastructure present a challenge to regulators from two fronts: fitting within the existing regulations and within existing physical infrastructure. Some areas the DoT is working to support innovations in transportation are:

- The Intersection Safety Challenge about how to apply integrated technologies to protect vulnerable road users (may lead to best practices)
- For unmanned aircraft systems (UAS), the market was misread, and underestimated how soon they would be ready to operate, and the complexity of the packages they would fly. The DoT is still catching up but the ANSI UAS Standards Collaborative[16] (UASSC) helped DoT understand the landscape rapidly and accelerate efforts.
- Efforts to support advanced air mobility (AAM) aircraft, operations, and the supporting infrastructure are underway.
- Standards for complementary and back up positioning, navigation, and timing (PNT) systems. DoT is responsible for all civil uses of GPS and other systems.

Following Mr. Klein's briefing, Clare Allocca (NIST) presented standards readiness considerations and Christine Bernat (ANSI) presented about standards readiness phases. A summary of both briefings is found in section 3.2).

5.2.2 Challenges and Opportunities and Standards Readiness Discussion Goals

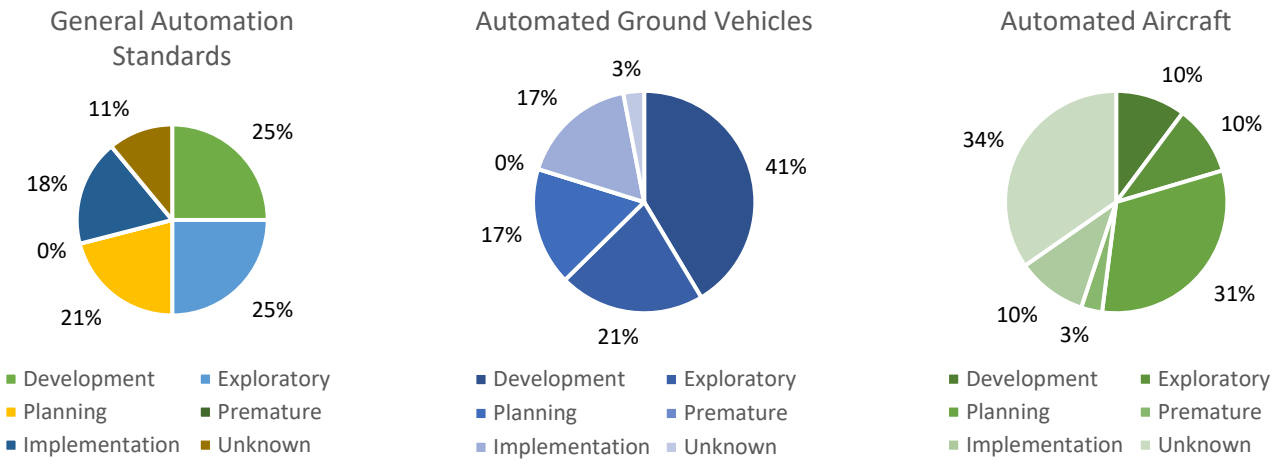
Various factors come into play when evaluating whether conditions are right to embark on a standardization activity for a given technology, and to help predict development needs and timing of a standardization strategy. Attendees were asked the following questions to support the healthcare and Manufacturing discussions:

- What are the challenges and opportunities presented by automated and connected transportation and is there sufficient public and private stakeholder awareness on these fronts?
- What role do stakeholders see standards playing in overcoming challenges?
- What is the role of industry vs government to maximize opportunities?

[16] See also the UASSC use case in the Appendix C.

- What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?
- What is the role of government to maximize opportunities? To support standards development?

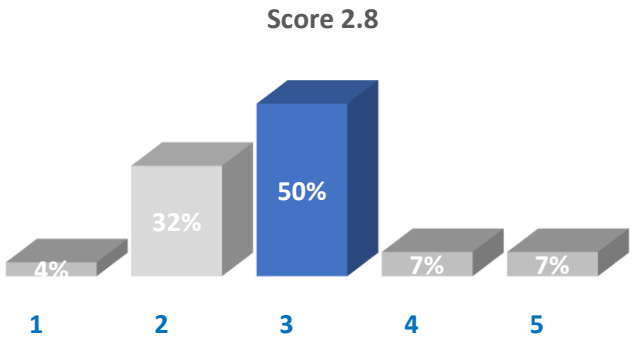
Before conversations began, attendees were asked in what phase of standards readiness are automation standards in general, standards for ground vehicles, and standards for aircraft. Their responses are as follows:



What is the overall awareness of automation standards activities?

Polling:

Attendees were polled to rate the perceived overall awareness of automation standards activities today. The score was a 2.8 out of 5, with 1 being low and 5 being high.



5.2.1.1 Automated and Connected Earth Moving and Mining Equipment Briefing

Presenter: Eric Moughler, ISO/TC 127 Earth Moving Machinery Chair

Mr. Moughler's presentation can be found here.

It is important to understand the differences between earthmoving and mining machines. Earthmoving and mining equipment and machines do not move people, they move earth. This equipment does not require infrastructure, is not manufacturing, and generally used in static environments. In 2013, the first set of machines began some level of autonomous operations. Applications of autonomous equipment in construction are newer and the types of machines used vary in design and tasks. Some applications involve machines working on their own doing basic and repetitive tasks.

In mining, the machines are not transporting people but instead performing work. One operator may be controlling up six machines at one time.

The Earth Moving Equipment Safety Roundtable (EMESRT) is an international safety by design initiative established by mining companies to fill the functional performance expectations gap between earth moving equipment users and designers. ESMSRT outlines nine defensive layers for process controls in their vehicle interaction defense control model. Experience has shown this sector that just having technology will not ensure a successful deployment of automation technologies. If the people (culture), operations, and procedures are not in place, deployment will fail. Lastly, surface vehicle interactions have several different operational scenarios which come into play in mining. Each interaction requires different algorithms, procedures, and sensors.

ISO TC 127 on Earth-moving machinery has 184 published standards and 18 in development. The work of this committee supports standards for collision avoidance, communications, autonomous safety, functional safety, etc. Some additional work needed includes standards on cybersecurity, data privacy, and artificial intelligence.

Subcommittee	Subcommittee Title	Published standards	Standards under development
ISO/TC 127/SC 1	Test methods relating to safety and machine performance	36	0
ISO/TC 127/SC 2	Safety, ergonomics and general requirements	78	12
ISO/TC 127/SC 3	Machine characteristics, electrical and electronic systems, operation and maintenance	43	3
ISO/TC 127/SC 4	Terminology, commercial nomenclature, classification and ratings	23	1

Some new technology and systems are being leveraged to support increased safety including:

- **Operator Fatigue and Distraction Management Systems** have been key in reducing accidents (97% reduction in most significant fatigue events and 91% reduction in distraction in distraction events). Utilizing AI, these systems help monitor eye-closure and head pose to detect fatigue and distribution and then issue an alarm for the operator and the central monitoring center.
- **Smart Cameras** help with detection of people versus objects. The machinery needs to hit objects so it is not complete collision avoidance. Utilizing AI, the machines can classify objects and reduce false alarms and operator fatigue.
- **Electronic Fences** help create avoidance zones and prevent machines from entering or reaching restricted areas.
- **Use of autonomous machines** such as haul trucks, dozers, blast hold drills, and excavators eliminate the need for an operator, reducing cases of human error, and resulting in no lost time. ISO 7334 Earth-moving machinery — Taxonomy and vocabulary for automation and autonomy defines levels for autonomy for this sector.

5.2.1.2 Automated and Connected Ground Vehicles Discussion

Moderator: Dr. Miles Johnson, Toyota North America

Opening Remarks: Mr. Johnson's work at Toyota is aimed at reducing fatalities on the road. Toyota is doing a great deal of product development on automation including on mapping, positioning, and control. Dr. Miles' department is specifically focused on automated driving systems (ADS) that support towing, trailering, steering control, and reverse assist; however, standards and policy activities have only just begun for these areas.

What are the challenges and opportunities presented by automated and connected ground vehicles and is there sufficient public and private stakeholder awareness on these fronts?

Discussion:

Attendees reviewed the feedback submitted prior to the event. Discussion focused on the following areas as summarized below:

- **Target of Standardization**: Primary goals for standards activities are ensuring safety, efficiency, sustainability, and quality of life improvements.
- **Distraction of Drivers**: Driver Monitoring systems (DMS) are critical because drivers are distracted by many things, including dashboard technologies, and phones. Automated steering and alerts for drivers when they start to go off course have helped but disabling dashboard technology is important.
- **Interaction with Road Users**: Communication technologies need to be used to communicate from automobiles to vulnerable road users, such as pedestrians and bicycle riders.
- **Global Acceptance**: The numbers of global deaths per year has been socially acceptable. This perception is impacted by a view of personal safety and individual desires of drivers. The attitude of drivers is focused on their own personal needs to get from one location to another.
- **Measurement of Safety**: What percentage of safety is good enough? Who defines that safety goal? How do you write specifications around this if we do not know or agree on what percentage of safety is sufficient?
- **Speed**: Safety is impacted by the speed at which people drive. The better automobiles are designed, the more comfortable a driver feels at faster speeds. This impacts a driver's perception of safety. Road infrastructure and visibility also impacts this. Line of sight for a driver is often less than what is needed for a driver to safely stop a vehicle (at the speeds we drive today).
- **Keeping Drivers Engaged**: Automation disengages the driver so how do we keep drivers engaged on the tasks involved to safely drive.
- **Personal Data Privacy & Protection**: On one hand, data protection is seen as a very important need, but on the other hand, drivers are giving away their information because a phone app like "Waze" gives drivers badges for reporting the location of potholes. Consumers are dictating what information they are willing to share. Data will be needed, especially with understanding automation in different operational contexts.
- **Understanding Change**: Vehicles 50 years ago versus vehicles today are significantly different. Digitization of vehicles has changed the way vehicle owners can operate and maintain their cars. For example, a software fix may impact a driver's ability to use their vehicle.
- **Digital and Physical Infrastructure**: Server infrastructure and data gathering needs have high costs. Stakeholders beyond the information technology companies may not be willing to front the costs. The updates needed to the physical information also has costs. Who pays for this and who benefits from those updates first? There are parallels among vehicles, software development, design, and standardization.
- **Regulations versus flexibility**: There is a strong desire for policy and guidance but then a strong need for flexibility. How does the sector approach balance between these?

Polling:
Additional challenges and opportunities were provided via Slido during the event, in addition to those collected prior to the event. Below is a list of the feedback ANSI received:

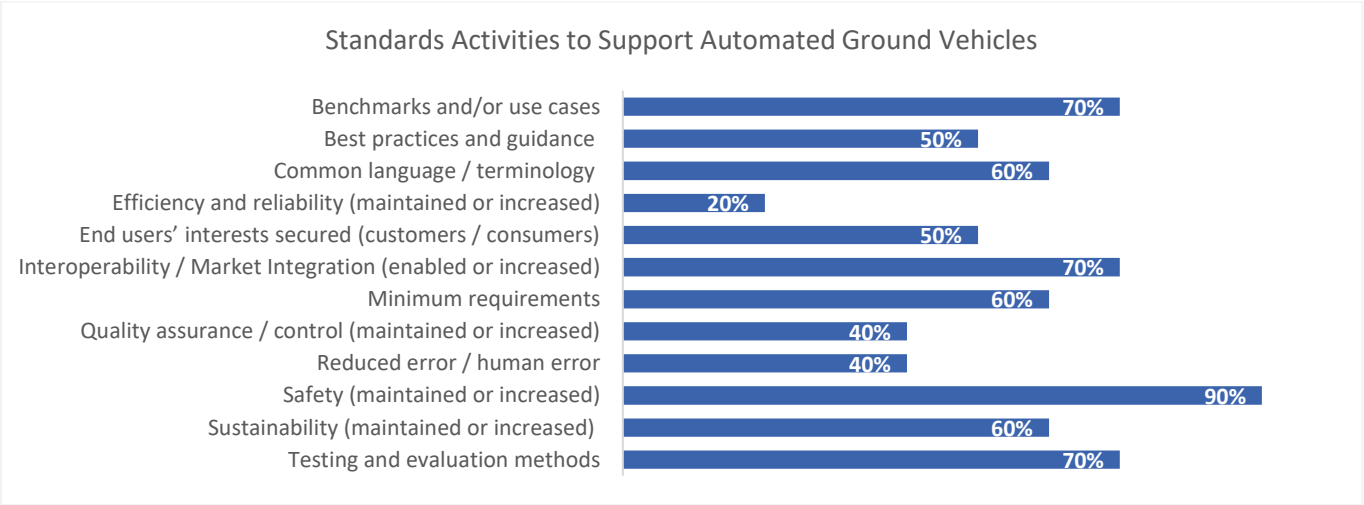
Opportunities	***Challenges***
Use-case based standardize coupler interface	Fear of change, public acceptance
CCS and MCS being the most broadly adopted, vis-a-vis Europe	Lack of use-case based standardized coupler interface new technology will not immediately be perfect
Cooperation & collaboration between roadway infrastructure and ADS development	Infrastructure (automated/connected) will take a lot of time, money & resources to implement and standardize
Improve performance and safety	Inadequate sensor output validation, behavior anomaly detection (high level & subsystem), safeguards against adverse system behavior
Transportation as a service for those with disabilities	Requirements (State regulatory, environmental)
Create the same expected behavior of driver assist features and functions across vehicle OEMs	Drivers understanding features – knowing what they do / do not do.

Volume/Traffic logistical information which can help for trip planning. Both for the roads and charging infrastructure.	OEMs product differentiation: Giving people "what they want" (giant screens) instead of "what they need" (physical buttons in the same place)
Free up commercial real estate by placing parking areas outside the "downtown" area and having cars drop off and pick up passengers when needed.	Automatic fault correction
	Accessibility
	Cybersecurity
	Reliability

What role do stakeholders see standards playing in overcoming challenges?

Polling:

Standards offer many benefits. Attendees were asked to the select which of the following standard work products or results would help enable automated and connected **ground vehicles**. Best practices and guidance were identified as the top need. The results are as follows:



What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?

Discussion:

- **Regulatory Sandboxes** – A regulatory sandbox can provide manufacturers the ability to understand how their products work in very specific operating parameters, and how they work against specific regulations. It can allow stakeholders to address very specific issues, such as addressing infrastructure needs. Regulations are risk adverse and are often looking backward, where sandboxes provide the opportunity to plan a path forward.
- **Misunderstanding about the role of standards**: Standards should not be seen as the only tools, but one of many tools that help support the ecosystem and solve questions.

Polling:

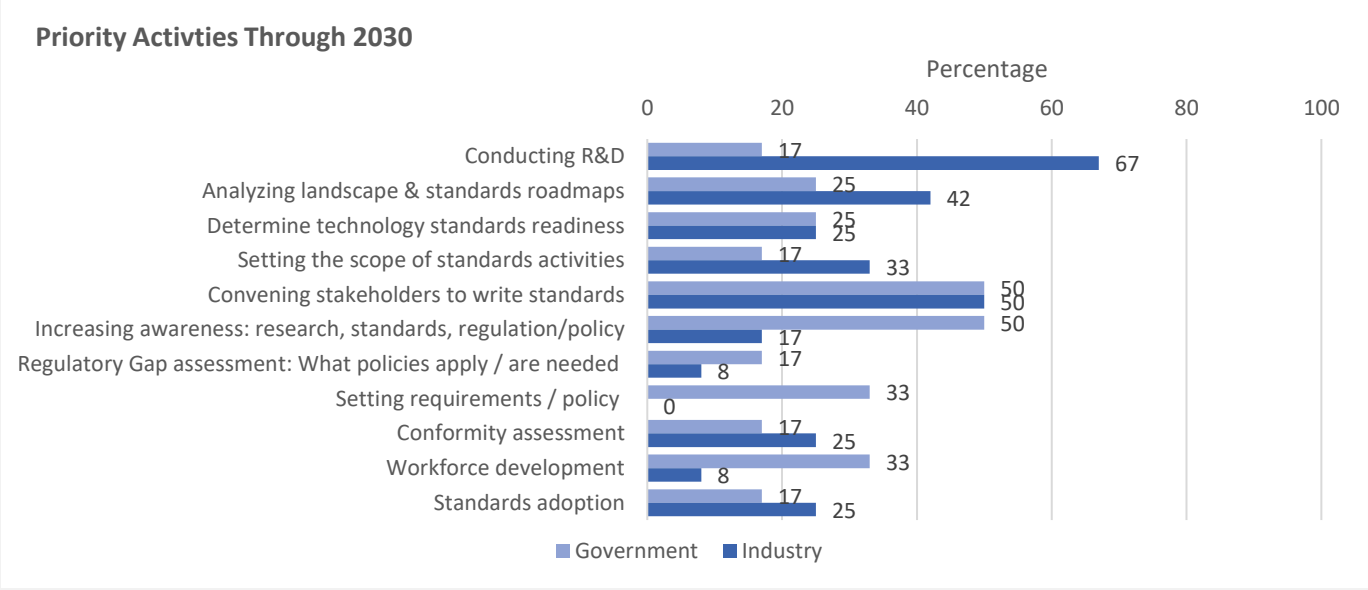
- Safety education and SOPs
- Emergency response requirements
- Inspection/revalidation schemes better than that for existing infrastructure operations
- Expanded guidance for new construction and maintenance requirements
- Regulators should include industry-developed standards and best practices into their policies and regulations when appropriate (Especially for CETs)

- EPA regulations, ISO 14001, ISO 27001, SOX compliance
- Enterprise Risk Management Frameworks
- Tools for state and local governments to make confident investment decisions in connected/automated infrastructure
- There needs to be a joint framework for roadbuilders/operators and OEMs. Roadway design criteria do not address quickly changing road markets. The lack of EV infrastructure is a good example of the need for a joint framework between these two sectors.
- A document that promotes a framework of requirements and recommendations for automated vehicle infrastructure that helps enable safe automated and connected vehicle deployment.
- Need to define a minimum level of security and develop a testing regime for each ADS level. This was attempted by NHTSA about five years ago and ended abruptly.
- A regulatory policy framework that defines minimum requirements of CV/AV which help to set baselines for liability.
- Without ITS spectrum regulatory stability OEMs won't invest in onboard connectivity technology.

What is the role of industry vs government to maximize opportunities?

Polling:

Attendees were provided a list of activities which could potentially enable automated and connected **ground vehicles**. They were asked to identify which the industry and government should prioritize over the next five years. The results are as follows:



What concerns have been raised about existing standards efforts?

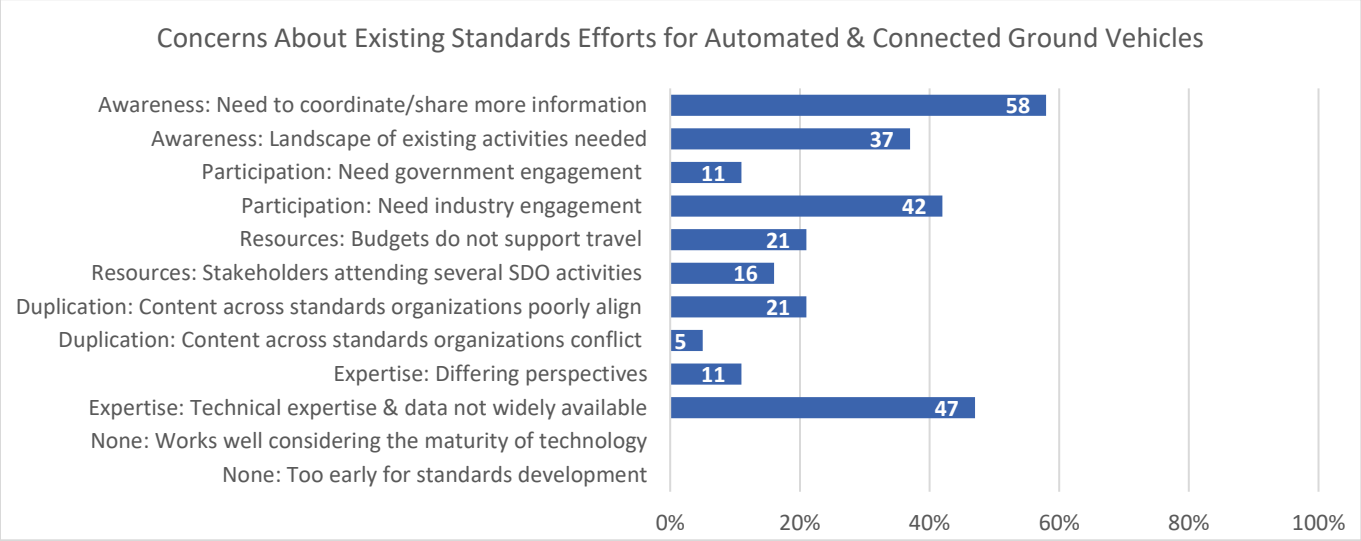
Discussion:

A few brief remarks were made during the discussion about challenges in standardization in addition to the polls. They were:

- **Chicken or the Egg? –** One challenge in standards efforts may be that it is too premature to create standards especially if we do not have regulations.
- **Stifling Competition –** There may be too much fear in stifling innovation or competition.
- **Terminology and Test Methods Development:** These may be the only two areas that industry is ready and able to standardize at this stage.

Polling:

Attendees were provided a list of common concerns which could potentially slow or hinder standards development. They were asked to identify which three have been raised from their perspective. The results are as follows:



5.2.1.3 Automated and Connected Aircraft Discussion

Moderator: Jonathan Archer, SAE International

Opening Remarks: Mr. Archer's day-to-day efforts at SAE International are forward looking. In aviation, safety is a very broad term which fundamentally seeks to ensure there is not loss of life, damage to third party property, and that new technology is implemented properly. The sector had a great deal of collaboration among stakeholders (industry, government, and academia) to ensure solutions development helps the full ecosystem. Standards, as one of these solutions, are leveraged as a statement of intent, statement of best practice, or as a means of compliance to regulations (not necessarily as law). Information captured in aviation standards is often tiered and not always developed as single solutions. How do we help support and not constrain the use of new technology?

Aviation is very complex and operates in four dimensions, but does not have pedestrians running in front of aircrafts. Automation in aviation is also complex but is more predictable than in ground transportation. Aviation currently does, and needs to, see-and-avoid, predict designations, navigate, and arrive in a timely manner. AAM seeks to do much of the same but in shorter trips, with electric aircraft and some flights without a pilot. The aircraft used could be a UAS or an electric vertical take-off and landing (eVTOL) carrying cargo or passengers (payloads). Emergency medical aircrafts have been landing in urban centers at heliports. The aviation sector has experience in executing several of the new technologies today. Automated and connected aircraft is focused more on changing the role of the pilot and how the aircraft interfaces with infrastructure. The sector also expects implementation though a phases approach.

Mr. Archer used the following graphic to show how Advanced Air Mobility Missions look in the current environment:

Illustrated examples of types missions for Advanced Air Mobility (AAM) vehicles (credit: NASA)

What are the challenges and opportunities presented by automated and connected aircraft and is there sufficient public and private stakeholder awareness on these fronts?

Discussion:

- **Doing more in less space:** AAM operations are working in a smaller operational environment. How can airspace segregation be safely executed? How do we apply what we are doing today to this new concept? What role does automation play in supporting this?
- **Electric and Hydrogen Fueled Propulsion:** Charging and 'refueling' aircraft with different propulsion systems will require ground equipment and energy supply. The energy supply will need to meet this new demand. Concepts of operations will need to factor in who to fuel/charge based on resource limitations (infrastructure or energy). Considering the megawattage needed, is the safety option to be charging aircraft by hand?
- **Air Traffic System (ATC):** The new aircraft are flying in different environments. Some areas are not covered by ATC. If not using ATC, how will aircraft and operators communicate? What spectrum will they use (5G/6G?)
- **Infrastructure:** Is new infrastructure needed or is existing infrastructure being utilized and retrofitted? What changes in infrastructure need to happen first? Basic systems exist; how could they be leveraged or augmented?
- **Vehicle to Vehicle Communications:** If there is no ATC or operations are dense, how can aircraft communicate with each other? Can existing spectrum support this? If something fails, what backup systems are in place. Automotive has traffic lights.
- **Public Acceptance:** Will the public get into a remotely piloted aircraft? How do we ensure that the public feel confident they will be transported safely? Education will be very important to overcome these challenges. Perception will be key. Reported accidents will have a huge impact.
- **Weather:** Weather prediction for safe flight comes into play especially in metropolitan areas. There is a lot of steel and concreate making these "heat islands." Satellite navigation does not function the same way in heat islands. This new paradigm will need to use position, navigation, timing (PNT) principles and potential use satellite augmentation.
- **Risk Frameworks:** The aviation sector has methods for doing analysis, more reliability testing, and mission related evaluations than the automotive sector may have. Safety is manifested and layered in many ways in aviation, in manufacturing and certification, operations and maintenance, in the public interaction (security).
- **Risk Perception:** Fatalities in the automotive sector are publicly acceptable (to some extent) but in aviation they are not although they are magnitudes less than in automotive.
- **Safety Management Systems:** SMS is about improving an organization's safety culture about making improvements along the way. From a technical side, SMS addresses what decisions an organization makes that could affect product safety (an aircraft in aviation). This is regulated now, for FAA in Part 5 and in EASA in Part21. The regulations are the same but done under a different framework.
- **Software Driven:** New products are mostly software driven. From a flight controls standpoint, it is less mechanical and more fly-by-wire. It is very reliable but has more software.

Polling:

Additional challenges and opportunities were provided via Slido during the event, in addition to those collected prior to the event. Below is a list of the feedback ANSI received:

Opportunities	***Challenges***
Introduction of new operational models to move people and products (e.g., eVTOLs)	Societal / Public acceptance: Noise conflicts with human populations or fear of change
Improve performance and safety	New technology will not immediately be perfect
Enabling automated responses, most efficient resource scheduling and predictive analytics across airport operations.	Infrastructure (automated/connected) will take a lot of time, operating costs & resources to implement and standardize
Real-time delivery of high-value goods.	Requirements (State regulatory, environmental, FAA)
Unique market niches open, especially in delivery/logistics, business to business as well as direct to consumer.	Safety against cyber terrorists or even bugs in the automation software. Sensors or communication modules going bad or unresponsive.
In some ways more advanced than ground vehicles- lessons to be learned and applied elsewhere	Siloed systems, shared cybersecurity vulnerability
A new way to travel regionally for consumers and shipment of goods.	Localized air traffic control (ATC)
Streamlined scheduling for runways and limited access air spaces, automated adjustments when the system is fed information such as delays, obstructions etc.	Systems management
Travel efficiency, faster emergency response, commerce, technology innovation and global leadership.	Substantial initial research investments
Efficiency, lower carbon footprint, increased safety, more rapid response to changed conditions (NOTAMS, TFRs, etc.)	Equity (access)

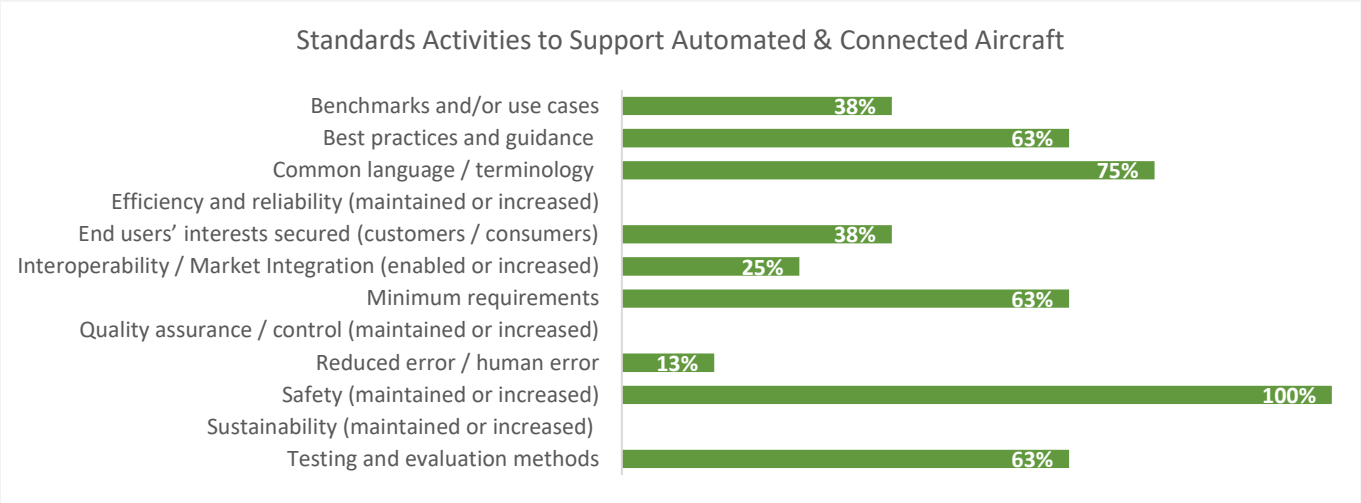
What role do stakeholders see standards playing in overcoming challenges?

Discussion:

- **Risk Management:** Can risk management standards help with public perception? Will it take a generation of experience before the broader public fully accepts automated aircraft and AAM?
- **Safety Management Systems (SMS):** This has helped from a corporate perspective but there has not been a measurable impact (from SMS) from the public. An analogy is the public's acceptance of seat belts. There was a culture of users that resisted its use until they had an experience (e.g., an accident) that encouraged them to voluntarily use their seatbelts. It was not until laws were passed requiring their use that you could see a safety trend.
- **Adoption:** Standards may help with the adoption of autonomy and new aircraft designs
- **Environmental Impact:** In surveys done with the public, results show more concerns regarding environmental factors than on safety of technology, including if operations come through their area, how they will impact their quality of life.
- **Terminology:** Terminology standards help newer technology stakeholders talk more productively amongst each other and with experts from applicable sectors. This can also help with identification of needs and challenges so discussions about standards, regulations, and other guidance needs can begin.

Polling:

Standards offer many benefits. Attendees were asked to select which of the following standard work products or results would help enable automated and connected **aircraft**. Best practices and guidance were identified as the top need. The results are as follows:



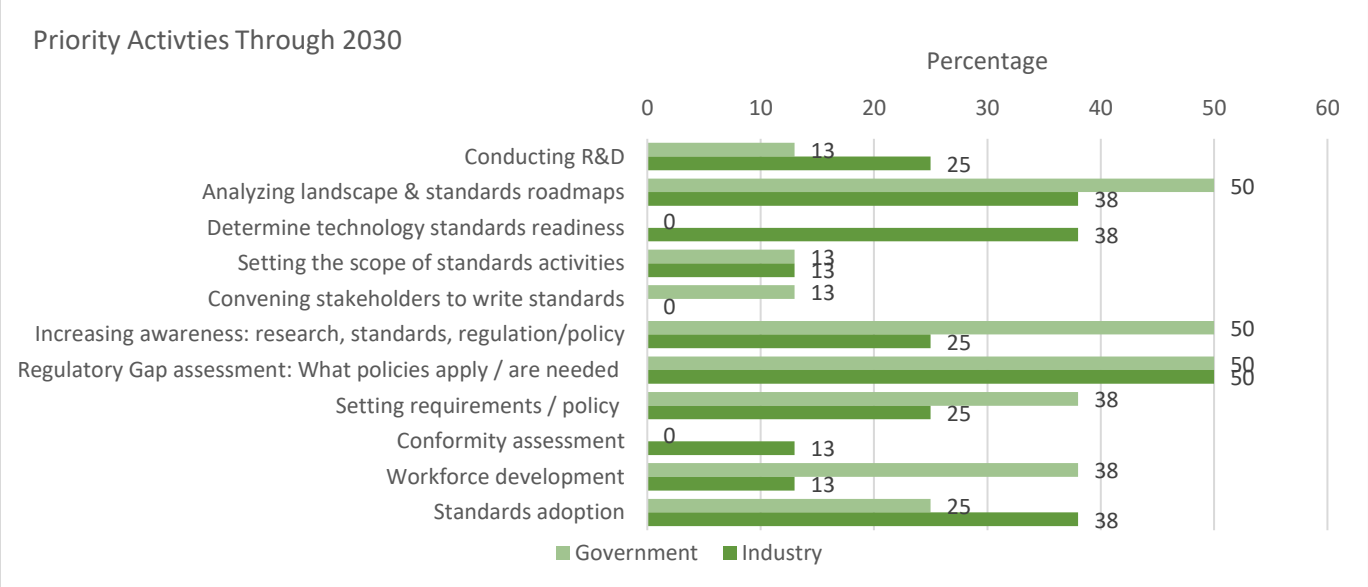
What is the role of industry vs government to maximize opportunities?

Discussion:

- **Collaboration:** It is less about one side or another and more on the collective getting together to share experiences and make improvements, including the effectiveness of standards.
- **Research:** Individual industry organizations fund R&D to help provide solutions to technology issues, but this view is narrow. Use a consortium to fund this same R&D and it helps a group of stakeholders understand the state of play. Using government funding provides broader public access and awareness. Regardless of the research results or where a technology is on the scale of maturity, this tends to be the trend.
- **Identifying the readiness:** Technology maturity influences standards readiness but so does the maturity of the conversation in industry.
- **Setting the Pace:** Industry and the marketplace drive the pace of incremental innovation.

Polling:

Attendees were provided a list of activities which could potentially enable automated and connect aircraft. They were asked to identify which industry and government should prioritize over the next five years. The results are as follows:



What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?

Discussion:

- **It is not just the Federal Government:** AAM requires more than just federal government engagement. It also impacts state and local government.
- **Has industry decided what they want:** Industry needs to determine what they want and communicate that to regulators (either as a single voice as a company or as a collective industry voice through trade associations), after which, authorities can help support those needs.

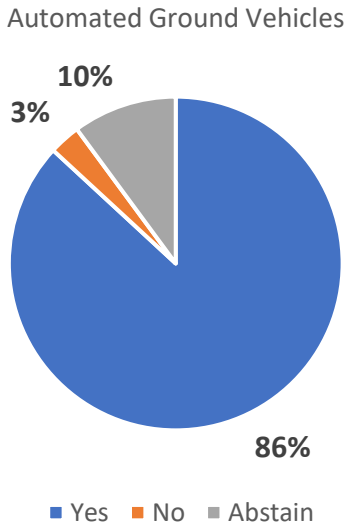
Polling:

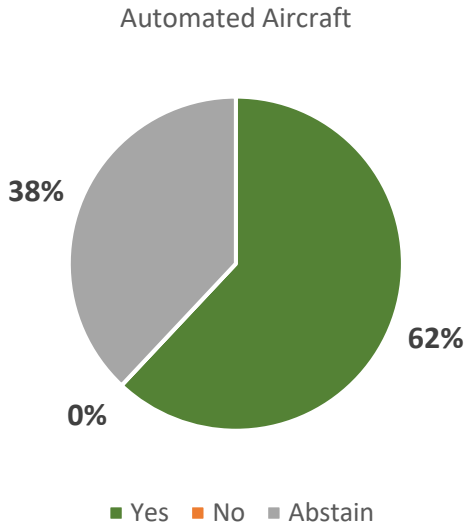
- Clear definition of Federal/state/local roles and abilities to either approve or deny deployment, including national & homeland security "redlines."
- Government can continue to develop and fund test sites to encourage more rapid development of autonomous mobile tech. Entry into test sites should be less bureaucratic. Safety education and SOPs
- Emergency response requirements
- Inspection/revalidation schemes better than those for existing infrastructure operations
- Expanded guidance for new construction and maintenance requirements
- Regulators should include industry-developed standards and best practices into their policies and regulations when appropriate (Especially for CETs).
- EPA regulations, ISO 14001, ISO 27001, Sarbanes-Oxley Act (SOX) compliance
- Enterprise Risk Management Frameworks

5.2.1.4 Should Automated and Connected Infrastructure Standards Development be Accelerated?

Polling:

Attendees were asked if standards development for automated and connected ground vehicles or aircraft needs to be accelerated.





5.2.3 Role of Standards-Driven PPPs for Automated & Connected Infrastructure Session

Standards-Driven Public Private Partnerships (SD-PPPs) Models

Christine Bernat, ANSI, briefed about five proposed SD-PPPs. Ms. Bernat's presentation can be found here. A summary of those models is found in Section 2.3.

5.2.3.1 Perspectives on Public Private Partnerships Briefings

Government Perspective: Natalia Globus Martin, National Institute of Standards and Technology (NIST)

Ms. Globus Martin's presentation can be found here. The same presentation was provided from the AI/ML event from July 17, 2024. See the summary found in Section 4.2.3.1.

SDO Perspective: Pat Picariello, ASTM International

Mr. Picariello's presentation can be found here.

Mr. Picariello shared the experience and approaches that ASTM International has taken in their centers of excellence, highlighting that there are multiple ways to establish a PPP and different models that can be built. However, a key driver is proactivity. Regardless of what type of organization leads the PPP, a dynamic sense of proactivity will impact the success. Not just in a PPP, but also in standards development, this motivation for proactivity is an enabler. ASTM strives to foster engagement with stakeholders as early as possible and consistency throughout the entire standards development process and implementation.

ASTM Additive Manufacturing (AM) Center of Excellence (COE)

The AM CoE was formed in 2018 to accelerate standards development for AM and other services to better serve the sector. The AM CoE is a collaborative partnership among ASTM International and organizations from industry, government, and academia, that conduct strategic R&D to advance standards across all aspects of AM technologies. The center aims to accelerate the development and adoption of technologies by supporting:

- Standardization and its acceleration
- Developing training and certification programs
- Providing market intelligence, business strategy
- Advisory services via Wohlers Associates, powered by ASTM International

There are five pillars in the CoE including R&D, education and workforce development, standards and certification, consortium, and advisory/intelligence. The R&D themes are defined by the R&D team, tied to the ANSI AMSC Roadmap, America Makes projects, and in collaboration with NIST. Each R&D project submission is required to include the proposed standards title, scope, and rationale, as well as the commitment of a technical expert to shepherd it through the ASTM standards development process. R&D is funded by ASTM, government, and the CoE industry consortium and projects are supported by several other partners.

Between its formation in 2018 and July 2024, the CoE has resulted in the approval of 17 new standards, 11 draft standards (in balloting) and nine draft (not yet in ballot).

5.2.3.2 Role of Standards-Driven Public Private Partnerships for Automated and Connected Infrastructure Discussion

Moderator: Ted Sienknecht, The MITRE Corporation

Opening Remarks: MITRE operates six federally funded research and development centers (FFRDCs) and supports several other PPPs. These efforts are typically striving to solve at-scale multi-sector challenges for a safer world. The goal

for this session is to tie the previous discussions together and explore the role of PPPs to support automated and connected infrastructure.

What benefits or challenges do you see with a PPP for these technologies?

Discussion:

- **Drivers Beyond Contracts:** Collaboration is hard; mutual, proactive drivers that every organization can commit to are necessary.
- **Structure:** Enough structure to keep people in sync, but does not overwhelm partners with administrative taskings.
- **Sharing of Best Practices:** PPPs can get people out of silos and collaborating on issues to develop best practices.
- **Education & Training:** PPPs can help industries plan how to prepare the next workforce.
- **Relationship Building:** Whether within the PPP or externally, building relationships helps stakeholders trust each other and be more willing to work together in the long term.
- **Pace of Funded vs not Funded Standards Development:** Even with funding there is no guarantee that the standards development will be accelerated. There are many examples of volunteer related standards development that work very rapidly. In some instances, funded standards development may move more slowly because it is not always open to broader participation.
- **Truncated Process:** Standards organizations are often requested to truncate their process to help accelerate standards development. However, when consulting their members, that is typically not desired. Industry has found it important that a standard is fully vetted through a voluntary consensus process. Even with a funded standards development model, the focus should be to produce the draft alone and then the draft should be reviewed through the SDO's normal approval process.
- **Data:** A trusted party of the PPP, or 3rd party, can aggregate data from various sources to anonymize it. When there are competing models and supporting IP, a PPP can help sandbox them together, or determine how they can interoperate in a way that is IP or privacy protective. Depending on how much data is in the mix, there are proven technical measures for allowing federated analytics, privacy protected analytics, and IP protected consortia and standards development to occur.

Polling:

Additional benefits and challenges were provided via Slido during the event, in addition to those collected prior to the event. Below is a list of the feedback ANSI received:

Benefits	***Challenges***
Mitigate risk for public & private sector	Align diverse objectives & priorities
Advance funded proof of concepts that test real world scenarios	Mitigate data/information sharing concerns: - Intellectual property protection - Sharing with government or competitors - Privacy, attribution, and appropriate use
Prepare end users to use new technologies	Obtain funding & resources
Enable timely rollout of new technologies	Address governance & management
Spur neutral R&D and broader industry acceptance	Ensure adequate & balanced representation of stakeholders
Draw on variety of perspectives	Operate at speed of collaboration/trust
Incentivize participating companies	Balance short-term profit and long-term technical goals
Deliver long-term impact analysis & cost justification of automated solutions	cultural + focus on "customer" or "specific product evaluation"
Share KPIs & best practices across stakeholders	Incentives to bring people to the table
Achieve greater impact together than what any individual entity could accomplish on their own	Establishing effective collaboration between dependent, but different industry sectors, e.g., CAV infrastructure and CAV developers

Networking/Relationship development with peers	Workforce development
Sandbox environment for new tech and mechanisms for scaling up from lab/test environment to implementation- identifying standards gaps at each step	Expectation that participation =endorsement of results, or commitment to implementation.
can orgs create evaluation models that could be used by OEMs without exposing OEM data?	Incentives to bring people to the table
More agile development process due to funded development, not volunteer development and better PM.	
Ability to bring in people from "tangential" sectors to really understand impacts and dependencies.	
Workforce Development	
Get people out of silos, "yokoten" incentivized best-practice-sharing	

What role can various types of stakeholder organizations play in PPPs for these technologies? e.g., consortia, trade associations, academia, standards organizations, centers of excellence

Discussion:

- Standards organizations and industry should provide education and training around standards, data-driven alignment, and successful use-cases.
- Trade organizations can generate enthusiasm and recruit practitioners and students. Trade associations that engage students should help mentor them early in their careers.
- Government can confirm a public benefit, implied or explicit protection (safe harbor for information sharing), and seed funding if there is a public benefit. The USG can use the standards process to develop solutions. (The example of Part 23 aircraft was mentioned (see Appendix D, General Aviation Aircraft use case.)
- There needs to be a consumer watchdog role to ensure it is open to existing and new providers and any negative impacts can be monitored and actioned if needed.
- Information dissemination involving students - pulling in emerging professionals and SMEs. Educate students about how standards are a focus to organize and affect change.
- Drive adoption of standards by policymakers and regulators.
- Engage non-traditional, "tangential" stakeholders.
- PPPs overall should share the value of standards.

What PPP short-term and long-term goals would have the broadest impact on success? e.g., standards focused R&D, workforce development, research and standards roadmaps, strategic planning

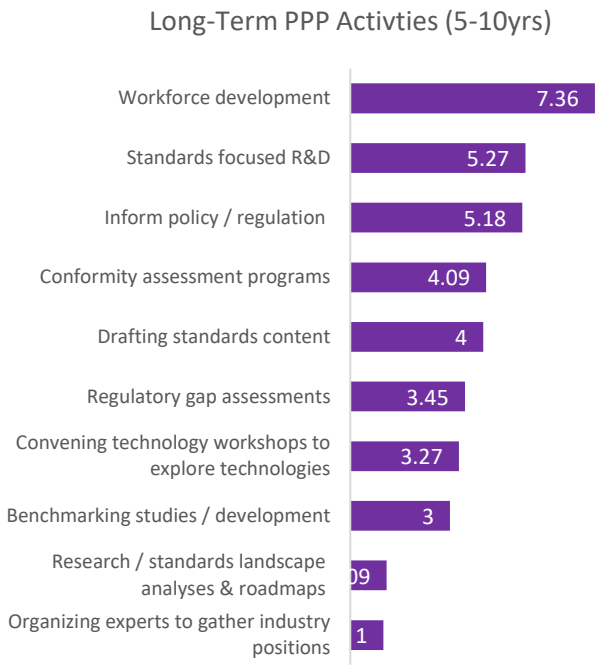
Attendees were asked to prioritize common PPP activities based on short-term (0-yrs.) and long-term (5-10 yrs.) needs for automated and connected infrastructure standards development, agnostic of sector. The selections and results were as follows:

Selections:

- Benchmarking studies / development
- Conformity assessment programs
- Convening technology workshops to explore technologies
- Drafting standards content
- Inform policy / regulation
- Organizing experts to gather industry positions
- Regulatory gap assessments
- Research and standards landscape analyses and roadmaps
- Standards focused R&D
- Workforce development

Results:

The order represents the ranking and the bar represents the average ranking score.



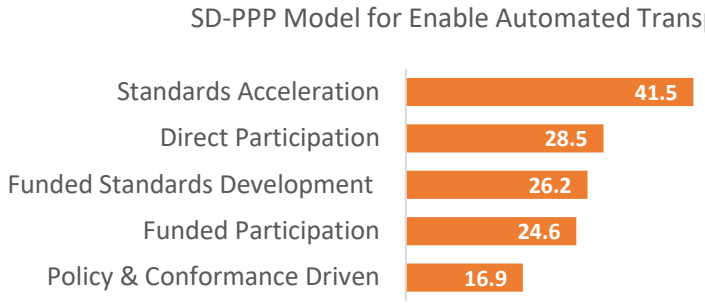
What type of PPP model or models could benefit these technologies?

With consideration of the potential PPP work products shown in Table 8, attendees were polled regarding which PPP model would be most beneficial to support this sector.

Table 8: SD-PPP Model Work Products

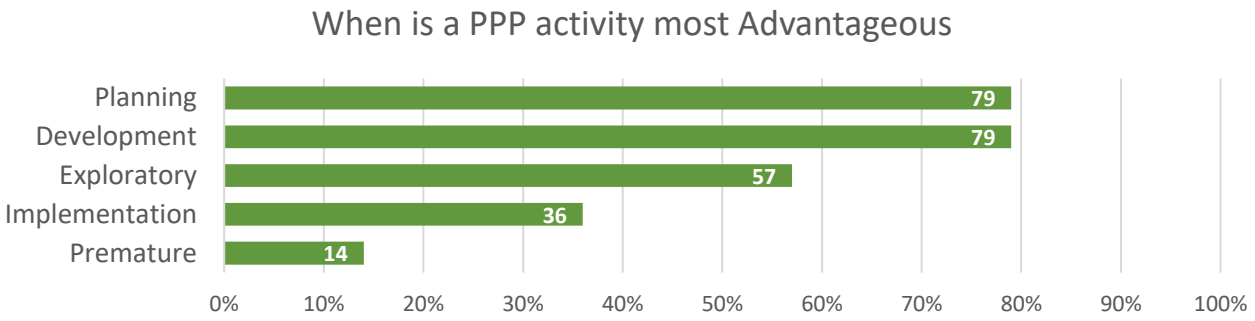
SD-PPP Models	Work Products
Direct-Participation	Pre-standardization: technical reports, strategic plans Standardization: Standards development Implementation: Increasing awareness, technical training, workforce development on standards
Standards Acceleration	Pre-standardization: Technical workshops and symposia, standards road mapping (landscaping and gap analyses), and other research and technology reports
Funded Participation	N/A, this supports increased participation to balance the representation of stakeholders in standards development
Funded Standards Development	Pre-standardization: Research, research reports, databases, statistics Pre-standardization: Formation of a new standards developing committee or SDO Standards Development: Draft proposed test methods, design specification, best practices Implementation: Increasing awareness, technical training, workforce development on standards
Policy and Conformance Driven	Pre-standardization: Strategic plans and roadmaps Standards Development: Standards (1 or more standards) Implementation: Increasing awareness, technical training, workforce development on standards

Polling:
The results are shown in ranking order and the bar represents the average ranking score shown via percentage.



At what (if any) point would an organized PPP activity be most advantageous?

Polling:
Attendees were asked to select during which of the five sub-phases of standards development would a PPP be most advantageous and the results are shown in percentage.



5.2.4 Current and Future State of Information Sharing Session

5.2.4.1 Current State of Information Sharing

Mary Saunders, American National Standards Institute (ANSI): What information is being shared today?

Ms. Saunders' presentation can be found here. The same presentation was provided from the AI/ML event from July 17, 2024, with a new summary of standards activities related to this technology area. See the summary found in Section 4.2.4.1. To avoid repetition, below is only a summary of the sector specific remarks.

Summary of Sector Specific Talking Points:

ANSI organizes standards collaboratives to advance cross-sector coordination in the standards and conformance programs needed to support and grow emerging technologies and markets including:

- Electric Vehicles Standardization Panel (EVSP), funded by DoE, published its third standards and code roadmap in June 2023. The roadmap identifies EV issues, standards, codes, guides, and related policies that exist (e.g., NEVI Final Rule) or that are in development with a focus on vehicle systems, charging infrastructure, grid integration, and cybersecurity. The report identified 37 gaps (14 high priority, 20 medium priority, 3 low priority), 23 of which require R&D. EVSP had participation of approximately 130 individuals from 80 organizations.

- UAS Standardization Collaborative (UASSC), funded by FAA, published its second standards roadmap in June 2020 and publishes gaps progress reports twice a year. The roadmap identified 71 gaps in airworthiness

standards and flight operations standards and was developed with participation of approximately 400 individuals from 250 organizations. Below is a timeline of its activity:

-

Maria Knake, National Institute of Standards and Technology (NIST): What did industry suggest in RFI responses and past listening sessions?

Ms. Knake's presentation can be found here. The same presentation was provided from the AI/ML event from July 17, 2024. See the summary found in Section 4.2.4.1.

5.2.4.2 Future State of Information Sharing

Moderator: Christian Thiele, SAE International

Opening Remarks: Information sharing topics have been a thread in discussions throughout the event. Communications is increasingly important in the current climate because the diversity of technologies being installed on ground vehicles and aircraft is significant. For example, discussions supporting ground vehicle standards used to focus solely on the vehicles, where now discussions include technologies outside the vehicle, such as how it interfaces with infrastructure. There are more stakeholders contributing to the marketplace making it necessary to reach a broader stakeholder community outside of transportation.

What communication standards challenges does this sector face? What could be done to improve it?

Discussion:

- **Intellectual Property:** The automotive sector has a strong desire to protect their IP and initially did not understand the benefit of sharing limited IP (in standards development) to help the broader public, increase adoption, and allow for economies as scale. The aviation sector is coming along but is more reserved on this front.
- **Hard to track various activities:** There are various efforts and organizations working in this area. In addition, there are different technologies that impact the sector. It is challenging to keep up on the activities and ensure a balanced representation of stakeholders at the table.
- **Support from Leadership:** Leadership does not always understand the value of participating and the return on investment. SAE is working on a standards benefits presentation to support this sector. SDOs do not communicate successful use cases but they are needed.
- **Engaging State/Local/Tribal Government:** Government and smaller organizations may not have the resources to track standards development and/or participate. Efforts need to be made to educate and help get them access. While SDOs may have membership fees to join committees, many SDOs now offer online participation to meetings and conduct balloting online. The access to participate does not have as many barriers, but employees getting the support to dedicate their time does have an impact.

Polling:

- Public perception of data security and privacy risk
- Competitiveness

- Linking all industry associations to this effort, and encouraging participation
- Several organizations impacted
- Different organizations have different goals
- Varying terminology & definitions
- Lack of standards driven by NGOs causes imbalance party involvement and results in one-sided "standards“
- Startups lack resources, networks, experience w/SDOs
- Strategizing - especially for startups and small companies, knowing where to focus your efforts is difficult
- Alignment of engineering standards with cyber standards
- Explaining the business case for engagement in standards development, vs. focusing on compliance costs
- Lack of integration of industry use cases with standards to show the benefits of standards

During the pre-standardization phases of technology, it is important to begin educating about the value and benefits of standards. How can we amplify this messaging to ensure it reaches the appropriate stakeholders?

Polling:

- Start with terminology - ask them all to define key terms and share the results. The realization that they are not even talking the same language drives engagement!
- Build standards activities incentives into (for example) USDOT funding opportunities
- Case studies, explanation of how and why the voluntary consensus process works and is beneficial

What standards education should be coordinated by the private sector (i.e., industry, SDO, academia)?

Polling:

- Standards "coverage" with respect to sponsored programs. For example, at mapping of standards activities to an institution’s projects (intra-institution awareness).
- Community of practice on campuses around technology specific standards
- Data-driven storytelling, visual storytelling, customer-first mindset
- Relevant standards and standard measures including testing and verification approaches

What standards education should be coordinated by the U.S. Government?

Polling:

- Safety related, Competition-sensitive, security related
- Data-driven storytelling, visual storytelling, customer-first mindset
- Life and safety issues, import or export controls standards and competitive nature and consumer protection of standard

This concludes the summary of the July 30th event. All the meeting materials and presentations are online. A summary of recommendations as it relates to project and the event discussions is included in Section 6.

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6. CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

6.1.1 Current State of the Standardization System in Relation to CETs

The private-sector led U.S. standardization system has a long-established and successful history of effectively supporting existing, new, and innovating technologies. The system has proven to be flexible and highly adaptive. To a great extent, stakeholders are dealing effectively with the fact that the pace of change in emerging technology areas is moving at an ever-increasing rate, while recognizing specific challenges. There are a larger number of global players – both government and private sector – actively engaged in standards processes as well. Some newer stakeholders aiming to promote critical and emerging technologies (CETs) may find it daunting to integrate into and navigate the standards community. The standards workforce is similarly challenged. Even if there is essentially a stable supply of standards professionals in the U.S., the ratio has shifted – more standards activities for the same number of experts to track, given limited resources. As technologies change, there is a related demand for a higher level of technical expertise among participants. It may be difficult for some standards professionals to keep up and engage effectively and with relevant technical input in some areas. Expanded information sharing, coupled with knowledge transfer, through training, education, and mentorship programs, is critical.

Appendix A outlines in more detail the common challenges that the standardization community faces and what approaches are commonly taken to address these challenges. The SD-PPP models that best align with these approaches are included as well.

6.1.2 Specific Lessons Learned

In addition to the common challenges and solutions, there are specific lessons learned (related to partnerships and standardization activities) derived from interviews and the brainstorming events:

- **Defined Mission**: Stakeholders must agree on the stated mission and objectives in order to understand their roles and why they are investing their resources. If there is misalignment, effectivity will decrease and pace of success will be slow, if not hindered.
- **Clear Benefits**: Stakeholders must foresee the benefit of their investments (e.g., revenue, gained insight or education, cost-sharing / reduced costs, increased safety/efficiency) to ensure continued motivation and understanding of their roles. Some aspects of this are elaborated further in section 6.2.2.
- **Resources Available**: Financial and non-financial investments can be contributed to the effort; however, the collection of contributions must sustain the activity. Stakeholders should understand what steps to take to gap fill if there is a decrease in resources at any given point (e.g., determine alternative revenue/funding sources, leverage a network of experts, succession planning for leadership).
- **Appropriate and Sufficient Engagement**: The success and derivative results of the effort will be driven by the stakeholders at the table. To ensure resulting work products are market relevant, the stakeholders at the table should be representative of the market. Engagement from stakeholders should be active as well as consistent, and options for engagement should be flexible. Having a groundswell of leading stakeholders engaged will also attract other stakeholders, such as small and medium-size enterprises and startups, which supports longevity of the program.
- **Communications and Awareness**: Effective internal and external communications are necessary to ensure effective program management and resource allocation decision-making. How this is executed may differ depending on the mission and type of activity. See also section 6.2.3 for more details.
- **Connectivity to Outside Activities**: Develop a communications plan. There are various initiatives that can support standards development, many of which are taking place in parallel. Establishing and maintaining liaisons should be viewed as an investment because awareness about which supporting or related activities are happening helps avoid duplication, saves resources, and accelerates implementation. Learn from each other, do not reinvent the wheel.

6.2 Recommendations:

6.2.1 General Considerations for CETs

All stakeholders have a role to play in supporting research, technology, and standardization efforts. When effectively executed, public and private sector coordination can strengthen the necessary relationships by which standards development activities are enabled or even accelerated. Many CETs have both technology-specific (horizontal) and sector-specific (vertical) implications. Additionally, some CET developers are hesitant to actively engage in standards activities at an early stage of technology development for fear of hindering innovation, relinquishing intellectual property, or wasting resources. Lastly, determining standards readiness is not always possible, especially when organizations arrive at this determination at different speeds. These factors make education, communication, and partnership essential for advancement.

6.2.2 Standards Education

Standards education is a form of information sharing and is specifically highlighted in this report because it serves as foundational knowledge that will assist CET stakeholders to understand how the global standardization system functions and how to effectively contribute to it. Education is not unique to CET stakeholders; however, it is especially important in securing their commitment of resources and instilling confidence when they take their seat at the table.

Various stakeholders can play a part in standards education by educating each other including:

Standards Organizations and U.S. Government:

- Educate about the value of standards and participation in standards development
- Communicate relevant use cases which exemplify the value(s) to specific stakeholder groups
- Connect with stakeholders to learn about the challenges they face and educate about how standards can provide solutions (cite examples)
- Educate about the role of standards in contracts, conformity assessment, regulations/policy, and international trade
- Educate about effective and proactive participation in standards, including benefits of taking a leadership role
- Educate about what to expect during implementation phases of standards development
- Educate about how to advocate for standards (draft or published) which benefit their organization's mission

Sector Specific Stakeholders and Users/Suppliers:

All:

- Educate about where their technology impacts existing standards activities
- Connect CET stakeholders with leadership in related standardization activities

Consortium/Associations:

- Establish liaisons with SDOs and invite them to educate members/partners about how to effectively participate in standards development on a reoccurring basis
- Create a standards webpage which includes standards education and relevant standards activities (link to outside resources where possible)

Users/Suppliers:

- Inform CET stakeholders about the benefit of standards they already utilize, and point them to SDOs they participate in so they can determine how best to engage.
- Share use cases of where standards have benefited their business

CET Stakeholders*:
- Educate sector-specific stakeholders about the benefits of the new technology and how it differs from what is in place - Educate other stakeholders about challenges that arise with integrating into the current market or with using existing standards - Educate regulators about intended use, design and/or performance variances from current technologies, and timelines to market

** These three suggested actions are also information sharing, but it is important to share this information about the technology so the standards community offer CET stakeholders the impactful standards education.*

6.2.3 Increased Information Sharing

Increased information sharing is targeted at improving awareness about standards and conformity assessment programs. Recommendations for information sharing are divided into two categories: existing activities and future needs. There are various options for sharing information, which may also depend on what phase of standards readiness a technology is in. Keeping in mind the standards' related education is addressed above, below are recommendations for what information needs to be shared and where it fits within the sub-phases of standards development.

Table 8: Information Sharing During Standards Readiness Phases

INFO-SHARING	EXPLORATORY	PLANNING	DEVELOPMENT	IMPLEMENTATION
Share information to increase awareness about **existing…**	- Related standards & supporting SDOs - Regulations - Conformity assessment programs - Benchmarking	- Related standards & supporting SDOs - Regulations - Conformity assessment programs - Benchmarking / Use cases	- Standards activities - Impact / relationship to existing regulations - Impact on conformity assessment programs - Impact on education & training - Use Cases - Standards meetings	- Publication of standards - Adoption by Regulators - Conformity Assessment Programs updates - Workforce education & training updates
Share information to increase awareness about **future…**	- variances from existing standards - R&D needs - Benchmarking/use case studies needs - Sectors impacted	- Standards needs - R&D needs - Benchmarking/use case studies - Sectors impacted - Policy/guidance needs	- Standards needs - R&D needs - Policy/guidance needs - Education & Training impacts	- Challenges in utilization of standards from users as well as from conformity assessment experience - Workforce education & training impacts
Information may be **shared via**…	- Direct communications - Briefings at industry events - Landscape analyses	- Direct communications - Position/issue papers - Standards Roadmaps - Landscape Analyses - Interactive Portals	- Direct communications - Position/issue papers - Standards Roadmaps - Landscape Analyses - Interactive Portals	- Direct communications - Standards Roadmaps - Landscape Analyses - Interactive Portals - Impact Studies - Use cases

**The "premature" phase is not included because it is described as a phase where information sharing is not yet occurring.*

6.2.4 Utilizing Standards-Driven Public-Private Partnerships (SD-PPP)

One resulting benefit of a public-private partnership is the exchange of information between or among partners. This result alone was identified by participants in the brainstorming sessions as both a need and an accelerator for the development of AI and automation standards. SD-PPP use cases in Appendix D offer various scenarios and work products beyond information sharing, including roadmaps, R&D, increasing participation and ensuring balanced representation. Section 2 describes markers of successful traditional PPPs (section 2.1.1) and outlines characteristics of

five SD-PPP models (section 2.2). Appendix B.2 aligns which SD-PPP models may best support standards development activities throughout standards readiness phases.

Of the five SD-PP models that ANSI has characterized, no one model is guaranteed to meet all the needs for any given technology. A combination of SD-PPP approaches and work products is anticipated to be leveraged across the lifespan of a technology.

Following are some considerations related to the decision to embark on a SD-PPP:

- **Is a new SD-PPP needed?** There may be an established PPP which could expand its mission to include standards and if needed, expand its membership. Discussions within a traditional PPP focused on R&D may mature and begin to develop landscape analyses and standards roadmaps. If the industry has matured into the exploratory or planning phases of standards development, it is possible that an existing PPP could support SD-PPP activities.

- **Does the SD-PPP need to be formal?** The most organic and common type of SD-PPP model is direct participation. This does not require formal agreements or funding. It simply means stakeholders organize and draft standards together. In the earlier phases of standardization, such as exploratory or planning, this development may be led by a consortium or the USG and result in a government or consortia standard. When a technology is more mature in standards development, such as the development phase, often the introduction of new standards work is decided and managed through an existing committee in standards development organization (refer to section 1.2.2 and section 1.3 for these differences).

- **What should the SD-PPP do?** SD-PPP activities depend on the maturity of the technology and are decided by the partners involved.

    - *Activities*: It is possible that standards are only a small focus of the SD-PPP mission. It is also possible that the sole mission of the SD-PPP is to develop a standards roadmap.
    - *Scope*: Partners need to determine if their efforts are technology-specific and/or sector-specific. There may be a need for multiple SD-PPPs addressing specific sector needs. If a technology is broad reaching, it be challenging to manage the diversity of stakeholders' interests. There may be added benefits to incorporating an open forum for broader stakeholder contributions (annual webinar, surveys or RFIs).

    However, the SD-PPP should have a clear scope of activities, and flexibility in place to allow for expanded scopes and membership. This allows the SD-PPP to evolve as industry evolves. Significant resources are expended to establish a PPP so building in some room for growth may save stakeholders from having to start a separate effort.

- **How is success measured?** The answer to this question could be different for each SD-PPP. However, in addition to solving the challenges the SD-PPP set out to accomplish, having a self-sufficient standards development activity that operates like a direct-participation model is a strong marker that the "standards-driven" component of the PPP has been successful. There may be one or more use cases where one or more standards have enabled technology integration into the marketplace or have informed regulations or policy.

- **How does SD-PPP work transfer into industry standards?** Part of the SD-PPP strategy and implementation plan should outline how to introduce priority standards related activities into one or more SDOs. If the SD-PPP is not a direct-participation model, it is important to identify an SD-PPP individual(s) to sit on the standards committees to act as a liaison and establish a plan for bringing proposals forward. That individual should determine what formal and informal processes exist to introduce standards proposals. Invite a representative from the SDO (staff or chairperson) to sit on the related SD-PPP working groups or advisory committees. These

direct relationships not only ensure proposals are introduced into the SDO process but can also accelerate decision-making.

- **When does an SD-PPP sunset?** If the SD-PPP objectives have been met or determined as no longer needed, the SD-PPP partners may consider sunsetting the initiative. If an SD-PPP has multiple objectives such as R&D, standards roadmapping and workforce development, and the standards roadmapping activity is concluded, the SD-PPP partners may elect to sunset that initiative.
    - If SD-PPP partners want to sunset their standards related activities, continued recommendations could be communicated into the standards developing committee however, the need for continued strategic efforts for standards development may best be managed through the committee.
    - Another indicator to sunset the activity is if the standards conversations taking place in the SD-PPP forum are repeated in the standards developing committees. It is more effective for those conversations to occur directly at the SDO meetings.
    - If the same conversation transpiring in multiple forums, or outside of the SDO, is causing confusion, the SD-PPP could help direct resources more strategically and therefore make standards development more effective in the various organizations. This is a different scenario from a mature SD-PPP efficiently integrating activities with an SDO that it no longer needs additional external coordination.

In summary, formal and informal standards-driven public-private partnerships have been utilized to increase information sharing and tackle standardization challenges for many decades. While there are many different drivers, scopes, work products and implementation methods, they all share a core mission of advancing standards development.

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APPENDIX A COMMON CHALLENGES AND SOLUTIONS IN STANDARDS DEVELOPMENT

Below are some of the common challenges the standardization community faces and what approaches are commonly taken to solve them. The challenges and solutions are divided into pre-standardization, standards development and implementation. The SD-PPP models that best align with those approaches are included as well.

Table 9: Pre-standardization Challenges and Solutions

Common Challenges	Common Solutions	SD-PPP Model
Determining Standards Readiness	- Technical Workshops - Consortium/Association Engagement - Focus Groups / Advisory Groups - Industry Roundtables	Standards Acceleration
Identifying an SDO	- Landscape Analysis - Understanding SDO membership & participation models - Understanding SDO member-base & current technical portfolio	Standards Acceleration
Avoiding Duplication	- Standards Roadmaps - Landscape Analysis - Technical Workshops - Outreach	Standards Acceleration
R&D Needs	- Public-Private Partnerships - Advocacy for Legislation and Appropriations - Industry-Academic Partnerships - Center of Excellence (engage w/or form) - Establish USG / Industry Roundtables - Sandbox Environments - Benchmarking - Use Case Development	Funded Standards Development Policy and Conformance Driven

Table 10: Standards Development Challenges and Solutions

Common Challenges	Common Solutions	SD-PPP Model
Establishing Critical Mass and Balance & Increasing Awareness	- Share Mission and Value of Standards Overall & Specific Activity - Direct Outreach to Experts - Direct Outreach / Invitation Letters to Company Leadership - Presentations at Industry Conferences - Press Releases, amplified through trade press - Social Media - Technical Workshops - Share Draft Standards for Informal Feedback	Standards Acceleration Funded Participation
Getting USG participation	- Share Mission and Value of Specific Activity - Direct Outreach - Formal invitations to Program/Regulatory Lead - Formal Invitations to Agency Standards Executive	Direct Participation
Resources to Attend Meeting	- Share Mission and Value of Standards Overall & Specific Activity - Direct Outreach / Invitation Letters to Company Leadership - Offer Online Participation - Ballot Early, Ballot Often	Funded Participation Direct Participation
Drafting Content	- Determine if draft needs one or more authors	Standard Acceleration

	- Divide and conquer - Assign lead, host frequent task groups meeting (online) - Ballot outline or early draft for feedback only - Host workshop or leverage committee meetings to elaborate on needs - Engage academia or graduate students or initial draft development	
Getting Consensus	- Share Draft Standards for Informal Feedback - Individual outreach to voters & frequent team calls - Ballot Early, Ballot Often - Consider incremental development, rescoping, and address areas without consensus as future action.	Direct Participation
Data Sharing	- Align on the activity objective and needs - Align on scope of individual projects - Identify which aspects of project stakeholders can share information on - Leverage a trusted 3rd party to anonymize information - (Re)Consider whether the topic is ready for standardization	Funded Standards Development

Table 11: Implementation Challenges and Solutions

Common Challenges	**Common Solutions**	**SD-PPP Model**
Increasing Awareness of Published Standards	- Direct Outreach to Experts, Leadership and USG - Presentations at Industry Conferences - Press Releases, amplified through trade press - Social Media - Facilitate webinars to consortia/associations	Direct Participation Standards Acceleration
Workforce Development (Training & Certification)	- Promote standards while in the drafting stages to allow for earlier engagement - Educate about what new or revised training / certification is needed during development and after publication - Consider company workflows during development	Direct Participation
Regulator Acceptance	- Promote standards while in the drafting stages to allow for earlier engagement - Communicate how industry believes the standard supports regulation/policy and be specific (informal or formal as needed) - Ensure outreach is to the correct contacts - Elevate issue if there are additional challenges	Direct Participation
Evaluating Performance & Maintaining Relevance	- Continue committee discussions after publication - Industry surveys about use and needs for improvement - Technical Workshops - Liaison with product / personnel certification bodies	Standards Acceleration Policy and Conformance Driven

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APPENDIX B ANSI NOTIONAL STANDARDS READINESS PHASES

B.1 Notional Standards Readiness Phases

	NOTIONAL STANDARDS READINESS PHASES				
	PRE-STANDARDIZATION		STANDARDS DEVELOPMENT		IMPLEMENTATION
	STANDARDS READINESS PHASES				
	PREMATURE	EXPLORATORY	PLANNING	DEVELOPMENT	IMPLEMENTATION
Standardization Activity	- No discussions/interest in standardization	- Identification & evaluation of existing related standards & conformity assessment programs of similar technologies - Benchmarking	- Landscape & gap analysis - Roadmapping - Terminology development - Soliciting stakeholder engagement	- Standards committee(s) formed - Soliciting leadership and stakeholder engagement - Standards drafted, approved & maintained	- Standards approved, maintained & utilized - Conformity assessments - Referenced in law or regulation, as applicable
Information Sharing & Awareness	- Internal prototyping/research has begun - Stakeholders working independently - Consortia/Association discussions not taking place, or do not exist for a particular technology	- Collaborative research takes place - Like-minded stakeholders sharing minimal information - Consortia/Association discussions & evaluation begin	- Research is being strategized - Like-minded stakeholders collaborating & sharing minimal information more broadly - Consortia/Association position/issue papers developed	- Research is ongoing - Balanced representation of stakeholders collaborating - Stakeholders investing resources to draft & vote on standards - Consortia/Association recommendations issued	- Research is ongoing - Balanced representation of stakeholders collaborating & doing business - Stakeholders investing resources to draft & vote on standards - Consortia/Association advocating for standards adoption

PREMATURE: At this stage, there are not enough stakeholders or consistency in technology to evaluate design and performance. Additionally, if there is more customization of technology rather stabilized and consistent designs, it is less likely that industry will wish to standardize. At this phase, the sector is looking towards existing standards to evaluate their technology internally and assess where it could fit in the market.

EXPLORATORY: Stakeholders have entered the exploratory phase of standards development if they have begun finding synergies with other technology in the marketplace. They know better who to engage with in the supply chain, are using related standards more consistently, and have begun exploring regulatory or compliance considerations. At this stage, more organizations are publicly speaking about their technology development or identifying as a player in the market.

PLANNING: The planning stage for standards development begins when industry starts discussing the need to identify existing standards which apply broadly or specifically to their technology. This landscape review will aid stakeholder in the identification of gaps. Terminology becomes increasingly critical at this phase so stakeholders may begin to convene to gain consensus on this front. Lastly, during this phase, industry agrees that standards are needed and begin to engage SDOs.

DEVELOPMENT: During the development phase, a balanced representation of stakeholders exists and engages with one or more SDOs. This may be done through an existing committee or by forming new committees. Development of one or more standards begins and may be done with or without a strategic plan. The pace of standards development at this phase varies and is dependent upon several factors. This stage will repeat indefinitely as new standards are developed, and existing standards are revised, stabilized, or withdrawn.

IMPLEMENTATION: The implementation phase is the phase where standards are effectively used by industry in contracts, certification programs or regulation and policy. Feedback on standards content is directed back to SDOs and updates are made as needed.

B.2 SD-PPP Models and Activities within Notional Standards Readiness Phases

	PRE-STANDARDIZATION		STANDARDS DEVELOPMENT		IMPLEMENTATION
	STANDARDS READINESS PHASES				
	PREMATURE	EXPLORATORY	PLANNING	DEVELOPMENT	IMPLEMENTATION
Standardization Activity	- No discussions/interest in standardization	- Identification & evaluation of existing related standards & conformity assessment programs of similar technologies - Benchmarking	- Landscape & gap analysis - Roadmapping - Terminology development - Soliciting stakeholder engagement	- Standards committee(s) formed - Soliciting leadership and stakeholder engagement - Standards drafted, approved & maintained	- Standards approved, **maintained** & utilized - Conformity assessments - Referenced in law or regulation, as applicable
Potential SD-PPP Model(s)	- No drivers for SD-PPP exist yet	- Standards Acceleration - Policy & Conformance Driven	- Standards Acceleration - Funded Standards Development - Policy & Conformance Driven	- Direct Participation - Funded Standards Development - Funded Participation - Policy & Conformance Driven	- Direct Participation - Funded Standards Development - Funded Participation - Policy & Conformance Driven
Potential SD-PPP Activities	- N/A	- Focus Groups - Technical Workshops - Landscape Analyses - Regulatory/Conformity assessment review	- Gathering critical mass & establishing balance of experts - Focus Groups - Technical Workshops - Technical/Research Reports - Landscape Analyses - Standards Roadmaps - Strategic Plans (R&D/Standards) - Regulatory gap assessments	- Sustain balance of experts & critical mass - Technical workshops - Technical/Research Reports - Continued R&D - Coordination on standards & policy development priorities - Continued strategic planning - Workforce development	- Sustain balance of experts & critical mass - Technical training / workshops to increase awareness & adoption - Workforce development - Continued R&D - Evaluation of standards impact along with refinements and expanding on portfolios
Information Sharing & Awareness	- Internal prototyping/research has begun - Stakeholders working independently - Consortia/Association discussions not taking place, or do not exist for a particular technology	- Collaborative research takes place - Like-minded stakeholders sharing minimal information - Consortia/Association discussions & evaluation begin	- Research is being strategized - Like-minded stakeholders collaborating & sharing minimal information more broadly - Consortia/Association position/issue papers developed	- Research is ongoing - Balanced representation of stakeholders collaborating - Stakeholders investing resources to draft & vote on standards - Consortia/Association recommendations issued	- Research is ongoing - Balanced representation of stakeholders collaborating & doing business - Stakeholders investing resources to draft & vote on standards - Consortia/Association advocating for standards adoption

APPENDIX C BRAINSTORMING SESSION AGENDAS

C.1 Final AI/ML Event Agenda

Enabling Artificial Intelligence and Machine Learning Brainstorming Session Agenda
July 17, 2024 | 9:00 AM – 5:00 PM EST
Association for the Advancement of Medical Instrumentation (AAMI)
901 N. Glebe Road, Suite 300 | Arlington, VA 22203

Event Registration and Slido Session # 2153-296

TIME	DISCUSSION TOPIC AND SPEAKER
8:30 – 9:00 am	**Check-in & Networking**
9:00 – 9:30 am	**Welcome & Brainstorming Session Objectives –** *Christine Bernat, ANSI*
Session 1	**Technology Convergence and Standards Readiness Briefings**
9:30 – 10:10 am	Attendees will hear perspectives about challenges associated with critical and emerging technologies, work underway to address technology convergence, standards readiness considerations, and about topics that would benefit from additional awareness to prepare for the subsequent discussions. ***Presentations:*** - Laura Lindsay, Microsoft: Technology conversion points (20 minutes) - Clare Allocca, NIST: Standards Readiness Considerations (10 minutes) - Christine Bernat, ANSI: Standards Readiness Phases (10 minutes)
Session 2	**Challenges, Opportunities, and Standards Readiness Discussion**
10:10 – 10:25 am	**Discussion Preparation: Challenges, Opportunities, and Standards Readiness –** *Christine Bernat, ANSI* Various factors come into play when evaluating whether conditions are right to embark on a standardization activity for a given technology, and to help predict development needs and timing of a standardization strategy. Slido will be used to gather additional details from attendees in addition to the following questions to support the **Healthcare and Manufacturing discussions.** - What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts? - What role do stakeholders see standards playing in overcoming challenges? - What is the role of industry vs government to maximize opportunities? - What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake? - What is the role of government to maximize opportunities? To support standards development?
10:25 – 10:40 am	**Networking Break**
10:40 – 11:45 pm	**AI & Machine Learning in Healthcare Discussion:** *Challenges, Opportunities, and Standards Readiness* ***Moderator:*** Shawn Forrest, U.S. Food and Drug Administration (FDA) Discussions will center around: - challenges and opportunities presented when AI/ML is leveraged by **healthcare**

	- maturity and pace of standards development - awareness about technology specific standards, conformity assessment and research and development activities underway or needed - what is needed to enable these technologies and to advance their success in the marketplace
11:45 – 12:45 pm	**Catered Lunch Break**
12:45 – 1:30 pm	**AI & Machine Learning in Manufacturing Discussion:** *Challenges, Opportunities, and Standards Readiness* **Moderator:** Franck Journoud, National Association of Manufacturers (NAM) Discussions will center around: - challenges and opportunities presented when AI/ML is leveraged by **manufacturing** - maturity and pace of standards development - awareness about technology specific standards, conformity assessment and research and development activities underway or needed - what is needed to enable these technologies and to advance their success in the marketplace
Session 3	**Standards-Driven Public-Private Partnerships (PPPs)**
1:30 – 1:40 pm	**Discussion Preparation: PPP Enabling CETs –** *Christine Bernat, ANSI*
1:40 – 2:10 pm	**Standards-Driven Public-Private Partnership Models Briefings** Attendees will gain a better understanding about various models and use cases of standards-driven PPPs, including lessons learned. Discussions will center around: the types of PPPs that would enable standards development; how PPPs may maximize specific opportunities and accelerate solutions; and the community interest in establishing PPPs. ***Panelists:*** - Government Perspective: Natalia Globus Martin, National Institute of Standards and Technology (NIST) - Industry Perspective: Rohit Israni, CertientAI - SDO Perspective: Kerri Haresign, Consumer Technology Association (CTA)
2:10 – 3:15 pm	**Public-Private Partnerships: Enabling CETs Discussion** ***Moderator:*** *Amanda Benedict, Association for the Advancement of Medical Instrumentation (AAMI)* ***Discussion:*** - What benefits or challenges do you see with a PPP for these technologies? - What role can various types of stakeholder organizations (e.g., consortia, trade associations, academia, standards organizations, centers of excellence) play in PPPs for these technologies? - What PPP short-term and long-term goals would have the broadest impact on success (e.g., standards focused R&D, workforce development, research and standards roadmaps, strategic planning)? - What type of PPP model or models could benefit these technologies? - At what (if any) point would an organized PPP activity be most advantageous? - Does a PPP require a formal agreement to be able to realize its purpose?
3:15 – 3:30 pm	**Networking Break**
Session 4	**Information Sharing Necessary to Support CET Standards Development**
3:30 – 3:50 pm	**Current State of Information Sharing Briefings** Attendees will gain a better understanding about existing information-sharing approaches in the standardization community today (tracking tools, standards roadmaps, workshops/webinars, etc.). Discussions will center around the types of information needed to be shared, how to best gather and deliver this information in order to reach appropriate audiences, as well as how that information would be utilized.

	Presentations: - Mary Saunders, American National Standards Institute (ANSI): What information is being shared today? - Natalia Globus Martin, National Institute of Standards and Technology (NIST): What did industry suggest in RFI responses and past listening sessions?
3:50 – 4:30 pm	**Future State of Information Sharing Discussion** ***Moderator:*** Muhammad Ali, HP ***Discussion:*** - What are the current communication challenges? - What information is typically discoverable (publicly available) versus not (and why not)? Does this vary according to the type of SDO? SDO or consortia/association? Etc. - Where is standards education needed to broaden stakeholder knowledge? - What education should be coordinated by the private sector, by academia, and/or by the U.S. government? - What role could a PPP play in supporting information sharing needs for CETs technologies? - Considering CETs are often driven by startups, are there specific communications needs for startups versus established organizations? - How can bilateral communications between the public and private sector support CETs?
4:30 – 5:00 pm	**Key Takeaways & Closing Remarks –** *Christine Bernat, ANSI*

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C.2 Final Automated and Connected Infrastructure Event Agenda

Enabling Automated and Connected Infrastructure Brainstorming Session Agenda
July 30, 2024 | 9:00 AM – 5:00 PM EST
University of Michigan-Dearborn | Institute for Advanced Vehicle Systems (IAVS)
223 Richard Dr, Dearborn, MI 48128
Event Registration and **Slido Session** # 2153 297

Attendees should review the standards-driven PPP Models and Standards Readiness Phases before discussions.

TIME	DISCUSSION TOPIC AND SPEAKER
8:30 – 9:00 am	**Check-in & Networking**
9:00 – 9:15 am	**Welcome Remarks –** Ghassan Kridli, Ph.D., University of Michigan-Dearborn
9:15 – 9:30 am	**Brainstorming Session Objectives –** Christine Bernat, ANSI
Session 1	**Technology Convergence and Standards Readiness Briefings**
9:30 – 10:15 am	Attendees will hear perspectives about challenges associated with critical and emerging technologies, work underway to address technology convergence, standards readiness considerations, and about topics that would benefit from additional awareness to prepare for the subsequent discussions. ***Presentations:*** 1. Timothy Klein, U.S. Department of Transportation: Technology convergence points (20 minutes) 2. Clare Allocca, NIST: Standards Readiness Considerations (10 minutes) 3. Christine Bernat, ANSI: Standards Readiness Phases (10 minutes)
Session 2	**Challenges, Opportunities, and Standards Readiness Discussion**
10:15 – 10:30 am	**Automated and Connected Earthmoving & Mining Vehicles Briefing:** Opportunities, and Standards Experience ***Presenter***: Eric Moughler, ISO/TC 127 Earth Moving Machinery Chair
10:30 – 10:40 am	**Discussion Preparation: Challenges, Opportunities, and Standards Readiness –** *Christine Bernat, ANSI* Various factors come into play when evaluating whether conditions are right to embark on a standardization activity for a given technology, and to help predict development needs and timing of a standardization strategy. Slido will be used to gather responses from attendees and the following questions will support the Automated and Connected **Ground Vehicles** and **Aircraft** discussions**.** 1. What opportunities and challenges are presented by automation and is there sufficient public and private stakeholder awareness on these fronts? 2. What role do stakeholders see standards playing in overcoming challenges? 3. What is the role of industry vs government to maximize opportunities? 4. What concerns have been raised about existing standards efforts? 5. What approaches could be taken to help align/maintain the pace of standards and technology development? 6. What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake? 7. What is the role of government to support standards development?
10:40 – 11:00 am	**Networking Break**
11:00 – 12:00 pm	**Automated and Connected Ground Vehicles Discussion** ***Moderator:*** Dr. Miles Johnson, Toyota Motor North America See question above. Discussions will center around:

	- challenges and opportunities presented with automated and connected **ground vehicles (all sizes/types)** - maturity and pace of standards development - awareness about technology specific standards, conformity assessment and research and development activities underway or needed - what is needed to enable these technologies and to advance their success in the marketplace
12:00 – 12:45 pm	**Break - Catered Lunch Provided** During the lunch break, attendees are invited to visit the UM-Dearborn Digital Engineering Laboratory and Power Engineering Simulator/Research Lab. Learn more here.
12:45 – 1:45 pm	**Automated and Connected Aircraft Discussion** ***Moderator:*** Jonathan Archer, SAE International See question above. Discussions will center around: - challenges and opportunities presented with automated and connected **aircraft (*all categories*)** - maturity and pace of standards development - awareness about technology specific standards, conformity assessment and research and development activities underway or needed - what is needed to enable these technologies and to advance their success in the marketplace
Session 3	**Standard- Driven Public-Private Partnerships (PPPs)**
1:45 – 1:55 pm	**Discussion Preparation: PPP Enabling CETs –** *Christine Bernat, ANSI*
1:55– 2:25 pm	**Standards-Driven Public-Private Partnership Models Briefings** Attendees will gain a better understanding about various models and use cases of standards-driven PPPs, including lessons learned. Discussions will center around: the types of PPPs that would enable standards development; how PPPs may maximize specific opportunities and accelerate solutions; and the community interest in establishing PPPs. ***Panelists:*** - Government Perspective: Natalia Globus Martin, National Institute of Standards and Technology (NIST) - SDO Perspective: Pat Picariello, ASTM International
2:25 – 3:15 pm	**Public-Private Partnerships: Enabling CETs Discussion** ***Moderator:*** Ted Sienknecht, MITRE ***Discussion:*** 1. What benefits or challenges do you see with a PPP for these technologies? 2. What role can various types of stakeholder organizations play in PPPs for these technologies (e.g., consortia, trade associations, academia, standards organizations, centers of excellence)? 3. What PPP short-term and long-term goals would have the broadest impact on success (e.g., standards focused R&D, workforce development, research and standards roadmaps, strategic planning)? 4. What type of PPP model or models could benefit these technologies? 5. At what (if any) point would an organized PPP activity be most advantageous? 6. Does a PPP require a formal agreement to be able to realize its purpose?
3:15 – 3:30 pm	**Networking Break**
Session 4	**Information Sharing Necessary to Support CET Standards Development**
3:30 – 4:00 pm	**Current State of Information Sharing** Attendees will gain a better understanding about existing information-sharing approaches in the standardization community today (tracking tools, standards roadmaps, workshops/webinars, etc.). Discussions will center around the types of information needed to be shared, how to best gather and deliver this information in order to reach appropriate audiences, as well as how that information would be utilized.

	Presentations: - Mary Saunders, American National Standards Institute (ANSI): ***What information is being shared today?*** - Maria Knake, National Institute of Standards and Technology (NIST): ***What did industry suggest in RFI responses and past listening sessions?***
4:00 – 4:45 pm	**Future State of Information Sharing Discussion** ***Moderator:*** Christian Thiele, SAE International ***Discussion:*** 1. What are the current communication challenges? 2. During the pre-standardization phases of technology, it is important to begin educating about the value and benefits of standards. How can we amplify this messaging to ensure it reaches the appropriate stakeholders? 3. During the standards development phases, how can stakeholders best socialize the standards development activity to get diverse and targeted stakeholders? 4. During the implementation phases, can we increase the adoption of a standard once published? Think about this from a market adoption, regulatory acceptance, and/or conformity assessment 5. How can bilateral communications between the public and private sector support CETs? 6. Where is standards education needed to broaden stakeholder knowledge? ▪ What education should be coordinated by the private sector, and/or by the U.S. government? ▪ Are there concerns about duplication, inconsistency, ambiguity of standards development efforts for these technologies today?
4:45 – 5:00 pm	**Closing Remarks –** Christine Bernat, ANSI
5:15 – 6:30 pm	**UM-Dearborn Driving Simulator Lab Tour and ImpLi-FI Technology Demo**

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APPENDIX D STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP USE CASES

D.1 SD-PPP Use Case Listing with Limited Details.

A listing of public-private partnerships is included below. Most of the PPPs are standards-driven PPPs; however, a few examples of general PPPs are included to provide comparison. The full details of each SD-PPP use case in this table are included in Appendix D.2, and were developed in collaboration with one or more of the PPP partners. ANSI is maintaining individual use cases at www.ansi.org/pppsforcets.

SD-PPP	SECTION LED				WORK PRODUCT	SD-PPP MODEL
Title	**Private**	**Public**	**Private Sector**	**Public Sector**		
Additive Manufacturing Center of Excellence (AM CoE)	X		Auburn University, EWI, MTC, NAMIC, NIAR, ISO, CEN, and others	FDA, FAA, NASA, NIST, DoD	Research and Standards Roadmaps, Industry Standards Development, Industry workshops and conferences	Standards Acceleration Funded Standards Development
Additive Manufacturing Standards Collaborative (AMSC)	X		ANSI, America Makes / NCDMM	CDC, DoD, DoE, FAA, FDA, NASA, NIST	Research and Standards Roadmap	Standards Acceleration
Engineering Biology Metrics and Technical Standards for the Global Economy	X		EBRC, Imperial College London, NUS	NIST	Research and Standards Roadmap	Standards Acceleration
Biometrics	X		ISO/IEC, Industry	DHS, DOJ, DOD, State Department., European commission	Industry Standards Development	Direct Participation
Clean Cookstoves and Cooking Solutions		X	ANSI, ISO, KEBS, Clean Cooking Alliance, United Nations Foundation, PCIA	EPA	Industry Standards Development	Funded Participation Funded Standards Development
Cloud Computing Standards Roadmap		X	Industry	NIST	Standards Roadmap	Standards Acceleration
Consumer Products Standards	X		ASTM, Industry	U.S. Consumer Product Safety Commission (CPSC)	Industry Standards Development	Policy & Conformance Driven Direct Participation
Electric Vehicles Standards Panel (EVSP)	X		ANSI	DoE, ANL, PNNL, INL, SNL	Research and Standards Roadmap	Standards Acceleration
Exo Technology Center of Excellence (ET CoE)	X		Exoskeleton Report, New Stone Soup, Prime Performance, HFES, NSC,	NIST, NIOSH, US Army DEVCOM SC	Research and Standards Roadmaps, Industry Standards Development, Design competitions	Standards Acceleration Funded Standards Development

			SCRA, Smart HLPR, AExG, LiUNA			
Federated Health Information Model (FHIM)	X		The Open Group, HL7	ONC, DoD, DHS, VA	Standards Implementation, Technology Transfer	Funded Standards Development
General Aviation Aircraft	X		GAMA, AEA	FAA, EASA	Industry Standards Development	Policy & Conformance Driven Direct Participation
Institute for Bioscience and Biotechnology Research (IBBR)	X	X	University of Maryland, University of Maryland - Baltimore, MilliporeSigma, NIIMBL	NIST	Research and Standards Gap Assessments, Government Standards	Funded Standards Development
Microelectronics Supply Chain and Operational Security	X		Various	DoD	Standards Landscape, Technical Workshops	Standards Acceleration
Nanotechnology Standards Panel (NSP)	X		NGOs (EDF, PETA), Legal entities, Academic institutions (Rice University)	CPSC, DoD, EPA, FDA, NASA, NIOSH, NIST, NNCO	Standards Landscape, Technical Workshops	Standards Acceleration
National Cybersecurity Center of Excellence (NCCoE)		X	National Cybersecurity Excellence Partnership (NCEP) Program	NIST	Government Standards	Standards Acceleration
Open Trusted Technology Provider Standard (O-TTPS) Certification Program	X		The Open Group	DoD, DHS, NASA	Industry Standards Development, Conformity Assessment	Direct Participation
Organization of Scientific Area Committees for Forensic Science (OSAC)		X	Various	NIST, DOJ	Industry Standards Development	Standards Acceleration Funded Participation
Regenerative Medicines	X		SCB	NIST, DHS, FDA	Standards Coordination, Education	Standards Acceleration
Unmanned Aircraft Systems Standards Collaborative (UASSC)	X		ANSI	DHS, DOT, FAA	Standards Roadmap	Standards Acceleration

D.2 SD-PPP Use Cases (Full Details)

ADDITIVE MANUFACTURING CENTER OF EXCELLENCE (AM COE)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ASTM International
Technical Committees:	F42 on Additive Manufacturing Technologies
Other Partnering Organizations:	Auburn University, EWI, MTC, NASA, NAMIC, NIAR, ISO, CEN, and many others
Government Organizations:	FDA, FAA, NIST, DoD
Industry Sector(s) / Technology:	Additive Manufacturing
Program / Activity Website URL(s):	https://amcoe.org/ & https://wohlersassociates.com/

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

In July 2018, ASTM International and its founding partners Auburn University, EWI Buffalo Manufacturing Works, the Manufacturing Technology Center, and National Aeronautics and Space Administration (NASA) launched the Additive Manufacturing Center of Excellence (AM CoE). The AM CoE is a collaborative partnership representing industry, government, and academia to conduct strategic research and development (R&D) to advance AM standardization. The center also aims to accelerate development and adoption of AM by developing training and certification programs, and providing market intelligence, business strategy, and advisory services.

PPP Goals:

The mission of the Center is to bridge standards development with R&D to better enable efficient development of standards, education and training, certification, and proficiency testing programs. AM CoE works to advance AM through this improved approach to standardization by providing:

- **Strategic guidance and funding**: $15M+ combined support from partnership, government agencies, and industry
- **Coordinated R&D and expedited standards development**: 38+ projects initiated that are addressing 38+ standard gaps and impact existing standards (10 published standards, 13 balloting/approval, and 15 drafts under development)
- **Programs and services to support education and workforce development**: over 100 global team members, 22+ training courses, three certification programs developed

There are five strategic goals:

1. Close standards gaps and meet standards needs
2. Carry out AM research and development (R&D) to support all major industry sectors
3. Create strong global partnerships
4. Develop training, proficiency testing, and certification program
5. Host expert-oriented AM events, workshops, and conferences

There are five core activities:

1. R&D: research needed to accelerate standards priorities
2. Training: world-class workforce development program
3. Certification: surveillance programs to audit the robust implementation of standards
4. Consortium: collaboration with industry to address needed R&D – focus on big data/AI
5. Market Intelligence/Advisory Services: provide intelligence and expert insight to support implementation/strategy development

Public Sector Role & Participation:

Founding and Strategic Partners: In late 2017, ASTM International began seeking key strategic partners to help launch the AM CoE. Through a request for proposals (RFP) process conducted in early 2018, four organizations were selected as founding partners. All five founding partners have been playing complementary roles to support major pillars of the AM CoE.

In addition to the founding partners, identified and selected by the management team, a limited number of strategic partners bring specific material, industry sector, or regional expertise to the AM CoE. Two such partners were added in late 2018:

- National Additive Manufacturing Innovation Cluster (NAMIC) coordinates R&D and related activities for the Asia-Pacific region.
- National Institute of Aviation Research (NIAR) leads efforts to qualify additively-manufactured materials and to further strengthen relationships with key aerospace regulators worldwide.

Program Partners: The AM CoE also partners with organizations that can uniquely support one or more of its programs, such as R&D projects, workforce training, certificate programs, or other significant offering. These partners are also identified and selected by the management team.

Implementation Methods:

The AM CoE leadership includes representatives from each of its key stakeholder groups: government, industry, and academia. It is also structured to strategically support each of the CoE's core activities.

- **Advisory Board:** provides vision and direction of the AM CoE to ensure that it stays current with existing and future drivers of the industry
- **Steering Committee:** provides support and oversight to the AM CoE, including long-term and growth strategies
- **Management Team:** coordinates the day-to-day management of each function of the AM CoE and ensures alignment of activities with AM CoE objectives
- **R&D Team:** sets annual R&D priorities and projects, defines and manages the proposal process, identifies funding needs and potential funding opportunities, locates potential subcontractors as needed, and communicates and disseminates R&D results and/or new capabilities
- **Consortia Team:** brings industry together through consortia to capture investment to rapidly develop AM standards that address industry-identified needs

In the original period of the AM CoE program, which was set for five years, twice a year, the CoE opened Requests for Ideas (RFIs) and Calls for Projects (CFPs) to allow industrial, research, and academic organizations to propose research in specific areas that align with its mission of accelerating the adoption of additive manufacturing by addressing standardization gaps. After the initial period, the CoE shifted their funding strategy to leverage both industry and government. The AM CoE has completed many government grants and currently has ten active government funded projects.

Standards Activities: Both public and private stakeholders also participate in the ASTM F42 on Additive Manufacturing Technologies technical committee, subcommittees, and working groups, serving in a diverse collection of roles (including sponsorship, contractual agreements, strategy development, research, technical or content contributions, leadership, voting/abstaining, and monitoring/active participation). Global authorities and industry continue to directly participate in ASTM F42 to maintain and develop new standards. ISO & CEN continue to help maximize the global relevance of the standards deliverables by embracing a joint and (in many cases) a tri-adoption model, generating standards that carry

ASTM, ISO, and EN designations. ASTM F42 is independent of the AM CoE and its operations also serve as another example of a public-private partnership.

ASTM technical (main) committees are divided into subcommittees which manage portfolios of standards on focused technical areas. Subcommittees form task groups (TGs) which work on individual drafts of standards. ASTM F42 has nine subcommittees (seven technical subcommittees and two administrative subcommittees), one of which is F42.90 Executive Subcommittee which is comprised of leadership from each subcommittees, as well as other representatives to give a balance of perspectives to the subcommittee. The executive subcommittee sets the strategic and technical direction of the committee.

Under F42.90 is a section referred to as F42.90.05 on Research & Innovation. This activity serves exclusively as an information conduit between the ASTM AM CoE and ASTM Committee F42. Its primary function is to provide feedback on standardization needs (either new standards, supporting work items under development, or updating existing standards), recurring R&D SOWs/proposals (focusing on specifically enumerated standards deliverables) under consideration by the AM CoE, including recommendation of an F42 subcommittee of jurisdiction, the possibility of any corollary program deliverables (training, PTP, certification, etc.), and any additional technical information they deem relevant to the proposals under consideration.

F42.90.05 does not develop standards and is closed to non-members. F42.90.05 meetings are held at least twice a year and face-to-face during biannual F42 meetings and as often as needed via teleconference. This section is typically chaired by an executive member of Committee F42. Proposals for F42.90.05 leadership may be submitted to ASTM staff and shall be considered by the AM CoE's Steering Committee and the AM CoE's Management Team.

Convening Experts: The AM CoE hosts several events such as webinars and workshops as well as an annual ASTM International Conference on Advanced Manufacturing (ICAM) which emphasizes standardization, qualification, and certification, with a particular focus on industry-specific requirements encompassing the entire advanced manufacturing processes and value chains.

Measurement of Success:

With input from government agencies, regulators, and subcommittee chairs within F42, the partners have identified, evaluated, and prioritized a critical set of topics that are forming the foundation of an R&D roadmap. The roadmap helps facilitate the development of high-value standards with quality characteristics that will ensure they are immediately beneficial to the AM community.

Since its inception in 2018, the AM CoE has launched over 35 R&D projects to accelerate AM standardization. Led by Center partners and research-to-standards (R2S) collaborators, these projects seek to generate technical data required for development of consensus-based standards by ASTM committees such as F42.

Key Takeaways:

1. **Incentivizing Participation:** Incentivizing involvement in research-to-standards programs is a crucial factor in accelerating standardization. Without proper incentives, participation and influence will remain limited, potentially slowing down progress.
2. **Defining Clear KPIs:** Establishing clear Key Performance Indicators (KPIs) from the outset is vital for the successful execution of these programs. Early definition of success criteria ensures that outcomes align with expectations and program objectives.
3. **Building an Ecosystem:** Creating a robust ecosystem around the program is essential to maximize engagement. The AM CoE program focuses on a variety of initiatives to foster and develop this ecosystem, ensuring broad participation and collaboration.

4. **Developing Skilled Talent:** One of the significant challenges was developing the right talent, particularly standard writers and technical experts, behind standardization drafts. While running a research-to-standardization project is manageable, success hinges on having the necessary skill set. The program placed a strong emphasis on cultivating talent to meet this need.
5. ASTM International was able to respond to industry needs very quickly. Bringing the relevant stakeholder population into the discussions during early stages of project development helped drive a rapid response and prepared stakeholders to maximize their productivity.
6. The implementation phase of activities is just as important as the development phases. To ensure this, especially with a collection of stakeholders relatively new to the development process, education and training (both early and ongoing) is critical.
7. Going to where the stakeholders are greatly improves the chances of their participation. For international acceptance, meetings (of both the COE & standards development arm via F42) should be held in a variety of locations. Additionally, co-locating meetings with industry events where members already plan to attend can help increase participation (especially for task group meetings).

Advice for Others:

In this PPP, there was a significant reliance on active participation from industry, government, academia, and trade associations/professional societies (also a Partner Standards Development Organization (PSDO) agreement with ISO). While some participants have restrictions on the level of interaction they are permitted to undertake, this is often mitigated via proactive hosting of training/educational programs. The success of any standards activity is predicated upon the buy-in from and contributions by stakeholders – while funding can be a motivator, it is not a guarantee of success.

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AMERICA MAKES & ANSI ADDITIVE MANUFACTURING STANDARDS COLLABORATIVE (AMSC)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	Various
Technical Committees:	n/a
Other Partnering Organizations:	ANSI, America Makes, National Center for Defense Manufacturing and Machining (NCDMM)
Government Organizations:	Various
Industry Sector(s) / Technology:	Additive Manufacturing
Program / Activity Website URL(s):	https://www.ansi.org/standards-coordination/collaboratives-activities/additive-manufacturing-collaborative

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

Formally launched in March 2016, the America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC) was formed because several standards-developing organizations (SDOs) were engaged in standards-setting for various aspects of additive manufacturing (AM), prompting the need for coordination to maintain a consistent, harmonized, and non-contradictory set of AM standards.

Work of the AMSC resulted in three standards roadmaps, several gaps progress reports, and technical events. Gaps progress reports are typically issued twice per year after the publication of a full roadmap. The 2023 roadmap (v3) was initiated following a 2022 survey about the use of the roadmap. The AMSC advisory group – comprised of industry, government, and standards developing organization (SDO) representatives – concluded that it was time to update the document to ensure it remains relevant and aligns with current practices and stakeholder needs.

America Makes, ANSI's partner in AMSC, was founded in 2012 as the Department of Defense's national manufacturing innovation institute for AM and the first of the Manufacturing USA network. America Makes is based in Youngstown, Ohio, and managed by the not-for-profit National Center for Defense Manufacturing and Machining (NCDMM). America Makes was and continues to be ANSI's funding partner for AMSC efforts.

PPP Goals:

AMSC is a cross-sector coordinating body whose objective is to accelerate the development of industry-wide AM standards and specifications consistent with stakeholder needs and thereby facilitate the growth of the AM industry.

The roadmap revision process will consider the previously identified gaps and priorities, including progress by SDOs and others to address the recommendations. It will also identify potentially overlooked issues. A new working group will be established to address data throughout the AM lifecycle. Gaps will be considered as they relate to different industry sectors, material types, process categories, and qualification and certification.

Public Sector Role & Participation:

For roadmap version 3.0, approximately 300 individuals from 150 public- and private-sector organizations supported the roadmap's development, including representatives of U.S. federal government agencies and national laboratories, SDOs, industry, academia, and others.

From its formation onward, all AMSC members offered their technical knowledge about issues, existing standardization activities, regulatory and policy activities, qualification and certification activities, and research and development (R&D) needs. There was no distinction between the roles of the public and private sector. Some representatives engaged in

AMSC as a member and others served in leadership roles. However, outreach efforts always targeted and advocated for both private and public sector engagement.

Implementation Methods:

To develop the roadmap, the AMSC held workshops and ultimately established a working group (WG) structure which typically held online meetings twice a month. The roadmaps evolved to expand the scope based on the needs and applicability that AM had at any given point (from roadmap v1 to v3). During the first few years of AMSC, more face-to-face events (with hybrid capabilities) were facilitated. These events served more as plenary meetings. WG meetings took place more often and as web-based meetings.

To maximize the effectiveness and relevance of the AMSC work, an Advisory Group (AG) was established. The AG membership included the WG chairs as well as standards organizations, government, consortia, and others to give a balance of presentation. The AG offered guidance and strategic direction as well as leveraged their networks to ensure the technical expertise in the WG was sufficient to ensure technical and market relevance.

To develop the third version of the roadmap, AMSC utilized online meetings only. AMSC members were divided into nine WGs, which also resulted in nine chapters of technical content. The WGs included:

- WG1 design
- WG2 pre-cursor materials
- WG3 process control
- WG4 post-processing
- WG5 finished material properties
- WG6 qualification and certification
- WG7 nondestructive evaluation
- WG8 maintenance and repair
- WG9 data

Some WGs were chaired by industry and others by the government. WG meetings only take place when the roadmaps are in development, but the AG meetings are held at least twice a year or more as needed.

Measurement of Success:

Roadmap efforts (and their resulting publications) help increase awareness about existing standard efforts and future standards needs. A deep quantitative analysis of the various standards over several years is challenging as work is constantly evolving. ANSI analyzed the numbers of standards identified, general and specific AM, from roadmap versions 1 through 3, which shows that the knowledge of standards activities, and the activities themselves have significantly increased (see table below). Additionally, feedback from the survey and outreach to industry stakeholders has shown that the roadmaps are leveraged to determine where to invest resources for standards at a company and committee planning level.

	All Identified Supporting Standards & Guidance			AM Specific Identified Supporting Standards & Guidance		
Roadmap	**Published Standards**	**Draft Standards**	**Total**	**Published Standards**	**Draft Standards**	**Total**
Roadmap v1.0 (2017)	242	39	281	24	25	49
Roadmap v2.0 (2018)	456	80	536	47	61	108
Roadmap v3.0 (2023)	513	155	668	144	126	270

On July 17, 2023, America Makes and ANSI announced the publication of the *Standardization Roadmap for Additive Manufacturing, Version 3.0*, developed by the AMSC. The roadmap describes the current and desired future standardization landscape for AM and focuses on industrial market sectors using AM technologies. A total of 141 standardization gaps (including 60 new gaps) are identified with corresponding recommendations across the AM lifecycle areas of design; precursor materials; process control; post-processing; finished material properties; qualification and certification; nondestructive evaluation; maintenance and repair; and data. The hope is that the roadmap will be broadly adopted by the user community to facilitate a more coordinated approach to the future development of AM standards.

In June 2018, the *Standardization Roadmap for Additive Manufacturing (Version 2.0)* was published. Some 320 individuals from 175 public- and private-sector organizations supported the document's development. The document considers the life cycle of an AM part, from initial design to materials and process selection, production, post-processing, finished material properties, testing, qualification, and maintenance. It describes the AM standardization landscape and identifies 93 "gaps" – 18 are high priority, with several of the new gaps involving polymers. In 65 of the 93 gaps, additional pre-standardization R&D needs are identified.

In February 2017, after a year of work, the *Standardization Roadmap for Additive Manufacturing (Version 1.0)* *was published.* 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 SDOs, were instrumental in the formation of this collaboration. More than 260 individuals from over 150 public- and private-sector organizations actively supported the document's development with substantial representation from the aerospace, defense, and medical industries. The roadmap provides a snapshot of the current AM standards landscape and identifies 89 "gaps" – 19 are high priority. In 58 of those cases, additional R&D needs are identified. Topical areas include standards for design, process, and materials (subdivided into precursor materials, process control, post-processing, and finished material properties), qualification and certification, nondestructive evaluation, and maintenance.

Key Takeaways:

1. A clear scope of what technical areas should be addressed as a whole, as well as the WG level is important to not overwhelm or slow efforts.
2. A balanced representation of expertise in each of the technical working groups is necessary to ensure market relevance and unbiased recommendations.
3. Allowing for public review of drafts before publications helps ensure broader input from directly and indirectly impacted stakeholders.

Advice for Others:

Standards roadmap development requires a significant investment of resources – both expertise and time – of stakeholders. It is important to have alignment on the scope and timeline. As standards are always evolving, theoretically a roadmap is out of date at time of publication or best described as a living document. Participants should focus on the priorities and high-level descriptions and not solve the issues. Development of the standards will take place as a result, and separate initiative, from the roadmap development. Updates on standards work can be provided post roadmap and future versions can be developed to maintain visibility of current work and needs over time.

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ENGINEERING BIOLOGY METRICS AND TECHNICAL STANDARDS FOR THE GLOBAL BIOECONOMY

ORGANIZATIONAL SPECIFICS

Standards Organizations:	n/a
Technical Committees:	n/a
Other Partnering Organizations:	Imperial College London, National University of Singapore (NUS), Engineering Biology Research Consortium (EBRC)
Government Organizations:	NIST
Industry Sector(s) / Technology:	Bioeconomy
Program / Activity Website URL(s):	https://ebrc.org/engineering-biology-metrics-and-technical-standards-for-the-global-bioeconomy/

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The Engineering Biology Research Consortium (EBRC) is a non-profit, public-private partnership dedicated to bringing together an inclusive community committed to advancing engineering biology to address national and global needs. A Task Force composed of EBRC and partners at Imperial College London, the National University of Singapore, and the U.S. National Institute for Standards and Technology led an initiative resulting in the report: "Engineering Biology Metrics and Technical Standards for the Global Bioeconomy."

This report was specifically created as there is a new sense of urgency pushing the bioeconomy and its many potential benefits to the forefront of discussions by policymakers, with new programs and funding streams being announced around the world. The driver for this effort was to identify appropriate standards and metrics that will better enable continued scale-up and enhance economic activity across the bioeconomy. A lack of shared and interoperable vocabulary, methodology, and metrology across the engineering biology pipeline is envisaged to create major challenges as the global bioeconomy grows.

PPP Goals:

EBRC promotes research in engineering biology, identifies pressing challenges and opportunities in research and application, and articulates compelling research roadmaps and programs to address challenges and opportunities in advanced engineering biology. The four focus areas, driven by member-led working groups, are Research Roadmapping, Education, Security, and Policy & International Engagement.

To support the above mission, EBRC and the Task Force members sought to identify community and stakeholder driven scientific, technical, operational, and semantics standards to enable and drive scale up capabilities, improve reproducibility across batches and geographies, and enhance the performance of microbial factories and bio-products.

The report, "Engineering Biology Metrics and Technical Standards for the Global Bioeconomy," identifies ten key areas as recommended for standards and metrics development. The report lays the groundwork to establishing open, voluntary standards for engineering biology to enable the rapid growth and success of the global bioeconomy.

Public Sector Role & Participation:

EBRC, with partners at the U.S. National Institute of Standards and Technology (NIST), Imperial College London, and the National University of Singapore (NUS), and supported by Schmidt Futures, made up the Task Force which led the development of the report.

In the U.S., the development of engineering biology/biotechnology standards is being driven primarily by industry, though bottlenecks around data and information sharing (in particular) are increasingly making this difficult, and much of this work is in its nascency. USG, primarily through NIST, is trying to drive many efforts to loosen the bottlenecks and encourage more engagement on establishing public metrics and standards, including through participating in and sponsoring PPP efforts around standards development.

While the Task Force for this initiative was led by academia, government, and non-profit entities, industry from the U.S. and Europe were participants and significant contributors to the development of strategies and recommendations. (In Asia, contributions came mostly from government and academic institutions; government plays a larger role in Asia in standards development, though the degree to which varies by country.)

Implementation Methods:

EBRC's efforts are accomplished through convening stakeholders, most often experts in engineering biology and related fields from academia, the biotechnology industry and nonprofits, and the federal government. For example, the report above reflects contributions from three stakeholder workshops which took place around the world: one in the Washington DC area for stakeholders from the Americas; one in Singapore for stakeholders across Asia and Australia; and finally, one in Brussels, for stakeholders from Europe and Africa.

Discussions that took place within each region, including during group plenaries and deeper-dive breakout sessions, were captured by the Task Force and summarized within workshop reports. The content of each workshop report was kept deliberately confidential until all three meetings had concluded, to avoid biasing any discussions with outcomes from another region.

This final report summarizes the key areas that emerged from those stakeholder discussions, pulling together common themes and identified needs that arose across the regions. The content was drafted in collaboration with stakeholders and peer-reviewed by workshop participants.

Measurement of Success:

The ten key areas for standards and metrics development are the outcome of workshop discussions that were observed and summarized by the Task Force and published in the final report. Stakeholders are encouraged to take these technical and non-technical topics, or a subset thereof, to motivate future projects for standards and metrics development in engineering biology.

Technical

1. Data standards to enable interoperability, integration, and efficient data transfer, accelerating technology development within the bioeconomy.
2. Metrology and metrics to quantify biological processes to better assess and quantify engineering biology phenomena to enable reproducibility, reliability, and scale-up.
3. Scale-up and scale-out supported by metrics that perform consistently across scales and across equipment and process conditions, and community driven standard practices to support startups in navigating the scale-up and commercialization process.
4. Lexicon and terminology to facilitate communication within the technical community, and with external stakeholders, at national and international levels.

5. Metrics and standardization for sustainability assessments to support comparability and develop market incentives for sustainable products and processes.
6. Standards to enable use of biomass feedstocks to complement technological and policy advancements to enable their adoption and use in the bioeconomy.

Non-technical

1. Training and education on standards and metrics to ensure understanding and adoption by those working in the sector, and to improve implementation of existing and new standards across the bioeconomy.
2. Public engagement, improvement of public perception, and building trust, addressing negative consumer perceptions by improving communication and transparency.
3. Regulatory clarity to efficiently commercialize new products and processes, through standards in documentation, assessments, and benchmarking.
4. Biosafety and biosecurity for consumers, workers, the public, and the environment, for future successful functioning and growth of the bioeconomy.

The published report has been referenced by participants in existing SDOs and informally during USG activities. Many of the workshop participants and report contributors continue to participate in technical standards development, including new and follow-on initiatives.

Key Takeaways:

1. The different role taken by public vs. private vs. government entities in the development of standards for the bioeconomy in different parts of the world: depending on where you are, the different entities take more responsibility and onus for standards development (e.g., in the US, industry leads the way; in Asia, it is more government led).
2. USG can play a significant role in easing bottlenecks and promoting communication and sharing between private and public entities in standards development for the bioeconomy.

Advice for Others:

EBRC notes it is valuable to have the audience and the stakeholders involved in the process, not just the experts.

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BIOMETRICS

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ISO, IEC, IEEE
Technical Committees:	JTC 1/SC 37 Biometrics
Other Partnering Organizations:	n/a
Government Organizations:	DHS, DOJ, DOD, State Dept., European commission
Industry Sector(s) / Technology:	Biometrics tech companies
Program / Activity Website URL(s):	https://www.dhs.gov/biometrics https://ucr.fbi.gov/fingerprints_biometrics/biometric-center-of-excellence/files/biometricschallenge2011.pdf NIST report on NSTC Standards & Conformity Assessment WG (SCA WG): https://www.nist.gov/system/files/documents/2021/11/18/nstc_supplementaldocument08-10-09_biometricregistry.pdf https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/nstc-biometrics-2008.pdf

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

After the September 11, 2001 attacks on the United States, a need to create better passports, secure borders, identify fraudulent documents, and increase travel security was identified. Shortly after, in 2002, the ISO/IEC JTC 1/SC 37 Biometrics subcommittee was created. The mission of JTC 1/SC 37 is to ensure a comprehensive and high priority, worldwide approach for the development and approval of international biometric standards.

In 2003, shortly after the formation of JTC 1/SC 37, the National Science and Technology Council (NSTC) established a Subcommittee on Biometrics to develop and implement multi-agency investment strategies to:

- advance biometrics disciplines to meet public and private needs
- coordinate biometrics-related activities of interagency importance
- facilitate the inclusion of privacy-protecting principles in biometrics system design
- ensure coordinated and consistent biometrics programs as government agencies interact with Congress, the press, and the public
- strengthen international and public sector partnerships to foster the advancement of biometrics technologies

Since 2002, JTC 1/SC 37 has worked to develop standards for chips in passports, e-passports, national identification (ID) programs, interoperability and security of the information systems, and to eliminate duplicates in national databases. As biometric standards have become more readily available, the NSTC is now participating in the work of JTC 1/SC 37.

PPP Goals:

Since the formation of JTC 1/SC 37 the goals have evolved. The current goals include:

- **Utilization of ISO/IEC 19794:** phased transition of ISO/IEC 19794 Information technology — Biometric data interchange formats series (15 parts): as passports are renewed, they are created with the new and updated requirements of the standards; however, backwards compatibility is necessary until the transition is complete.
- **Next generation passports**: standards around the new security features, enhanced security to make altering more difficult
- **e-Passports**: biographic and biometric data contained in the electronic chip can be compared to both the traveler and the travel document being presented. There are multiple layers of security in the e-Passport process that prevent duplication.

- **AI Bias:** bias in artificial intelligence (AI) technologies used in biometrics, as governments are dependent on facial recognition technology, needs to be fully inclusive.

One of the NTSC goals was to establish a comprehensive and widely accepted open standards process for biometric information, and the devices that capture it, to include conformity assessment testing processes for broadly accepted certification. Most of these have been met now.

Public Sector Role & Participation:

ISO/IEC JTC 1/SC 37 standards are developed through consensus processes that bring together industry, government, consumers, academia, etc. Each ISO/IEC member country has the opportunity to consult their stakeholders and participate in the work of JTC 1/SC 37. U.S. participation in JTC 1/SC 37 includes engagement from both the public and private sector, each contributing to the development of standards based on their respective needs.

Implementation Methods:

This partnership is primarily executed through JTC 1/SC 37 committee activities. This includes committee meetings which take place regularly to review and update documents as technology and industry needs evolve.

There are instances where results from industry workshops influence the committee work. For example, in 2010 and 2011, NTSC held workshops to bring together academia, government and industry experts in biometric systems and cybersecurity with the charge of identifying the fundamental research challenges for trustworthy biometric systems. Outputs related to standards and testing included:

- Develop best practices and standards to support large-scale framework for e-government, personal information, and business transactions
- Develop standards for revocable biometrics (biometric template protection)
- Provide support for ongoing programs to develop fraud detection standards and develop evaluation methods for fraud detection
- Continue development of biometrics system performance testing standards
- Continue development and standardization of image quality metrics for face and iris
- Define and standardize “plug-and-play” interfaces and software practices
- Provide continued standards developing organization support including developing reference implementations, conformance test suites and testing of standards prior to publication (Extended Fingerprint Feature Set is a prime example of such testing prior to publication).
- Provide institutionalized support to government testing entities to develop certification programs
- Conduct technology testing for operational effectiveness, suitability, and interoperability

Given that many biometrics use cases impact the global community, it is important that the standards work is done at the international level to ensure interoperability and implementation across various countries. JTC 1/SC 37 also works closely with ICAO’s New Technologies Working Group to ensure the appropriate JTC 1/SC 37 standards are referenced as it impacts interoperability across borders.

Measurement of Success:

Progress in government biometric applications has been significant. Some accomplishments related to standards development include:

- **National ID Programs**: Many countries use biometric standards for creating and managing national identification systems, ensuring that biometric data can be used consistently and securely across different platforms and agencies.

- **Passport and Visa Systems**: Biometric standards are crucial for international travel documents like passports and visas. Adopting these standards helps facilitate cross-border travel and enhances security by ensuring that biometric data is accurately captured and verified.
- **Law Enforcement**: Standards from JTC 1/SC 37 are used in law enforcement for criminal identification, forensic investigations, and maintaining databases of biometric data such as fingerprints and facial images.
- **Border Control**: Governments use biometric standards to enhance border security and streamline immigration processes, enabling the reliable identification of travelers and ensuring secure entry and exit processes.
- **Social Services and Welfare Programs**: Biometric standards help in the management and distribution of social services and welfare benefits, reducing fraud, and ensuring that benefits reach the intended recipients.
- **Healthcare Systems**: In some countries, biometric standards are used to improve patient identification, secure access to medical records, and manage healthcare services.

Key Takeaways:

1. The U.S. government has supported technology testing and standards development. This support has created a framework and a strong stimulus for continued technological improvement through coordinated and focused research and product development.

2. Because of active global participation from the public and private sector, standards have matured significantly and have contributed to improved system and biometric device interoperability.

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CLEAN COOKSTOVES & CLEAN COOKING SOLUTIONS

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ISO
Technical Committees:	ISO/IWA 11 and ISO/TC 285 Clean cookstoves and clean cooking solutions
Other Partnering Organizations:	ANSI, KEBS, Clean Cooking Alliance, United Nations Foundation, PCIA
Government Organizations:	EPA
Industry Sector(s) / Technology:	Household energy
Program / Activity Website URL(s):	https://www.iso.org/committee/4857971.html; https://www.ansi.org/iso/ansi-activities/ansi-administered-tags/tc-285-clean-cookstoves-clean-cooking-solutions

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

In 2011, the U.S. Environmental Protection Agency (EPA) issued an RFQ entitled "Development of Fuel Efficiency, Emissions and Safety Performance Standards for the Partnership for Clean Indoor Air," to provide support for the development of voluntary performance standards for emissions, fuel efficiency, and safety of cooking and heating technologies and fuels being promoted in parts of Asia, Africa, and Latin America. These performance standards were intended to provide policy makers, donors, stove programs, and other stakeholders with a credible basis for: comparing stove performance and safety; helping all stakeholders have a common set of terminology (Clean, Efficient, Safe, Durable) for communicating and understanding stove performance; giving stove makers affirmation of product quality; letting stove users know that they are making a worthwhile investment; driving innovation in the industry; and enabling governments and non-governmental organizations to certify that locally available technologies meet uniform performance benchmarks based on the current state of knowledge. ANSI was interested in partnering in order to align the activity with the existing U.S. and international standards landscape, which includes a robust system designed to produce standards and other deliverables in a consensus process, inclusive of the viewpoints of affected stakeholders.

PPP Goals:

The objectives were to:

1. Identify existing and in-progress performance standards related to cooking and heating stoves and fuels (e.g., biomass, kerosene, coal) commonly used in developing countries.
2. Conduct detailed consultations with key individuals to solicit input on existing performance standards, as well as suggestions for new performance standards.
3. Draft proposed fuel efficiency, emissions, and safety performance standards for a variety of cooking and heating technologies and fuels for public comment.
4. Convene a well-attended international workshop of key stakeholder organizations and subject matter experts to resolve the public comments, further refine the performance standards, and develop a list of proposed actions to promote the adoption of voluntary cook stove performance standards.
5. Document the discussions and the outcomes of the workshop for dissemination via Partnership for Clean Indoor Air communication channels (e.g., bulletin, website, and emails) and publication in a peer reviewed journal.
6. Develop additional ISO standards to support efforts identified through the workshop.

Public Sector Role & Participation:

ANSI was awarded a contract with EPA and EPA provided funding to the Global Alliance for Clean Cookstoves (GACC) through a Cooperative Agreement. The Global Alliance for Clean Cookstoves had built a network of technical experts from around the world and ANSI brought expertise as the U.S. member body to ISO, coordinator of the U.S. standards system, and connections with other standards bodies around the world. Together, ANSI, EPA, and GACC developed a multi-step plan to build on the initial work done through the technical expert network by introducing a proposal for an ISO International Workshop Agreement (IWA). The IWA provided an opportunity to expand the stakeholder input into the interim draft technical document, expand consensus around parameters of a future standard, and introduce the subject and stakeholders to the ISO process. EPA and GACC organized the meeting, including ensuring that stakeholder voices were present, EPA staff chaired the workshop meeting, and ANSI staff served as the secretariat, facilitating the meeting, drafting the document, and communicating with stakeholders.

Once the workshop was complete, and IWA 11:2012 was published, ANSI, with support from GACC and EPA, proposed the creation of a new ISO Technical Committee that would continue the progress made with the goal of developing international standards for clean cookstoves and cooking solutions. As the work transitioned to ISO Technical Committee TC 285 Clean cookstoves and clean cooking solutions, EPA, GACC, and all other affected U.S. stakeholders continued to provide their input and vote on the standards under development, participating through ANSI and its established process for U.S. Technical Advisory Groups (TAGs), or if located outside the U.S., through one of the other 21 participating member countries and 27 observer countries that sit on TC 285.

After the initial funding provided by EPA that supported ANSI's preliminary consultations and the logistics of the IWA, funding was also provided by GACC to support ANSI to serve as secretariat of TC 285, and engage in a twinning arrangement with Kenya Bureau of Standards (KEBS), the ISO member from Kenya, with the goal of transitioning the secretariat to Kenya, which occurred in 2018.

Today, Kenya serves as the secretariat of the international committee, while ANSI, through EPA funding, continues to serve as the U.S. TAG administrator for the committee. And GACC, now called the Clean Cooking Alliance, is a member of the U.S. TAG.

Implementation Methods:

A phased approach was used.

- **Phase 1**: The purpose of Phase 1 was to identify the standards, documents, and procedures in place for cookstoves around the world, with the goal of defining the parameters for a globally accepted standard for clean cookstoves. The activities in Phase 1 included: identifying a core "working group" of individuals that supported and provided guidance towards the initiative, as well as a broader group of cookstove stakeholders; identifying the existing national and international standards, policies, procedures, and documents pertaining to cookstove performance; and conducting consultations with key representatives of cookstove stakeholders such as national standards bodies (NSBs), domestic and international policy-makers, donor organizations, and other stakeholders.
- **Phase 2**: Using the information gathered in Phase 1, the activities in Phase 2 were geared toward identifying potential paths forward in advancing a globally accepted standard for testing the performance of cookstoves and reporting that performance for a number of attributes like emissions, efficiency, and safety, and gathering stakeholders to reach consensus on a recommended path. A workshop was held to present the findings in Phase 1 and then moderated discussion to gather feedback, identify elements that should be included in a globally recognized standard for clean cook stove technology, and begin to work towards consensus. The output of this work was published as IWA 11:2012 Guidelines for evaluating cookstove performance.
- **Phase 3**: Using the information gathered in Phases 1 and 2, ANSI proposed the formation of an ISO Technical Committee on Clean cookstoves and cooking solutions (ISO/TC 285) to further elaborate on the work in IWA 11:2012 and create additional standards.

To date, ISO/TC 285 has published seven standards and has membership from over 40 ISO member countries.

Measurement of Success:

The PPP goals were met and standards were produced, leveraging the expertise and input from both public and private sector stakeholders throughout. At the five-year review cycle for ISO 19867-1:2018 *Clean cookstoves and clean cooking solutions — Harmonized laboratory test protocols — Part 1: Standard test sequence for emissions and performance, safety and durability*, the following countries indicated that they have adopted or intended to adopt the standard: Austria, Burundi, China, Ethiopia, Germany, Ghana, Kenya, Mexico, Rwanda, Tanzania, Uganda, UK. It is also likely other countries that did not respond to the five-year review are using the document as well.

It is important to note that more than 200 representatives from more than 40 countries participated in regional action-planning workshops to disseminate the ISO standard and to encourage its adoption or adaptation. These workshops were co-organized by EPA, CCA, the ISO capacity building division, and the World Health Organization, and two in-person workshops were held, in Asia and East Africa, and given Covid barriers, two virtual workshops were held, in French for Francophone African countries and Haiti, and in Spanish for Latin America countries.

Key Takeaways:

One takeaway from this experience was confirmation of the value that international standards provide to achieving public policy and development goals and the needs of users and industry. Even though the subject of clean cookstoves had not previously been addressed through international standards at the scale of this project, the work successfully progressed from a lack of relevant standards, to an international deliverable (IWA), to a suite of seven ISO international standards, increasing the level of consensus each step of the way.

Advice for Others:

The development of ISO standards requires both time and travel in many cases. This PPP was able to eliminate some of the barrier by funding the travel of experts (equally distributed among the members) and allowed experts to focus on the technical content of the documents.

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NIST CLOUD COMPUTING STANDARDS ROADMAP

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ISO, IEC, IEEE, INCITS
Technical Committees:	JTC 1/SC 38
Other Partnering Organizations:	n/a
Government Organizations:	NIST
Industry Sector(s) / Technology:	IT/Cloud Computing
Program / Activity Website URL(s):	NIST Cloud Computing Roadmap https://www.nist.gov/publications/nist-cloud-computing-standards-roadmap

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

On February 8, 2011, Vivek Kundra (the U.S. Chief Information Officer) released the Federal Cloud Computing Strategy commonly referred to as "Cloud First." The federal government's current information technology (IT) environment was characterized by low asset utilization, a fragmented demand for resources, duplicative systems, environments which are difficult to manage, and long procurement lead times. The Cloud First policy was designed to address those weaknesses using cloud computing.

The National Institute of Standards and Technology (NIST) was identified as a key player and was tasked with finding ways to help accelerate the safe adoption of cloud computing by the United States government (USG). To achieve that goal, NIST formed a public working group comprised of government agencies, private companies, and academia. The public working group worked to identify concerns that the stakeholders had with migrating to cloud computing. Those concerns then became the basis of the NIST Cloud Computing Roadmap which identified ten concerns that were potentially holding back cloud computing adoption. This roadmap was then used by various standards organizations as a guideline of what to work on to speed the adoption of cloud computing by industry.

PPP Goals:

The scope was to identify major concerns (as identified by stakeholders) that were potentially slowing or preventing the adoption of cloud computing by the USG (and by extension everyone else). The end goal was to create a roadmap that could be used by USG agencies, private industry, academia, and standards bodies that identified the issues and standards needed to be worked on to speed the adoption of cloud computing.

Public Sector Role & Participation:

The NIST public working group was an open forum for participation by various stakeholders that had a vested interest in seeing cloud computing successfully adopted by the USG. NIST staff served as the officers of the public working group. Participants varied over time, but included members of private industry, academia, various USG agencies, members of standards bodies, and individual technical experts. At the time it was created, NIST staff was identified to chair the public working group, a scope was crafted, rules were published for the participants, and a general deadline was set. All other work was largely determined by the participants that operated in a consensus-based format.

Implementation Methods:

NIST established the public working group and set the structure and management. NIST provided advertisement, technically neutral management of the working group, a data repository, and teleconferencing services. The workshops invited the public working group participants and government agencies. NIST's promotional efforts engaged more than 400 participants. The public working group set its own schedule and work goals as determined by consensus of the participating stakeholders. At first, the public working group ran as only one group but later divided into subgroups to address various specific concerns or technical issues as the roadmap discussions advanced. Lastly, the public working group sponsored an in-person workshop at NIST to help advance the work on the project.

Measurement of Success:

The NIST Cloud Computing Roadmap has been used as a seed document by several standards development organizations (SDOs). For example, the roadmap was submitted to the ISO/IEC JTC1/SC 38 and became the core of their cloud computing roadmap. Over the last several years, industry and SDOs have been addressing those ten concerns identified in the document and by some measures nine of the ten have been addressed. The JTC 1/SC 38 current work program can be reviewed here.

In addition, some JTC 1/SC 38 standards are now referenced in some U.S. Department of Defense (DOD) purchasing lists. This included the ISO/IEC 18384-1:2016 Information technology — Reference Architecture for Service Oriented Architecture (SOA RA) — Part 1: Terminology and concepts for SOA.

Key Takeaways:

1) A public forum enabled stakeholders to feel invested in the project and they worked together to make it succeed.
2) A public forum enabled NIST to get a wide variety of technical expertise ensuring that the project would be a higher quality then if NIST tried to do it by itself.
3) Rather than trying to solve everything at once, a roadmap provided a guideline that could be used by several organizations at once, enabling quick and substantial progress.

Advice for Others:

When appropriate, public forums can be very successful. The NIST Cloud Computing Technology Roadmap was so successful it became a model that NIST used for other projects including Smart Cities and Communities and Internet of Things (IoT).

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CONSUMER PRODUCTS

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ASTM
Technical Committees:	ASTM F15
Other Partnering Organizations:	
Government Organizations:	U.S. Consumer Product Safety Commission (CPSC)
Industry Sector(s) / Technology:	Consumer Products
Program / Activity Website URL(s):	https://www.astm.org/get-involved/technical-committees/committee-F15 https://www.astm.org/get-involved/consumer-participation/consumer-safety-standards.html

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

In 1972, the U.S. Consumer Products Safety Commission (CPSC) was created, through the Consumer Product Safety Act, to protect the public from unreasonable risks of injury or death associated with the use of consumer products. The act directed the CPSC to defer to voluntary consensus standards and shortly after the establishment of the CPSC, the agency asked ASTM International to create a dedicated committee, F15 Consumer Products, to develop standards. Since then, CPSC has relied on ASTM to deliver standards to help improve consumer product safety.

PPP Goals:

The Consumer Product Safety Commission (CPSC) can either initiate work in voluntary standards through rulemaking or through participation and requests for the creation of voluntary standards. One example of this public-private partnership occurred in 2008, when Congress passed the Consumer Product Safety Improvement Act (CPSIA), which required CPSC to promulgate consumer product safety standards for children's toys and durable infant and toddler products in over two dozen categories such as cribs, strollers, infant seats, and highchairs among others. The act also required that the CPSC address the standards at an accelerated rate of two standards every six months.

The language of the CPSIA mandated that the standards development process begin with the product categories that the CPSC determines to be of the highest priority. The list included in the Act identified many common juvenile products for which a weak standard or no previous technical standard existed at all.

Public Sector Role & Participation:

CPSC staff participates on ASTM's committee on consumer products (F15), along with industry and other stakeholders such as industry associations, manufacturers, testing laboratories, end users, consumers/consumer advocates, health professionals, product engineers, and regulatory agencies. CPSC staff are recognized members of the committee similar to other stakeholders, though CPSC staff participate in other ASTM technical subcommittees. These committees cover areas such as paint, packaging, soaps, textiles, sports equipment, tires, fences, and more. Over 70 CPSC staff work within ASTM committees overall, with much of their work dedicated to consumer products.

While a vote within the ASTM process is possible, CPSC staff must be granted permission to hold an official vote within a standards body under the requirements 16 CFR 1031. However, CPSC staff have access to and can provide comments on all ballots where they participate for consideration by the committees.

In some cases, the CPSC may make a request to ASTM International seeking a revision to an existing standard or the creation of a new standards activity targeting a hazard, new product, material, or process. One example includes standards developed to address entrapments with adult portable bed rails to mandate compliance with the voluntary standard. Another example is the development of a voluntary standard for liquid laundry packets after exposures and ingestions caused a series of injuries and deaths.

Regardless of the hazard or request, CPSC staff participate as stakeholders in the standards-development process to revise standards or create new standards when injury and incident data signal a need for responsive standards through ASTM.

CPSC provides the consumer products committee with incident data, which is reported through various channels including the NEISS database and incident reports made directly to CPSC. This data helps identify trends and patterns in injuries and incidents that help inform the direction of standardization.

The work between ASTM and CPSC is further strengthened by the important role of the CPSC Voluntary Standards Development Coordinator, who works as a liaison between ASTM and CPSC, supervising standards activities.

ASTM committees are an open and neutral forum to engage with the regulatory community. The process is iterative and requires all parties to collaborate in order to come to consensus. The venue allows for discussion on common sense solutions that can be implemented in a timely manner. Dialogue is also important to ensure all comments and concerns are heard, with the process working best when stakeholders leverage perspectives from a variety of disciplines. ASTM's consensus-based process allows all stakeholders to contribute.

Implementation Methods:

Standards development work begins when a relevant stakeholder identifies the need for a new document or revision to an existing standard. CPSC will also initiate revisions or requests for new standards based on information received from the public and/or recalls to address various safety concerns.

The committee on consumer products publishes, maintains, and updates numerous standards that help to address the safety of pools, spas, and playgrounds; prevent strangulation by clothing drawstrings; reduce bunkbed and baby walker injuries; eliminate the toxicity of crayons and other art supplies; enhance the fire safety of candle products; and much more. Because ASTM standards are living documents, revisions can be made at any time when the need arises.

Measurement of Success:

Since the establishment of the consumer products committee, most of the CPSC work has been conducted under its auspices. Many ASTM standards are incorporated by reference into regulation. One example is the standard consumer safety specification for full-size baby cribs (F1169). The standard is regularly updated and has been a mandatory safety standard in the U.S. since 2011. According to CPSC data, there has been an 80% reduction in crib deaths from 1973 to 2018.

Other key documents F15 has produced include:

- The standard consumer safety specification for highchairs (F404)
- The standard consumer safety specification for infant walkers (F977)

Recall statistics in particular illustrate the effectiveness of the CPSIA and its impact on toy safety, according to consumer advocate Rachel Weintraub. "In 2007, there were 109 recalls of children's products and toys for lead," she says. "In 2017 there was one such recall for lead. I think that's a very powerful statistic." Toy recalls have also decreased according to Weintraub, declining from 207 in 2007 to 15 in 2017, an 89 percent reduction that may be attributed in part to the CPSIA.

F15 standards have and continue to play a preeminent role in reducing the number of injuries and death associated with the use and performance of consumer products based on identified hazards. The committee, with a current membership of 1423 participants on 63 technical subcommittees, has jurisdiction of over 100 standards.

Key Takeaways:

1. Updating a voluntary standard can be quicker than updating a government-developed standard or other regulatory action.

2. CPSC, like many government agencies, has been understaffed at various times. Using the PPP model, they are able to leverage additional technical expertise that did not exist within the commission.

3. All stakeholders must stay engaged and communicate.

Advice for Others:

ASTM and other SDOs are an open place to engage with the regulatory community. They foster dialogue among a diverse group of stakeholders to develop common-sense safety requirements.

An important consideration for a committee in its standards-development process is risk assessment versus performance.

In standards-development work, the ideal solution is when an issue can be engineered out. If a problem must remain, then finding a way to change or improve it is another solution. If all else fails, then a warning label should be added for the consumer's benefit.

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ANSI ELECTRIC VEHICLES STANDARDS PANEL (EVSP)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	Various
Technical Committees:	Various
Other Partnering Organizations:	ANSI
Government Organizations:	Argonne National Laboratory (ANL), National Renewable Energy Laboratory (NREL), Oak Ridge National Laboratory (ORNL), Pacific Northwest National Laboratory (PNNL), Idaho National Laboratory (INL), and Sandia National Laboratories (SNL)
Industry Sector(s) / Technology:	Automotive
Program / Activity Website URL(s):	www.ansi.org/evsp

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The ANSI Electric Vehicles Standards Panel (EVSP) was initially formed in March 2011 with the purpose of developing a roadmap of standards and conformance programs needed to facilitate the safe, mass deployment of electric vehicles (EVs) and charging infrastructure in the United States. The decision to form the Panel was made at a meeting of key stakeholders in March 2011, which ANSI convened in response to suggestions that the U.S. standardization community needed a more coordinated approach to keep pace with electric vehicle initiatives moving forward in other parts of the world. The EVSP developed the initial roadmap in 2012 and revised versions in 2013 and 2023.

The Biden Administration's goal for a clean energy future resulted in the issuance of a June 2021 lab call funding opportunity announced by the U.S. Department of Energy (DOE) Office of Energy Efficiency & Renewable Energy (EERE) Vehicle Technologies Office (VTO). The lab call included a pillar on codes and standards with the goal to "identify and address challenges and barriers to the integration of electric vehicles at scale (EVs@Scale) charging with the grid created by the uncoordinated development of codes and standards and the rapid advances in vehicle and charging technologies." The EVs@Scale lab consortium, formed in response, committed to develop a 2022 roadmap like earlier ANSI EV standards roadmaps. Argonne National Laboratory (ANL) is the lead lab for the codes and standards pillar, supported by consortium members National Renewable Energy Laboratory (NREL), Oak Ridge National Laboratory (ORNL), Pacific Northwest National Laboratory (PNNL), Idaho National Laboratory (INL), and Sandia National Laboratories (SNL). The EV@Scale initiative supports federal and state funding associated with deploying EV charging infrastructure nationwide.

PPP Goals:

The ANSI EVSP is a cross-sector coordinating body whose objective is to foster coordination and collaboration on standardization matters among public- and private-sector stakeholders to enable the safe, mass deployment of electric vehicles and associated infrastructure in the United States with international coordination, adaptability, and engagement. Outputs of the EVSP in the 2011-2014 timeframe included a Standardization Roadmap for Electric Vehicles (Version 1.0 in April 2012 and Version 2.0, May 2013), a gaps progress report (November 2014) against same, and a standards compendium. Though the priorities have shifted in many respects with the new focus on EVs@Scale, aspects of the earlier EVSP work were drawn upon to support the 2023 Roadmap of Standards and Codes for Electric Vehicles at Scale.

The priorities of the 2023 codes and standards effort was to identify the most critical standards for EVs at scale, including for standards to address high-power DC charging, storage (i.e., microgrid, distributed energy resource

management systems) integrated with DC charging, vehicle grid integration, high-power scalable/interoperable wireless charging, cybersecurity, vehicle-to-everything (V2X) communications, and vehicle-oriented systems.

Public Sector Role & Participation:

Some 80 individuals from 130 public- and private-sector organizations supported the 2023 roadmap's development, including U.S. federal government agencies and national laboratories, standards and codes developing organizations, industry, academia, and others. The roadmap represents the culmination of the EVSP's work over eight months to identify key safety, performance, and interoperability issues for EVs and charging infrastructure, relevant published and in development standards, and to assess gaps.

All EVSP members offered their technical knowledge about issues, existing standardization activities, regulatory and codes activities, and R&D needs. There was no distinction between the roles of the public versus private sector. Some representatives engaged in EVSP as a member and others served in leadership roles. However, outreach efforts always targeted and advocated for both private and public sector engagement. Participation was open to EV stakeholders that have operations in the U.S. Membership in ANSI was not a prerequisite and there was no fee to participate.

The EVSP efforts were partially funded by ANL and supported through sponsorships including UL Standard and Engagement (ULSE) and the Kiosk Manufacturers Association (KMA).

Implementation Methods:

In 2011, before forming the EVSP, ANSI hosted a stakeholder workshop to explore the needs for collaboration and identify stakeholders. Once there was a consensus regarding the need, a structure for the EVSP was established. To maximize the effectiveness and relevance of the EVSP work, a Steering Committee (SC) was established. The SC membership included the working groups chairs as well as standards organizations, government, consortia, and others to give balance to the SC. The SC offered guidance and strategic direction, as well as leveraged their networks to ensure the technical expertise in the WG was sufficient to ensure technical and market relevance.

The 2023 roadmap met completely virtually and did not utilize a Steering Committee (SC) as it had in the past. To develop the roadmap, the EVSP established three working groups that typically held online meetings twice a month:

- WG1: Vehicle Systems
- WG2: Charging Infrastructure
- WG3: Grid Integration and Cybersecurity

Measurement of Success:

The roadmap increases awareness about research, standards, and codes to support electric vehicles. It also highlights existing and needed standardization efforts, aimed at accelerating standards development and adoption.

Of the 37 gaps, 14 gaps are identified as high priority, 20 as medium priority, and three as low priority. In 23 cases, additional pre-standardization research and development (R&D) are noted. The roadmap also provides prioritized timeframes for when standards work should occur, and identifies SDOs or others that may be able to develop the standards or perform the R&D. It is envisioned that a mechanism will be established to assess progress to implement the roadmap's recommendations.

The target audience for the roadmap includes vehicle manufacturers, entities that will be installing and operating charging infrastructure, SDOs, U.S. federal, state, and municipal government agencies, electric utilities, and others.

It is too early to determine the impact the 2023 roadmap will have on EV stakeholders, but feedback from EVSP participants has been positive. The roadmap has been downloaded approximately 800 times.

Key Takeaways:

1. A clear scope of what technical areas should be addressed as a whole, as well as the WG level is important in order to not overwhelm or slow efforts.
2. A balanced representation of expertise in each of the technical working groups is necessary to ensure market relevance and unbiased recommendations.
3. Allowing for public review of drafts prior to publications helps ensure broader input from directly and indirectly impacted stakeholders.

Advice for Others:

The initial plan for the 2023 roadmap was to leverage the 2014 version and update it. However, as the work began, it was determined that too much time had passed and the content was outdated. This resulted in a delay in WG progress. After re-strategizing, progress started heading in the right direction. It may be beneficial to leverage a steering/advisory committee model with balanced representation of industry to proactively head off delays or confusion. Additionally, or alternatively, an industry survey could aid in scope refinement and gauge the readiness of stakeholders to support the effort.

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EXO TECHNOLOGY CENTER OF EXCELLENCE (ET COE)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ASTM International
Technical Committees:	F48 on Exoskeletons and Exosuits
Other Partnering Organizations:	Exoskeleton Report, New Stone Soup, Prime Performance, HFES, NSC, SCRA, Smart HLPR, AExG, LiUNA
Government Organizations:	NIST, NIOSH, US Army DEVCOM SC
Industry Sector(s) / Technology:	Exo Technology
Program / Activity Website URL(s):	www.etcoe.org/

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

Established in 2019, the ASTM International Exo Technology Center of Excellence (ET CoE) is a collaboration between ASTM (and its more than 30,000 members) and consumers, industry, government, healthcare, and academia. The ET CoE seeks to improve the quality of life and participation of the general public through accelerating exo technology research, standards, testing, and training.

PPP Goals:

The ET CoE behaves as an exoskeleton for the global exo community. It augments, enables, assists, and enhances the exo community through initiatives that include:

- identifying high priority needs and sponsoring research & development (R&D) through groundbreaking Research to Standards (R2S) framework;
- providing unbiased high value advice and counsel on exo technologies, including existing standards and those under development around the globe;
- developing and delivering education, training, and workforce development products;
- collaborating and partnering with other organizations passionate about exo technologies;
- testing and evaluating exemplar products, processes, and laboratories to establish a trusted network of testing and certification organizations;
- connecting people and organizations to promote innovation and collaboration;
- providing a neutral venue for stakeholder groups to discuss common challenges;
- curating and sharing knowledge;
- promoting exo technology through various outreach mechanisms

Ultimately, the ET CoE's mission is to accelerate exo technology research, standards, testing, and training.

Public Sector Role & Participation:

The ET CoE initiatives are supported through partnerships. In addition to ASTM, the founding partners are Exoskeleton Report (ExR) LLC, New Stone Soup (NSS) VT LLC, and Prime Performance. The partners were chosen, in part, because of the diverse expertise they brought to the COE's initiatives. Creating and sustaining a partnership that will ebb and flow as the ET space does is of paramount importance. The CoE also has collaborative, research, and education and workforce development partners as follows:

- **Collaborative Partners** bring their networks and expertise to increase awareness and education about the CoE activities and exo technologies. The Human Factors and Ergonomics Society (HFES), National Safety Council (NSC), and South Carolina Research Authority (SCRA) are collaborative partners.
- **Research Partners** bring their experience and resources to assist with CoE research initiatives. The U.S. National Institute of Occupational Safety and Health (NIOSH), National Institute of Standards and Technology (NIST), and Smart HLPR are research partners.
- **Education and Workforce Development Partners** support education and workforce initiatives for exo technologies the Automotive Exoskeleton Group (AExG), Boston Engineering Corporation, LiUNA TriFund, and U.S. Army Combat Capabilities Development Command, Soldier Center (DEVCOM SC) have partnered with the CoE.
- **Research-to-Standards (R2S) Team** is based on the idea that standards should be constructed and integrated with high-quality, objective research. The ET CoE plans to identify, evaluate, and prioritize key topics to form the foundation of a R2S roadmap with input from government agencies, regulators, and subcommittee chairs in ASTM committee F48. The roadmap will help facilitate the development of standards to benefit the global exo community.

ASTM International Committee F48 Exoskeletons and Exosuits: Acting as a separate entity from the ET CoE, this committee supports the standards development activities for this technology. Both public and private stakeholders participate in the F48 Exoskeletons and Exosuits technical committee, subcommittees, and working groups, serving in diverse roles (including sponsorship, contractual agreements, strategy development, research, technical or content contributions, leadership, voting/abstaining, and monitoring/active participation). Global authorities and industry continue to directly participate in ASTM F48 to maintain and develop new standards.

Implementation Methods:

The ET CoE has an Advisory Board which is chartered to provide vision and direction of the CoE to ensure that it remains current with the existing and future drivers of the exo technology industry. Its members include industry, government and academia. The CoE supports research and standards related activities through their partners and organizes design challenges through their Exo Games. The Management Team coordinates the day-to-day management of each function of the ET CoE and ensures activity alignment with ET CoE objectives.

CoE projects are led by partners and several of the projects have resulted in standards development. The standards development is conducted through ASTM F48. ASTM technical (main) committees are divided into subcommittees which manage portfolios of standards on focused technical areas. Subcommittees form task groups (TGs) which work on individual drafts of standards. ASTM F48 on Exoskeletons and Exosuits is divided into nine technical subcommittees (seven technical and two administrative), each with an executive subcommittee which sets its strategic and technical direction.

Section **F48.90.01 on Research & Development** resides under the F48.90 Executive Subcommittee and serves exclusively as an information conduit between the ASTM ET CoE and ASTM Committee F48. It does not develop standards. Its primary function is to provide feedback on:

- standardization needs (either new standards, supporting work items under development, or updating existing standards);
- recurring R&D SOWs/proposals (focusing on specifically enumerated standards deliverables) under consideration by the ET CoE, including recommendation of an F48 subcommittee of jurisdiction;
- the possibility of any corollary program deliverables (training, PTP, certification, etc.);
- any additional technical information they deem relevant to the proposals under consideration.

F48.90.01 meets at least twice a year and face-to-face during biannual F48 meetings and as often as needed via teleconference and is closed to non-members. F48.90.01 is typically chaired by an executive member of Committee F48.

Proposals for F48.90.01 leadership may be submitted to ASTM staff and shall be considered by the ET CoE's Advisory Board and the ET CoE's Management Team.

Exo Games: The Exo Games is sponsored by the ET CoE and aims to enhance student involvement and education in the dynamic field of exo technologies, with a special focus on first responder applications. The Exo Games provides a unique platform for university teams of students from various institutions to connect with exo industry professionals. This competition is designed to foster lifelong working relationships with the standards community, offering participants hands-on experience with the latest exo standards.

Working collaboratively, student teams embark on the challenge of designing, building, and testing a self-contained exoskeleton based on a provided project specification. Their design solutions will be rigorously evaluated against the predefined standards established by ASTM's exoskeletons and exosuits committee (F48). The competition not only promotes innovation but also mirrors the actions of first responders, making it a truly impactful experience.

NIST is partnering with the ET CoE to support the Exo Games through a CRADA agreement and develops the underpinning metrology for exoskeletons and promotes student STEM involvement.

Measurement of Success:

The ET CoE initiative is still in its early years. However, efforts have already started to produce standards and the Exo Games have helped expose emerging professionals to standards. One success story is related to the CoE project "Rapid Development of Exoskeleton Test Method Standards." The following list of standards topics (identified in the F48.03 on *Task Performance and Environmental Considerations Roadmap of Standards to Develop*) have been supported by the CoE, four of which are approved and two others which are in development. When ready, completed drafts will go to ASTM ready for evaluation and testing.

- Approved - F3528 Test method for exoskeleton use: gait
- Approved - F3581 Test method for exoskeleton use: hurdles
- Approved - F3582 Test method for exoskeleton use: gaps
- Approved - F3584 Test method for exoskeleton use: obstacle avoidance: Walking
- WK76431 - Test method for exoskeleton use: stairs
- WK83509 - Test method for exoskeleton use: crawling

Key Takeaways:

8. ASTM International was able to respond to industry needs very quickly. Bringing the relevant stakeholder population into the discussions during early stages of project development helps drive a rapid response and prepare stakeholders to maximize their productivity.
9. The implementation phase of activities is just as important as the development phases. To ensure this, especially with a collection of stakeholders relatively new to the development process, education and training (both early and ongoing) is critical.
10. Going to where the stakeholders are greatly improves the chances of their participation. For international acceptance, meetings (of both the COE & standards development arm via F48) should be held in a variety of locations. Additionally, co-locating meetings with industry events where members already plan to attend can help increase participation (especially for task group meetings).

Advice for Others:

In this PPP, there was a significant reliance on active participation from industry, government, academia, and trade associations/professional societies. While some participants have restrictions on the level of interaction they are permitted to undertake, this is often mitigated via proactive hosting of training/educational programs. The success of

any standards activity is predicated upon the buy-in from & contributions by stakeholders – while funding can be a motivator, it is not a guarantee of success.

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FEDERATED HEALTH INFORMATION MODEL (FHIM)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	The Open Group
Technical Committees:	
Other Partnering Organizations:	
Government Organizations:	Office of the National Coordinator for Health IT (ONC), Department of Defense, Veterans Affairs, Department of Health and Human Services
Industry Sector(s) / Technology:	Healthcare
Program / Activity Website URL(s):	https://fhim.org/about/intro-to-fhim

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

Federal Health Information Model (FHIM) development started in 2007 under the authority of the Clinger-Cohen Act of 1996 and was managed by the Office of the National Coordinator for Health IT (ONC) and its Federal Health Architecture (FHA) program. The purpose of the FHIM project was to coordinate efforts of the Veterans Affairs (VA), Department of Defense (DoD), Department of Health and Human Services (DHHS), and other "partner" federal agencies involved in the development of electronic medical records and engage with multiple private sector standards development organizations (SDOs). The FHIM uses standards from SNOMED International CT, LOINC, and RxNorm and coordinated with HL7 International, NCPDP, ANSI's ASC X12, and other SDOs. It has been implemented in the U.S. public sector and the private sector worldwide.

In 2019, ONC named The Open Group as the sole steward of the FHIM. The Open Group is a global consortium that enables the achievement of business objectives through technology standards and open-source initiatives by fostering a culture of collaboration, inclusivity, and mutual respect among our diverse group of 900+ memberships. The Open Group membership includes customers, systems and solutions suppliers, tool vendors, integrators, academics, and consultants across multiple industries.

PPP Goals:

The goal of the PPP was to make the FHIM available as an open-source resource to users worldwide by locating it at The Open Group and the FHIM-dedicated website. The FHIM website includes a wide variety of resources, including:

1. A six-minute plain-language animation describing why the FHIM is needed, how it works, and who can benefit from it.
2. The FHIM model, newly conceptualized as the **Federated** Health Information Model.
3. Introduction of the **FHIM Profile Builder (FPB)**, a standards-based API profile builder, along with two training videos.
4. Multiple resource documents about the FHIM, the FHIM model, USCDI requirements, The Open Group assessment of the FHIM, and key transfer papers and presentations.

Public Sector Role & Participation:

The alpha version of the FPB was funded by ONC during the FHIM transition to The Open Group. However, it did not provide additional funding to advance its development. The FHIM has been stable since its transfer to the Open Group. Should public and/or private entities wish to extend the FHIM and its FPB, the Open Group Healthcare Forum would facilitate this work through The Open Group standards development process.

Because The Open Group is the steward and not the owner of the FHIM, it is not in a position to create the FHIM as a commodity. It can track how many unique hits the site receives, but cannot track how the FHIM is used by those who go to the site. If, however, an entity wanted to join the Healthcare Forum to work together with other members to advance the FHIM or to further develop the FPB, this opportunity exists and is consistent with the ONC decision to invest in this PPP.

Implementation Methods:

From 2018-2019, with the support of ONC, The Open Group convened over two dozen internationally recognized public and private sector healthcare interoperability experts (the FHIM Transition Council, or FTC) on a regular basis to talk about the FHIM and published a report entitled Analysis of the Feasibility and Benefits of Moving Stewardship of the FHIM to The Open Group. The report notes that members unanimously agreed that one of its highest value propositions lies in its ability to help developers and clinical stakeholders build interoperability components (using HL7 FHIR, CDA, V2, etc.) that can be used easily, without special effort, in APIs, components, and services. Further details can be found in Appendix B of the report.

The FTC agreed:

- FHIR is immensely popular, in large part because it is easy to use and solves the data transfer problem in interoperability.
- However, the architecture of FHIR standards does not ensure that health data shared in one implementation instance can be shared in other instances.
- As a result, the widespread adoption of FHIR is producing thousands of profiles that cannot be reused without special effort.
- A FHIM profile builder would assist the FHIR, CDA, V2 communities by producing consistent, reusable standard-based profiles, and thereby help significantly advance interoperability.

Thus, the transfer of the FHIM to The Open Group began the development of a FHIM Profile Builder, which can assist the FHIR, CDA, V2 and other communities by producing consistent, reusable, standards-based profiles, and thereby help significantly advance interoperability

Measurement of Success:

All goals of the FHIM transition PPP were met and the development of the FPB went beyond the initial scope. Since the transfer to The Open Group, there have been over 20,000 unique visitors to the FHIM website and over 36,000 page views.

Key Takeaways:

1. In this PPP, the federal government invested over $5M and approximately 200k person-hours to develop the FHIM platform to address the significant interoperability needs of the federal partners. In 2018, after about a decade of work, the decision was made to pursue interoperability through other means and, if possible, to find a public SDO to adopt the role of FHIM Steward.
2. The Open Group accepted the role of FHIM Steward in 2019 and, in the process of doing so, convened a council of experts who advised on the most productive next steps.
3. The FHIM now resides at www.fhim.org at The Open Group. As an open-source standard, others are free to use the standard and tens of thousands have visited the FHIM website since its establishment in 2019.

Advice for Others:

This PPP was successful when viewed from its original scope of work. However, during the collaboration, it became apparent that additional positive contributions could be made through further development of a FHIM Profile Builder

(FPB). This work could have been coordinated with the ONC and collaborations could have been pursued with other SDOs and private sector organizations, such as Epic and Cerner, for example. This can still be done. The federal government can help leverage such an outcome, but if it does not, it is less likely to occur given that private companies are not incentivized to collaborate in the development of a common information model to enhance interoperability more broadly than they do today.

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GENERAL AVIATION AIRCRAFT

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ASTM International
Technical Committees:	F44 General Aviation Aircraft
Other Partnering Organizations:	General Aviation Manufacturers Association, Aircraft Electronics Association
Government Organizations:	U.S. Federal Aviation Administration, European Aviation Safety Agency
Industry Sector(s) / Technology:	Aviation
Program / Activity Website URL(s):	www.astm.org/get-involved/technical-committees/committee-f44

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

In 2009, a joint team comprised of members of the U.S. Federal Aviation Administration (FAA) and industry conducted a Part 23 Certification Process Study (CPS), which recommended the reorganization of Part 23 based on performance and complexity rather than weight and propulsion divisions. Part 23 is the section of the federal aviation regulations (FAR) related to the manufacture and airworthiness of aircraft under 19,000 pounds [8,600 kg], with seating for 19 or fewer passengers. In the decades prior to the study Part 23 regulations had not kept pace with advances in aviation technology. The Part 23 Reorganization Aviation Rulemaking Committee (ARC) was charged with making recommendations to bring increased flexibility to the certification process for new aircraft.

In 2011, the ARC published a report that echoed the sentiments of the CPS. The ARC accepted that: "One set of consensus standards would be created and maintained by ASTM International and would follow their processes for standards development that would satisfy the FAA. Their consensus standards process ensures the standards are agreed to by a balanced group of representatives from regulators, industry, operators, and others." In 2012, formed the committee on general aviation aircraft (F44) at the request of aviation industry organizations to aid the efforts of the FAA's Part 23 ARC. These rulemaking efforts were reinforced by the Small Airplane Revitalization Act of 2013, which required the FAA to issue a final rule revising the certification requirements for small airplanes.

While the driver for forming F44 was a recommendation from a U.S. government rulemaking committee, it is significant that this was a global effort. At the same time the FAA was strategizing the Part 23 rules, the European Union Aviation Safety Agency (EASA) was doing the same with their CS 23 Normal, Utility, Aerobatic and Commuter Aeroplanes rules. EASA and FAA went to great lengths to harmonize their rules and collaborate with industry to ensure safety and enable innovation in general aviation. EASA speaks to their efforts in the explanatory note for the reorganization of CS-23. Other civil aviation authorities worldwide, including Brazil, New Zealand, Canada, China, and others, participated in this effort.

In December 2016, the FAA published the "Revision of Airworthiness Standards for Normal, Utility, Acrobatic, and Commuter Category Airplanes" (Part 23, Amendment 64), and in May 2018, the FAA issued the first Notice of Acceptance (NOA) of thirty F44 standards in support of new performance-based standards for Part 23 aircraft. In the time between the final rule and the first NOA, FAA issued advisory circular AC 23.2010-1 FAA Accepted Means of Compliance Process for 14 CFR Part 23

In March 2017, EASA published CS-23 Amendment 5 and in December of that same year, released their first issue of the Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Certification Specifications for Normal-Category Aeroplanes (CS-23), which accepts F44 standards as means of compliance.

PPP Goals:

The primary goal of the work was to ensure that the former prescriptive rule language from the FAA and EASA was translated into the industry consensus standards. The anticipated new rules will state the conditions that applicants need to meet, however, the means to demonstrate compliance – or the "how" – will be reviewed, edited for redundancies, and organized in various new F44 standards.

The scope of work was strictly limited to CS/Part 23 aircraft. However, industry representatives consistently considered what innovations were expected to enter the marketplace. Throughout committee deliberations, they were careful to ensure the scope of standards met the needs of current aircraft but did not unintentionally hinder future innovations such as electric propulsion, simplified vehicle operations, or vertical take-off and landing (VTOL) aircraft. New technologies in need of specific standardization were considered a "future action" in the initial year until the first suite of standards supporting the revised rules were accepted (which took place in 2017-2018). New technologies and approaches are considered part of the current scope of work.

Public Sector Role & Participation:

Public and private stakeholders both participated in the F44 technical committee, its subcommittees, and its working groups. Before rulemaking began, EASA and FAA staff participated in each of the working groups responsible for migrating former rule language into the standards. Once rulemaking began, some government staff withdrew from F44 activities to avoid conflict of interest.

All standards go through a balloting process, in which members vote affirmative, negative, or abstain. U.S. government representatives opted to abstain with comments, out of concern for undue influence, conflict of interest, or perception of conducting rulemaking outside of a formal rulemaking process.

Once the standards were approved, ASTM International published them and supported promotional efforts to increase awareness. During EASA and FAA public review of draft rules, ASTM provided free read-only access to the standards so the general public could review the standards and the rules at the same time. Industry, trade associations, authorities, and academia continued their work on the standards before, during, and after rulemaking and are still active today.

Global authorities and industry continue to participate directly in F44 to maintain and develop new standards. EASA and FAA continue to issue AMC/NOA's of updated standards.

Implementation Methods:

ASTM technical (main) committees are broken down into subcommittees that manage portfolios of standards on focused technical areas. Subcommittees form task groups (TGs) that work on individual drafts of standards. The committee on general aviation aircraft was divided into six technical subcommittees, which covered the same areas as the sections of the aircraft certification rule (general, flight, structures, powerplant, systems and equipment, and terminology). Three administrative subcommittees were also formed:

- **Regulatory Liaison Subcommittee (F44.92)**: Only government representatives can join this subcommittee. The primary goal of the subcommittee is to provide global authorities with a forum to discuss needs, concerns, or opportunities. The subcommittee meets at each of the face-to-face meetings of the committee. F44.92 was co-chaired by EASA and FAA and provided report-outs at the main committee meeting. Ultimately, this subcommittee provides global authorities with the ability to coordinate and increase the chances of global harmonization and consistent messaging back to industry.

- **Industry Liaison Subcommittee (F44.93)**: Only industry representatives can join this subcommittee. The primary goal of the subcommittee is to provide industry with a forum to discuss needs, concerns, or opportunities

without authorities present. The subcommittee meets at each of the face-to-face meetings while the F44.92 subcommittee meets.

- **Executive Subcommittee (F44.90)**: The executive subcommittee is comprised of leadership from each subcommittee as well as other representatives in order to provide a balance of perspectives to the subcommittee. The executive subcommittee sets the strategic and technical direction of the committee.

In the first several years after F44 was formed, the committee met four times per year, alternating between the U.S. and Europe to increase representation of global stakeholders at face-to-face discussions. Task groups met weekly or biweekly virtually, and subcommittees met virtually if official business was necessary. As the committee matured and a full suite of standards necessary for the new rules were published, the committee met less often. Today the committee consistently leverages hybrid meetings and balloting is done online.

Measurement of Success:

Pre-standardization:
Prior to the formation of F44, global industry and global authorities worked to identify challenges with the existing certification rules; collaborated to determine how to best support performance-based regulations; and created a strategy to develop a solution. These efforts were successful, as the new rules were published and the standards were developed.

Standardization:
F44 published 31 standards in three years, demonstrating a level of commitment from stakeholders, as well as alignment on the mission and scope of the activity. In a very short period of time, industry was able to move 80% of the former rules into industry consensus standards and establish cross-reference back to the old – and new – rules This aids both the public and private sectors. F44 continues to update and develop new standards to support legacy and emerging general aviation technologies. These efforts were also successful, as the authorities accepted the standards as means of compliance after their new rules were published.

Implementation:
The issuance of the rule and subsequent acceptance of the standards was just one step of many taken to prepare the global marketplace for the largest rewrite of general aviation aircraft certification in half a century. Applicants have experienced challenges with effectively leveraging the new rules. In November 2020, the Government Accountability Office (GAO) published the "Aircraft Certification Report: FAA Needs to Strengthen Its Design Review Process for Small Airplanes," which offered seven recommendations to improve the implementation of the new rules.

Key Takeaways:

1. ASTM International has an effective process for forming new technical committees. Because [AUTHOR WHO IS "THEY"]: they were part of the FAA Part 23 ARC discussions, they were able to respond to industry very quickly. Bringing SDOs into the discussions early on helped them respond more rapidly and prepare stakeholders to ensure an efficient start.
2. The implementation phase of standardization activities is just as important as the development phases. To ensure a successful implementation, especially for such a significant change as the Part 23 rewrite, education and training should be planned.
3. Going to where the stakeholders are greatly improves the chances of success. For international acceptance, meetings should be held in a variety of locations. Additionally, co-locating meetings with industry events that members already plan to attend can help increase participation (especially for task group meetings).

Advice for Others:

There was a significant reliance on active participation by both industry and government. Participants occasionally have restrictions on the level of participation permitted. Educating those decision-makers about the impact of, and options for, participation is as important as understanding the process itself and how to effectively engage. The success of a standards activity hinges upon the contributions of stakeholders, so effective leadership and participation are paramount.

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INSTITUTE FOR BIOSCIENCE AND BIOTECHNOLOGY RESEARCH (IBBR)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	n/a
Technical Committees:	n/a
Other Partnering Organizations:	University of Maryland – College Park, University of Maryland - Baltimore, MilliporeSigma, AstraZeneca/Medimmune, NIIMBL
Government Organizations:	NIST
Industry Sector(s) / Technology:	Biotechnology
Program / Activity Website URL(s):	www.ibbr.umd.edu; www.nist.gov/programs-projects/nist-monoclonal-antibody-reference-material-8671; www.nist.gov/programs-projects/nistcho

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

Pharmaceutical and biotech companies, academic and government institutions, and regulatory agencies and standards organizations all have an essential part to play in the bioeconomy. For this reason, the Institute for Bioscience and Biotechnology Research (IBBR) is structured to bring together all of the critical elements necessary to pursue solutions to major health challenges while strengthening the state and nation's bioeconomy. The IBBR serves as a catalyst to advance the understanding of biomolecular structure-function relationships which underpin biotherapeutic discovery, development and manufacture require a wide array of resources, perspectives, and expertise.

PPP Goals:

IBBR exists to foster integrated, cross-disciplinary team approaches to scientific discovery, translational development and education, and to the foster and expand the bioeconomy in the United States. IBBR works towards these goals by:

- Leveraging the collective research strengths of the partnering institutions in medicine, biosciences, technology, quantitative sciences, and engineering
- Creating innovative cross-functional collaborations that break down traditional silos and lead to pioneering research and development
- Working with a wide range of academic, government, and industry partners to move ideas from promising theory to real-world applications

Public Sector Role & Participation:

IBBR supports a dynamic research environment that facilitates interactions and collaborations among their scientists, partners, and stakeholders and promotes new research directions that complement and build on their existing strengths. In addition to research, IBBR provides resources, such as the IBBR Commons, which is structured to provide a multidisciplinary environment for postdoctoral and graduate training, as well as undergraduate and high school research internships. The IBBR Commons also provides collaborative opportunities for pharmaceutical and biotech companies, other academic and government institutions, regulatory agencies, and standards organizations to be involved in research and standards development.

Implementation Methods:

IBBR hosts and holds public workshops and conferences to identify research, measurement science, and standards gaps. Typically, these events will include a mix of researchers and stakeholders from industry, academia, and other government agencies. The IBBR facilities provide high-end technology and scientific instrumentation that support research, which makes IBBR a valuable place to host round-robin testing and other collaborations.

Measurement of Success:

Two of the most successful developments from NIST that have leveraged the IBBR partnership are the NISTCHO and the NISTmAb reference materials. In most cases, biopharmaceutical companies use their own bioprocesses to manufacture formulated biopharmaceuticals for regulatory approval and eventual commercial sale that are not accessible for open-access and are considered intellectual property. The NISTCHO and NISTmAB were developed in cooperation with IBBR, MilliporeSigma, and the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

- NISTCHO was developed to make an industry-grade cell line openly accessible and to support innovation in CHO based industrial manufacturing. NISTCHO serves as a biomanufacturing research, educational and R&D tool. It also supports benchmarking and enables interlaboratory studies to demonstrate fit for purpose and robustness.
- NISTmAb is a monoclonal antibody (mAb) reference material that can be used in analytical research to improve measurement techniques applied to mAb biopharmaceuticals. Since its release in 2016, NISTmAb has become a ubiquitous tool for studying mAb pharmaceuticals in fundamental research, development, manufacturing, and quality analysis settings.

Since the NISTmAb has been available there have been a significant number of units sold for R&D and 113 patent applications to date that use NISTmAb as a benchmark material to demonstrate the performance of new technologies. This number is expected to rise.

Key Takeaways:

- IBBR helps pre-standardization efforts: The NISTmAb and NISTCHO helped facilitate innovation by providing an openly accessible cell-line that researchers can then use to test and improve upon. This can then lead to benchmarking of new technologies, which accelerates adoption and use of these technologies in pharmaceutical research, development, and manufacturing.
- IBBR can establish research programs based on, for example, FDA priorities, and potentially fill gaps in measurements and standards that support regulatory policy and decision making.

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MICROELECTRONICS SUPPLY CHAIN & OPERATIONAL SECURITY

ORGANIZATIONAL SPECIFICS

Standards Organizations:	Various
Technical Committees:	Various
Other Partnering Organizations:	Various
Government Organizations:	DOD
Industry Sector(s) / Technology:	Microelectronics
Program / Activity Website URL(s):	www.ansi.org/standards-coordination/workshops-and-other-coordination-activities#micro

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

Microelectronics (ME) support all industry sectors including information technology, telecommunications, critical infrastructure, utility management, national defense, and more. The ME supply chain is inherently global and the U.S. is very reliant on overseas suppliers. The ME lifecycle, including phases such as design, fabrication, packaging, and testing, is decentralized, resulting in challenges to accessing trusted and assured ME. These challenges increase with the procurement of commercial-off-the-shelf (COTS) products. Against this backdrop, *Section 224 of the Fiscal Year 2020 (FY20) National Defense Authorization Act (NDAA)* directed the U.S. Department of Defense (DoD) to establish trusted supply chain and operational security standards for the purchase of ME products and services.

The law specifies that the standards shall not be military standards or specifications and shall systematize best practices relevant to manufacturing location, company ownership, workforce composition, access to manufacturing data, reliability of the supply chain, and related matters. It also specifies that the established standards shall be, to the greatest extent practicable, generally applicable to the trusted supply chain and operational security needs and use cases of the United States Government (USG) and commercial industry, such that the standards could be widely adopted by government agencies, commercial industry, and allies and partners of the United States as the basis for procuring microelectronics products and services.

Recognizing the importance of ME to the U.S. economy, DoD has a goal of substantially increasing the percentage of ME produced in the United States. The Department wants to aggregate information across government agencies, programs, and policies to help DoD in its planning, discovery, and innovation efforts. Accordingly, the workshop continued the information exchange begun in July to look at acceptable levels of assurance (LoA) for COTS ME across four supply chain practice areas: procurement management, information and IP protection, secure design, and supply chain traceability (SCT).

PPP Goals:

Given Section 224's mandate requiring broad consultation among industry and government stakeholders, DoD invited the American National Standards Institute (ANSI), as the national coordinator for the U.S. private-sector system of voluntary standardization, to convene two workshops. The scope of the workshops was limited to commercial off-the-shelf (COTS) devices, not custom devices.

The efforts were focused on gathering and assessing information regarding relevant standardization activities to fulfill its mandate under Section 224 of the NDAA (FY20) requiring that DoD microelectronics products and services meet trusted supply chain and operational security standards. Stakeholders identified for targeted outreach include DoD, the Departments of Homeland Security, State, and Commerce (especially the National Institute of Standards and Technology

(NIST), along with suppliers of microelectronics products and services, representatives of major industry sectors that rely on a trusted supply chain and the operational security of microelectronics products and services, and the insurance industry. Ultimately, DoD sought to foster an ecosystem where trusted supply chain and operational security standards for procuring microelectronics products and services are widely adopted by U.S. government agencies, allies, partners, and commercial industry.

Public Sector Role & Participation:

Supported by DoD funding, ANSI led the planning, facilitation, promotion, and reporting of the events. To support planning and event discussions, ANSI issued an request for information about published industry consensus standards, standards activities underway, or other relevant guidance documents. ANSI compiled a ME standards landscape spreadsheet which lists over 200 standards and guidance documents from 27 organizations. ANSI and DoD both worked to engage a balance of stakeholders from the public and private sector.

To support the workshop agenda development and discussions, DoD provided technical guidance about the various supply chain practice areas that attendees would explore. At both events, DoD briefed sets of assumptions (detailed more below) that established parameters to scope the discussions and questions to target industry feedback.

- ***1st workshop:*** DoD presented its strategy for protection against risks, vulnerabilities, threats, and for determining mitigations – referred to as the CIA Triad – based on three core components: confidentiality, integrity, and availability. Nonrepudiation was also called out by the standards community as an important consideration, due to the distributed nature of the ME lifecycle. These four components became a common thread throughout the workshop discussions.
- ***2nd workshop:*** DoD provided definitions of four notional LoAs, baseline assumptions, and relevant supporting documents. To prepare for the breakout discussions, DoD went through a group exercise where attendees identified candidate considerations and criteria against the four LoAs for SCT, with a focus on non-repudiation.

Implementation Methods:

The workshops were held on July 27-29, 2022 and October 26-28, 2022.

- **July Workshop**: Approximately 140 subject matter experts representing academia, industry, various branches of the USG, standards development organizations (SDOs), and trade associations participated in the workshop, with a hybrid of both in-person and remote participation. Following several presentations and panels to level set the discussions, workshop attendees were separated into three breakout groups to discuss existing standards being leveraged by the commercial sector, and to make recommendations for candidate standards that the DoD should consider when developing their requirements for COTS ME products and services. The breakouts focused on three supply chain practice areas: procurement management, information and IP protection, and secure design. After the breakouts concluded, the group came back together for breakout session reports and closing discussions.
- **October Workshop**: Following the same format as the July workshop, approximately 108 subject matter experts participated in the second workshop, with a hybrid of both in-person and remote participation. Accordingly, the workshop continued the information exchange begun in July to look at acceptable levels of assurance (LoA) for COTS ME across four supply chain practice areas: procurement management, information and IP protection, secure design, and supply chain traceability (SCT). The event breakout sessions corresponding to these practice areas addressed three objectives:
    - Identify the appropriate set of candidate considerations for each supply chain practice area
    - Develop baseline candidate criteria for secure microelectronics that can be used in DoD systems and national critical infrastructure
    - Identify appropriate references (standards, guidance, regulations, policy, etc.) that apply

To facilitate the workshop discussions, ANSI hosted two virtual standards briefing webinars on September 30 and October 6, 2022, highlighting various technical standards and related guidance which could support ME.

Reports of both events were developed and distributed to DoD and the workshop attendees. They were not made available to the public.

Measurement of Success:

At the conclusion of the project, there was an increased understanding about the existing and future standards needs. Additionally, attendees from both the public and private sector felt more informed about DoDs needs (standards and continued general feedback from industry) which would support Section 224 requirements development. Feedback from attendees was positive with regards to the format of the workshops as well as the level of information sharing.

The initiative was scoped to support two workshops so the project was complete after the events. Continued work was set to be supported directly by the DoD.

Key Takeaways:

- The topic area was very complex and two workshops helped get the discussions started but more time was needed to develop actionable outcomes.
- There are several standards development activities that were supporting ME technology and ME sector standards. It is beneficial to provide that information in advance to the events so attendees can review.
- Hybrid engagement at the workshops was very helpful; however, it can be challenging to solicit their engagement in the live discussion (instead of just chat). Online interactive poll and Q&A tools would help augment their contributions.

Advice for Others:

Critical and emerging technology areas like microelectronics have very broad technology and sector impacts. It is challenging to gather all the perspectives in a short time period. Using a combination of information collecting practices (RFIs, webinars, workshops, direct outreach) helps accelerate those efforts. Hosting informational webinars prior to events is a good alternative to trying to include them in the face-to-face discussions. Especially with standards briefings, which are inherently technical, the webinars allow attendees to digest portions of information, have longer Q&A with the presenters, and do additional research so they may come to the face-to-face events and make informed decisions.

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ANSI NANOTECHNOLOGY STANDARDS PANEL (ANSI-NSP)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	ASTM, IEEE, IEST, UL, ASME, SEMI, NEMA, AIHA, USP
Technical Committees:	ISO/TC 229 (established after initial ANSI-NSP meeting)
Other Partnering Organizations:	NGOs (EDF, PETA), Legal entities, Academic institutions (Rice University)
Government Organizations:	NNCO, OSTP, EPA, NIST, NIOSH, FDA, DoD, NASA, CPSC
Industry Sector(s) / Technology:	Nanotechnology, chemicals, semiconductors
Program / Activity Website URL(s):	www.ansi.org/nsp

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

In June, 2004, ANSI received a request from Dr. John Marburger, Director of the Office of Science and Technology Policy in the Executive Office of the President, to coordinate the development of standards (including nanotechnology terminology nomenclature) to be utilized by academics, industry, investment communities, and government. Dr. Marburger said, "As new materials, structures, devices and systems are developed that derive their properties and function due to their nanoscale dimensions, it will become increasingly important to the researchers, manufacturers, regulators, and other stakeholders to have agreed upon standards." In response, ANSI established its Nanotechnology Standards Panel (ANSI-NSP), initially with three co-Chairs: Dr. E Clayton Teague, Director of the National Nanotechnology Coordination Office (Government), Dr. David Bishop of Lucent Technologies (Industry), and Dr. Vicki Colvin of Rice University (Academia).

PPP Goals:

The purpose of the ANSI-NSP is to serve as the cross-sector coordinating body and provide the framework within which stakeholders can work cooperatively to promote, accelerate, and coordinate the timely development of useful voluntary consensus standards to meet identified needs related to nanotechnology. These needs include: nomenclature and terminology, research, development, and commercialization.

The NSP does not develop the standards themselves; rather, it relies on relevant SDOs whose scopes of work may include nanomaterials and nanotechnology applications. As nanotechnology is a relatively new field, and as new materials and applications emerge, the NSP holds meetings and workshops of impacted stakeholders to discuss standards needs for topics as they are identified.

The NSP also works to promote various nanotechnology standards activities via news items to NSP membership as well as an online standards database, a freely accessible database that captures information about standards and associated documents (standards, best practices, guidelines) that directly relate to nanomaterials and nanotechnology-related processes applications and products.

NSP Terms of Reference:

1. Coordinate and provide a forum for academia, industries, standards developing organizations, and governmental entities to identify and define needs, determine work plans, and establish priorities for updating standards or creating new standards.
2. Solicit participation from nanotechnology-related sectors and academia that have not traditionally participated in the voluntary standards system, and work cooperatively to achieve the mission of the ANSI-NSP and to address standards needs in the area of nanotechnology.

3. Facilitate the timely development and adoption of standards responsive to identified needs in the area of nanotechnology in general and nomenclature/terminology specifically.
4. Facilitate and promote cross-sector collaborative efforts between standards developing organizations to establish work plans and develop joint and/or complementary standards.
5. Where standards do not exist, obtain agreement from a standards developer to initiate and complete development of the standard in a timely manner.
6. Establish and maintain liaison with other national, regional, and international standards efforts addressing nanotechnology issues to create identical or harmonize existing standards.
7. Establish and maintain a database of nanotechnology standards, accessible from the Internet, and capable of generating updates, notices, and reports.

Public Sector Role & Participation:

The U.S. Government played an integral role in the development of the NSP. From the initial communication from Dr. Marburger requesting ANSI take on this activity, to the engagement of NNCO Director Dr. Clayton Teague as a NSP co-Chair from 2004 - 2011, the U.S. Government has been a leader in this initiative. As NSP co-Chair, Dr. Teague helped set the strategic direction of the NSP, and guided NSP members through the process of developing the U.S. position and technical inputs to ISO relative to the creation of ISO/TC 229 Nanotechnologies (for which Dr. Teague also acted as U.S. TAG Chair from 2005 – 2011).

Various U.S. government employees from a number of federal agencies continue to play a role in the NSP, participating in NSP workshops as panelists, speakers, and moderators and contributing technical input in workshop developments.

Implementation Methods:

The ANSI-NSP held its initial meeting September 29 – 30, 2004, at NIST in Gaithersburg, Maryland. (A meeting of the ANSI NSP Steering Committee, a subset of relevant stakeholders and experts, was held on September 28, 2004.) Prior to this meeting, ANSI sent out a call for participation to relevant stakeholders, including: SDOs, government agencies, academic institutions, NGOs, and industry representatives. In addition, a number of news items (both from ANSI and external sources) were shared to announce the purpose of the meetings and call for participants. During that initial meeting, a series of breakout sessions took place in which all were asked the same questions, from a variety of perspectives, including:

- Morphological, Geometrical, and General Terminology
- Inorganic nanomaterials
- Carbon nanostructures
- Top-down assembled structures and devices
- Hybrid nanostructures

ANSI developed an executive summary as well as recommended topics needed relative to nanotechnology standardization, which were distributed via ANSI to SDOs to request their consideration to develop relevant standards. The SDO responses to ANSI's call were presented in a subsequent meeting of the NSP Steering Committee, held in January 2005.

The trajectory of the NSP changed on January 20, 2005, when the British Standards Institute submitted a proposal to establish a new technical committee (TC) in Nanotechnology to ISO. At that time, the NSP worked on the development of the U.S. position on this new TC in terms of: the identification of the ISO/TC 229 TAG Administrator (ANSI); deciding which working group the U.S. would want to lead (health, safety, and environment); and connecting with relevant experts. Several of the NSP members also participated in the ANSI-Accredited U.S. TAG to ISO/TC 229 Nanotechnologies, which became the major focus of activity as it was developing specific standards.

However, the NSP remains a relevant and vital resource to the Nanotechnology community. Since 2005, the NSP has held workshops and meeting as needs and relevant topics are identified. Below is the list of NSP meetings and workshops that have taken place since 2005. All presentations and reports are available online.

- 2008 – Focus on U.S. engagement in nanotechnology standardization and identification of scientific areas for U.S. leadership – Reports of key areas for U.S. leadership shared with NSP members
- 2009 – Information sharing relative to relevant U.S. domiciled nanotechnology standards activities
- 2013 – Progression of nanotechnology standards: Was there focus on the right topics? Was there enough collaboration? A meeting report with recommendations (including the development of the NSP Database) was distributed
- 2017 – Workshop focused on Graphene: Current state of the science, identification of relevant standards and if existing standards efforts met stakeholder needs?
- 2018 – Workshop focused on Graphene (Part II): Consideration of existing standards documents in the areas of graphene; presentation from EPA relative to potential regulation of graphene materials
- 2019 – Meeting to discuss the relationship between Nanotechnology Standards and Regulation
- 2020 – Workshop to consider Advanced Materials – Report shared with NSP members and meeting participants
- 2022 – 2nd Workshop to further consider Advanced Materials and needs relative to terminology, categorization, and regulation. Conclusions from the Workshop, including areas of categorization and standards needed, were shared with NSP members and meeting participants

The following future topics are being considered:

- Nanoplastics (proposed workshop for fall 2024)
- Nanomedicine

In addition to the meetings and workshops, the NSP has also:

- Developed a NSP quarterly newsletter (suspended in 2019)
- Launched nanostandards.ansi.org – a community driven database
- Engaged SDOs in celebration of National Nanotechnology Day (websites/news items), including the following:
  - ANSI-developed Q&A of Nanotechnology experts (2021)
  - ANSI webpage devoted to celebrating 15 years of the ANSI NSP and a timeline of its development and activities (2019)
  - ANSI webpage devoted to the various standards organizations developing nanotechnology-related standards (2017)

Measurement of Success:

The initial goals of the NSP were achieved by the initiation of relevant standards in the three identified areas of initial interest: Terminology and nomenclature (ASTM E56.01, ISO/TC 229 80004 series), Measurement and characterization (ASTM E56.02, IEEE, ISO/TC 229) and Health safety and environmental standards (ASTM E56.03, ISO/TC 229).

Several the standards that were developed have been identified and utilized by the U.S. Government, including:

- Identification by the National Nanotechnology Coordination Office (NNCO) as "Illustrative examples of documentary standards" in nanotechnology
- FDA has identified a number of these standards as "recognized standards," which are "national or international standard that medical device manufacturers can use to show that they meet a relevant requirement of the FD&C act."
- EPA has also referenced specific nanotechnology standards as part of their TSCA Reporting and Recordkeeping requirements.

A number of the SDOs that either participated in the initial NSP meetings or were established as a result of the NSP (ASTM, NEMA, ISO/TC 229, IEC TC 113) are still actively developing standards within this space, whether in the three originally identified priority areas, or in new areas that have developed as the technology has developed/additional data is established (such as material-specific standards for graphene and cellulose, product standards relative to nanomedicine, consideration of terminology for advanced materials).

The standards that have been developed by these various SDOs are a strong foundation for the industry to utilize and develop their sector-specific nanotechnology-related standards.

Key Takeaways:

1. Engaging the government in PPPs is important, but just as important is the engagement and input from industry and other relevant affected stakeholders (as the users of voluntary standards). It is important to ensure that the private sector does not look to the government as the solution to the development of standards – industry, academic, and organization participation and support is critical to the success of standards efforts.
2. New topics always solicit excitement and engagement, but as technologies mature/change, the interest and participation dwindle. It is necessary to continue to outreach to interested parties to determine what standards needs exist and how the PPP can help.

Advice for Others:

It would be beneficial to find (at the most two) intelligent, effective, and engaged leaders/chairs to help drive the direction and work of the PPP. While there were initially three co-chairs to help recognize the importance of industry, academia, and government in the development of nanotechnology standards, this also caused difficulty, with competing philosophies and agendas trying to identify the direction of the group. This number has now been reduced to two co-chairs (government and industry) that are able to work together in a more cooperative manner.

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NATIONAL CYBERSECURITY CENTER OF EXCELLENCE (NCCOE)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	3GPP, IETF, NIST
Technical Committees:	www.nccoe.nist.gov/get-involved/collaborate-us-technical-contributions
Other Partnering Organizations:	The National Cybersecurity Excellence Partnership (NCEP) program
Government Organizations:	www.nccoe.nist.gov/get-involved/collaborate-us-government-organizations
Industry Sector(s) / Technology:	Sectors covering: Consumer Data Protection; Energy; Financial Services; Healthcare; Manufacturing; Public Safety/First Responder; Water/Wastewater Technology: 5G Cybersecurity; Applied Cryptography; Artificial Intelligence; Critical Cybersecurity Hygiene; Cybersecurity for the Space Domain; Data Classification; Data Security; DevSecOps; Digital Identities – mDL; Genomics Cybersecurity; Internet of Things (IoT); IPv6; Mobile Device Security; Supply Chain Assurance; Trusted Cloud; Zero Trust Architecture
Program / Activity Website URL(s):	www.nccoe.nist.gov

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The National Cybersecurity Center of Excellence (NCCoE), run by the National Institute of Standards and Technology (NIST), brings together government agencies, industry organizations, and academic institutions to collaborate on cybersecurity challenges and protect the nation's critical infrastructure. The drivers for this partnership are both internal and external. NIST is often internally driven to seek new connections to understand the needs of industry, academia, or federal or local government communities within a specific program area. Information Technology Lab (ITL) has the broad mission to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology through research and development in information technology, mathematics, and statistics. Therefore, NCCoE fills a gap in a technical area while also being influenced by external drivers (e.g., congressional mandates) to initiate projects and partnerships. For example, NIST formed the NCCoE as a result of calls from other agencies, the intelligence community, and then-Senator Barbara Mikulski (D-MD) to "work to strengthen U.S. economic growth by supporting automated and trustworthy e-government and e-commerce."

PPP Goals:

The National Cybersecurity Center of Excellence (NCCoE) is a collaborative hub where industry organizations, government agencies, and academic institutions work together to address businesses' most pressing cybersecurity challenges. Through this collaboration, the NCCoE develops modular, easily adaptable example cybersecurity solutions using standards, best practices, and commercially available technology. The standards produced are known as the 1800 series.

NCCoE goals include:

1. **Provide practical cybersecurity:** help organizations secure their data and digital infrastructure by equipping them with practical ways to implement standards-based, cost-effective, repeatable, and scalable cybersecurity solutions
2. **Increase rate of adoption:** enable companies to rapidly adopt commercially available cybersecurity technologies by reducing their total cost of ownership
3. **Accelerate effective innovation:** empower innovators to creatively address businesses' most pressing cybersecurity challenges in a state-of-the-art, collaborative environment

Public Sector Role & Participation:

The primary leaders for the NCCoE are as follows:

- NIST/NCCoE: leadership role, convener, responsible for the outcomes
- The MITRE Corporation: federally funded research and development center (FFRDC) partner for the NCCoE; operates the NCCoE
- FFRDC: supports technical and operational activities

In addition, other groups are engaged in certain specifics including:

- Other government agencies: participate and often co-sponsor projects
- Private sector: both a benefactor of the solution and a developer via projects, or a partner through the National Cybersecurity Excellence Partnership
- Academia: students, faculty, researchers, and administrators from K-12 and higher education communities through the Academic Engagement Community of Interest

In addition to contributing to individual projects, the NCCoE forms long-term relationships with industry organizations through the National Cybersecurity Excellence Partnership (NCEP) program. As part of the NCEP program, industry organizations pledge to contribute physical infrastructure such as hardware and software components, intellectual knowledge including best practices and lessons learned, or guest researchers to work side by side with federal staff in NCCoE's test environments. NCEP organizations are accepted based on the feasibility of their proposed collaboration with NCCoE, their relevance to NCCoE's strategy, and the potential to advance cybersecurity through their partnership. Qualified companies are invited to join a memorandum of understanding (MOU) with NIST and NCCoE.

Implementation Methods:

FFRDCs are public-private partnerships that are established to meet special long-term research or development needs that cannot be met as effectively by existing in-house or contractor resources. FFRDCs are a major endeavor for NIST to initiate, requiring significant implementation time and effort. However, FFRDCs can be well worth the initial implementation effort—more than paying for their investment in terms of quality outputs and deep partnership growth over time. NIST's only FFRDC (NCCoE) continues to achieve success year after year. Working with its FFRDC partner the MITRE Corporation, NIST engages with the larger cybersecurity community through the NCCoE, including specific sectors like transportation, energy, and healthcare, on a scale it would not be able to otherwise.

Each NCCoE project is led by a NIST Principal Investigator (PI). The PI provides oversight for the development of the project and manages a team of subject matter experts and the FFRDC operational support. NCCoE uses a phased approach:

1. NCCoE works with industry to generate a technical description and scope of work for addressing a pressing cybersecurity challenge. During this phase, NCCoE solicits public comment on the draft project description to ensure that the project will be as broadly applicable as possible. At the end of this phase, NCCoE publishes a final version of the scope of work that outlines the cybersecurity challenge and a draft architecture on its website.
2. NCCoE assembles a team of industry organizations, government agencies, and academic institutions to address the scope of work. NCCoE releases a Federal Register Notice (FRN) that announces the collaboration opportunity and defines the desired capabilities of the team members. Potential team members are invited to respond to the FRN with a Letter of Interest (LOI). NCCoE accepts LOIs on a first-come basis. Collaborators that join the build team sign a Cooperative Research and Development Agreement (CRADA) with NCCoE to provide commercially available products and expertise to the project.
3. NCCoE team builds a practical, usable, repeatable solution to address the cybersecurity challenge outlined in the statement of work. Industry collaborators provide support to install and configure their technologies. They also provide support throughout the build to address issues such as interoperability. As part of the development, the reference architecture is finalized. NCCoE documents the example solutions in the NIST Special Publication 1800

series, which maps capabilities to the NIST Cyber Security Framework and details the steps needed for another entity to recreate the example solution.

NCCoE also hosts several communities of interest (COIs) through which public- and private-sector organizations share business insights, technical expertise, challenges, and perspectives. NCCoE relies on the COIs to identify and define problems that NCCoE should address. Anyone is welcome to sign up for a COI.

Measurement of Success:

NCCoE has successfully produced many cybersecurity solutions over the past decade. NCCoE attributes its success in creating practical cybersecurity solutions to three key elements: collaboration, documentation, advocacy and education. NCCoE ensures each of these elements is present in every phase of its projects by:

- Engaging in regular, robust collaboration with experts and innovators from various sectors in addition to the broader technology community to help identify and address businesses' most pressing cybersecurity challenges;
- Documenting its work across media such as the NIST Special Publication 1800 series, industry-specific cybersecurity papers, technical notes, videos, and interactive guides, as well as mapping capabilities to the NIST Cybersecurity Framework and detailing the steps needed for another entity to recreate example solutions in part or in full; and
- Promoting what it does and how it does it, and teaching others ways to improve their cybersecurity posture.

Since its inception, the NCCoE has established over 500 collaborations through Cooperative Research and Development Agreements (CRADAs), NCEPs, academic affiliates, and interagency agreements. Each NCCoE project resulting in publication generally serves as a "how to" guide that demonstrates how to implement and apply standards-based cybersecurity technologies in the real world. The guides are designed to help organizations gain efficiencies in implementing cybersecurity technologies, while saving them research and proof of concept costs. Some specific examples include among others:

- The 3G Partnership Project (3GPP) specifications cover cellular telecommunications technologies (e.g., radio access, core network and service capabilities). NIST extended 3GPP's standards security protections to 5G networks supporting components for secure deployments.
- NIST's NCCoE Applied Cryptography program bridges the gap between development of fundamental cryptographic algorithms and their use in commercial off-the-shelf technology. NIST has been soliciting, evaluating, and standardizing quantum-resistant public-key cryptographic algorithms. To complement this effort, the NCCoE is engaging with industry collaborators and regulated industry sectors and the U.S. Federal Government to bring awareness to the issues involved in migrating to post-quantum algorithms and to prepare the crypto community for migration.
- NCCoE has produced a practice guide to demonstrate the practicality and effectiveness of using the Internet Engineering Task Force's (IETF) Manufacturer Usage Description (MUD) standard to strengthen security for IoT devices on home and small-business networks. This guide demonstrates how organizations can use MUD to reduce the vulnerability of IoT devices to network-based threats such as distributed denial of service attacks (DDoS) and mitigate the potential for harm resulting from exploitation of IoT devices.
- NIST's NCCoE analyzed risk factors in and around the infusion pump ecosystem by using a questionnaire-based risk assessment. With the results of that assessment, the NCCoE then developed an example implementation that demonstrates how healthcare delivery organizations can use standards-based, commercially available cybersecurity technologies to better protect the infusion pump ecosystem, including patient information and drug library dosing limits.

Key Takeaways:

Partnerships that were proactive and timely in nature have been successful. Lending NIST expertise to areas of critical national importance such as cybersecurity. For NCCoE, the timeliness of the partnership has meant that the FFRDC continues to have strong support for collaboration and involvement from/with other entities, even more than the partnership can support at any one time, allowing the partnership to grow and continue to be in demand. This allows NIST to consistently collaborate, develop deeper relationships with partners, and keep the partnership going indefinitely.

Advice for Others:

Measures of success depend on the PPP's purpose and goals. In addition to quantifying factors, qualifying measures including economic and social returns such as technology innovation, education, creation of new businesses, jobs, and social well-being should be considered. Strategic investments and financial sustainability, or the degree of sufficiency for federal funds should be another factor to consider. The long-term needs of the infrastructure should be considered as part of the PPP's funding model.

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OPEN TRUSTED TECHNOLOGY PROVIDER™ STANDARD (O-TTPS) CERTIFICATION PROGRAM

ORGANIZATIONAL SPECIFICS

Standards Organizations:	The Open Group
Technical Committees:	
Other Partnering Organizations:	
Government Organizations:	Department of Defense (DoD), Department of Homeland Security (DHS), National Aeronautics and Space Administration (NASA)
Industry Sector(s) / Technology:	ICT
Program / Activity Website URL(s):	https://ottps-cert.opengroup.org/

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The Open Trusted Technology Provider™ Standard (O-TTPS) was established to address growing supply chain security concerns from U.S. Department of Defense (DoD), U.S. Department of Homeland Security (DHS) as well as the private sector for integrity and security in technology supply chains.

PPP Goals:

The Open Trusted Technology Forum (OTTF), formed under The Open Group, brings together major industry representatives along with governmental entities. This collaboration aims to create and implement standards focused on supply chain security to establish a unified view of practicing supply chain risk management (SCRM) for information and communication technology (ICT) products. The OTTF focuses on mitigating risks from counterfeit and maliciously tainted products by establishing best practices and certification programs. These efforts ensure that organizations conform to stringent standards for maintaining the security and integrity of their supply chains.

Public Sector Role & Participation:

The Open Group serves as a neutral facilitator and brings together private sector entities as well as government to discuss their needs. In this model, all participants contributed on an equal level to develop standards. The OTTF remains an active group where members can continually discuss their issues and revise the standards and supporting materials as needed.

- Government representatives engage in The Open Group activities through direct-participation, the same way any other stakeholder participates. Additionally, NASA sits on The Open Group's Governing Board. Moreover, the US government was instrumental in providing sponsorship to establish the O-TTPS as an International Standard as ISO 20243.
- The Open Group is a membership-based consortia group. Membership is based on the revenue of the member and whether the organization is a technology vendor or end user. There are also membership options for academic institutions and government organizations.
- The OTTF meets regularly, based on participating member preferences and availability, to continue iterating the O-TTPS, develop additional guidance and supporting materials, and collaborate with other forums of The Open Group.

Implementation Methods:

The OTTF provided a vendor-neutral collaborative environment (through forums and working groups) where technology vendors, government agencies, and other stakeholders could come together to develop and refine standards. This

environment facilitated the creation of a unified voice to address supply chain security issues and to influence international standards and policy initiatives.

Industry experts and government representatives worked together within the OTTF to develop the O-TTPS. This process involved identifying and codifying best practices for securing the ICT supply chain, covering all stages of a product's lifecycle from design through disposal. This full lifecycle approach is also reflected in the O-TTPS Certification Program. The partnership established a certification program allowing organizations to be accredited as Open Trusted Technology Providers™. This program involves independent assessments by recognized third-party assessors to ensure conformance to the O-TTPS standard. The accreditation process is designed to be rigorous and transparent, providing assurance to customers about the integrity of certified providers.

Measurement of Success:

The first version of O-TTPS was published in April 2013, with Version 1.1 following in July 2014. This version was later approved by ISO/IEC in 2015 as ISO/IEC 20243:2015 Information technology — Open Trusted Technology Provider™ Standard (O-TTPS) - Open Trusted Technology Provider™ Standard (O-TTPS) — Mitigating maliciously tainted and counterfeit products. The 2023 version is the current version.

The O-TTPS has been widely adopted by major technology providers and integrators, enhancing the overall security of the technology supply chain. This broad adoption demonstrates the effectiveness of the standard in meeting industry needs and its alignment with both government and private sector requirements.

Government agencies, including the Department of Defense (DoD) support and endorse the standard. For instance, the National Defense Authorization Act (NDAA) for Fiscal Year 2016 required the assessment of O-TTPS or similar standards for procurement of secure information technology and cybersecurity systems. In many cases today, an organization or company if required to submit proof of certification for government procurement and/or contracts.

In February 2014, The Open Group launched the O-TTPS Certification Program, ensuring the Program complies with requirements dictated by the NIST NVLAP. This program allows organizations to certify their conformance to the O-TTPS standard, which helps assure customers of the integrity and security of commercial off-the-shelf (COTS) information and ICT products. The certification process involves independent assessment by recognized assessors, ensuring that applicants meet the stringent requirements set out in the standard.

Also, during the COVID-19 pandemic, there was an increase in O-TTPS certifications when many people worked from home and employers needed assurance that their systems were secure.

Key Takeaways:

In this instance, as government was a customer and a participant, industry was able to produce a standard that was practical for both the public and private sector and not customized for government only needs.

With support and active participation from the U.S. government, the OTTF was able to produce an International Standard and certification program.

Advice for Others:

Established standards development organizations (SDOs) and consortia already have procedures and infrastructure in place to foster collaboration. All parties involved (public and private sector entities) can focus on the technical aspects of the standards instead of developing procedures on how to write the documents and gather consensus.

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ORGANIZATION OF SCIENTIFIC AREA COMMITTEES FOR FORENSIC SCIENCE (OSAC)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	
Technical Committees:	
Other Partnering Organizations:	
Government Organizations:	NIST – Organization of Scientific Area Committees for Forensic Science (OSAC)
Industry Sector(s) / Technology:	Forensic Science
Program / Activity Website URL(s):	www.nist.gov/organization-scientific-area-committees-forensic-science

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The Organization of Scientific Areas Committees (OSAC) for Forensic Science was established in 2014, in collaboration with the National Institute of Standards and Technology (NIST) and the U.S. Department of Justice (DOJ) to help the forensic science community address some of the issues identified in the National Research Council (NRC) report titled *Strengthening Forensic Science in the United States: A Path Forward*. The report specifically identifies the need to establish standards and best practices within and between disciplines related to terminology, methodologies, and training. The initial DOJ and NIST collaboration was formalized in a Memorandum of Understanding (MOU) signed in February 2013 and later updated in an MOU signed in April 2015. In February 2014, the concept of OSAC was announced to the National Commission on Forensic Science (NCFS). The activity is administered by NIST and is part of NIST's Forensic Science Program.

PPP Goals:

OSAC's mission is to strengthen the nation's use of forensic science by facilitating the development and promoting the use of high-quality, technically sound standards. These standards define minimum requirements, best practices, standard protocols, and other guidance to help ensure that the results of forensic analysis are reliable and reproducible. The efforts work to address a lack of discipline-specific forensic science standards in 22 forensic disciplines, by convening forensic science practitioners and individuals with expertise in scientific research, measurement science, statistics, law, quality, human factors, and policy to work jointly on documents. OSAC fills this gap by:

- drafting proposed standards and sending them to standards developing organizations (SDOs), which further develop and publish them
- evaluating and approving standards for the OSAC Registry
- promoting the use of OSAC endorsed standards throughout the forensic science community

Inclusion on the OSAC Registry indicates that a standard has undergone a technical and quality review process that actively encourages feedback from forensic science practitioners, research scientists, human factors experts, statisticians, legal experts, and the public. Placement on the Registry requires consensus (as evidenced by 2/3 vote or more) of both the OSAC subcommittee that proposed the inclusion of the standard and the Forensic Science Standards Board. Recent additions to the registry cover DNA mixture interpretation, digital evidence examination, and wildlife forensics. The OSAC Registry includes two types of standards:

- **SDO-published standards** have completed the consensus process of an external standards developing organization (SDO) and have been approved by OSAC for placement on the Registry.
- **OSAC Proposed Standards** have been drafted by OSAC and given to an SDO for further development and publication. They have undergone the same OSAC technical and quality review process as the SDO-published

standards on the Registry. Each OSAC Proposed Standard may be revised during the SDO development process; once available, an SDO-published standard will replace the OSAC Proposed Standard on the Registry after completing the technical and quality review at OSAC. To help fill the standards gap while an SDO completes its process, OSAC encourages the forensic science community to implement the OSAC Proposed Standards.

In addition to drafting standards, OSAC may develop and share other work products that support standards advancement and implementation. For example, OSAC documents any research and development (R&D) needs that are identified during the standards development process and shares it with the forensic science community. These needs may benefit a wide variety of stakeholders both associated with the NIST and external to the agency. Documenting R&D needs helps inform NIST researchers and NIST's Center for Statistics and Applications in Forensic Science (CSAFE) regarding valuable projects to consider as they perform research to advance the practice of forensic science. They can also serve as useful input for the National Institute of Justice (NIJ) when making decisions about funding opportunities as NIJ awards various grants and agreements for research, development and evaluation projects that support the forensic science community.

Public Sector Role & Participation:

Administered by NIST, OSAC's 800+ volunteer members and affiliates work in forensic laboratories and other institutions around the country. Following core principles of balance, consensus, harmonization and openness, these experts work together to draft and evaluate forensic science standards via a transparent, consensus-based process that allows for participation by all stakeholders. OSAC collaborates with and supports a wide range of stakeholders with varied interests:

- NIST
- U.S. Department of Justice (DOJ)
- Federal, state, and local government agencies
- Forensic science service providers
- Representatives of the criminal justice system
- International and national standards development organizations (SDOs)
- Professional organizations (forensic science and others)
- Private sector manufacturers and service vendors supplying forensic service providers
- Quality system providers (e.g., accrediting and certifying bodies and proficiency test providers)
- Academic institutions
- The public

OSAC members are appointed on an annual basis (each October) to the Forensic Science Standards Board (FSSB), scientific area committees (SACs), subcommittees and interdisciplinary committees and may also serve on task groups. OSAC affiliates are appointed as needed to serve on task groups. For example, OSAC subcommittees routinely form task groups to address specific forensic science issues. OSAC affiliates are selected from the applicant pool and appointed by the chair of the relevant OSAC committee to help with the specific task group assignments. OSAC membership positions have three-year terms and are eligible for reappointment to a second three-year term.

To ensure balance of representation, NIST also provides funding for OSAC members to attend OSAC's in-person meetings.

Implementation Methods:

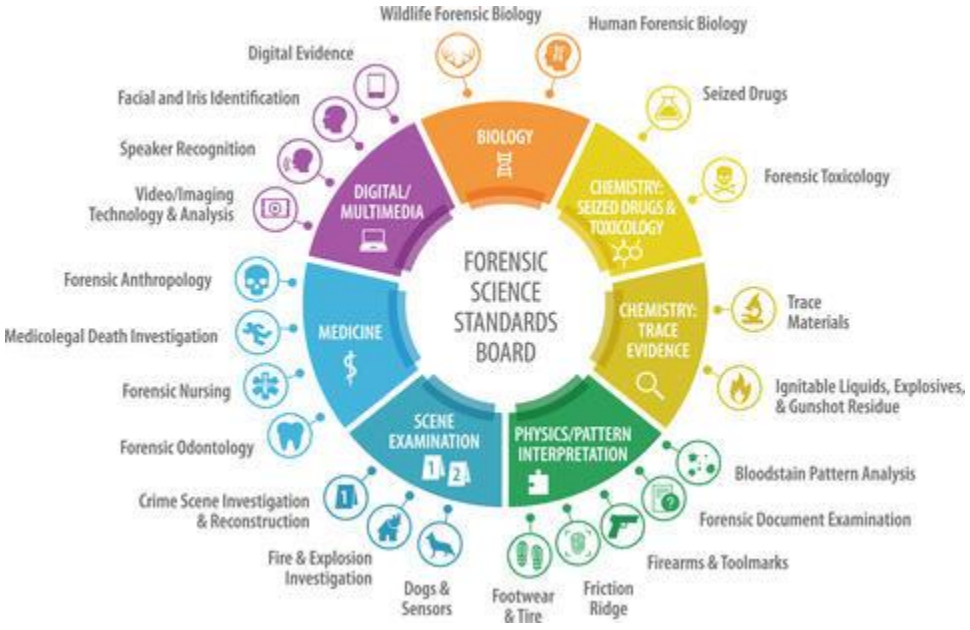
OSAC is governed by a Forensic Science Standards Board (FSSB) which meets virtually each month and in-person each quarter to:

- facilitate the promulgation of standards that will support the development of quality benchmarks and enhance consistency across the forensic science community
- discuss and address issues related to the OSAC standards development process

- coordinate the activities of OSAC's Scientific Area Committees (SACs), subcommittees, and interdisciplinary committees

OSAC's technical mission is carried out by its volunteer members and affiliates organized into committees, subcommittees and task groups including:

- Seven Scientific Area Committees (SACs)
- 22 discipline-specific subcommittees (SCs)
- FSSB Resource Task Groups



The OSAC Program Office at NIST manages OSAC communications including issuing OSAC News, a monthly Standards Bulletin, and a quarterly newsletter.

Measurement of Success:

As of August 26, 2024, there were 199 standards posted on the OSAC Registry in 22 forensic science disciplines, including interdisciplinary standards. As of the same date, there were also 182 FSSPs that had completed and submitted an OSAC Registry Standards Implementation Form from 31 states and four foreign countries. The 182 FSSPs' forms contain the implementation status related to the relevant standards on the OSAC Registry applicable to the disciplines practiced within the agencies. The number of standards reported by the 182 FSSPs that have been implemented either fully or partially continues to grow and OSAC holds a focused open enrollment period each summer encouraging FSSPs to submit new implementation forms or update existing implementation status information.

In measuring the success of OSAC, it is key to assess the degree to which standards on the OSAC Registry have been implemented by the agencies which have submitted implementation forms as of August 2024. While there are many more FSSPs that have implemented standards that have not shared that information and remain unknown to OSAC, the important point is that each year more standards are added to the OSAC Registry and more FSSPs are implementing these standards into their practice, thus making improvements in forensic science in the U.S.

To further illustrate the extent of implementation, the status table lists the 178 standards on the OSAC Registry (categorized by discipline in alphabetical order) as of January 2024 and the number of FSSPs that have implemented those standards. This data was reported as part of the *Measuring the Impact of Implementation: 2023*.

Key Takeaways:

- The makeup of the U.S. justice system and the forensic science community includes public and private sector experts. The testing and data collection services (for example) make an impact on court rulings and the lives of citizens in every region of this country. Having a balanced representation of experts directly participating in OSAC is critical.
- An open and transparent process to develop standards within OSAC and SDOs, and a mechanism for reviewing all standards that are included in the OSAC registry, helps ensure the technical content is relevant.
- There are complexities in which forensic science standards are utilized in the U.S. and there is not one final acceptance of a standard like there are for other industries. The OSAC Registry provides users with confidence in the standards' technical merit and one location to identify them. This access and trust help the system by which forensics are evaluated and decision making, and society at large.

Advice for Others

OSAC brings together members from the practicing forensic science community and academic researchers, legal experts, quality experts, human factors experts, and statisticians. The diversity of input that goes into documents generated by OSAC is a strength. The practicing forensic science community brings the reality of working in operational laboratories, which include casework backlogs and limited financial resources. The other members share academic research, quality assurance practices, and legal and human factors perspectives which tend to be different than the practicing community. The technical discussions and trade-offs made by these individuals in pursuit of producing useful guidance that continues to move the forensic science community forward is a foundational driver of OSAC's success.

Other public-private partnerships and industries can benefit by involving diverse stakeholders in their document development process to generate healthy discussions which leads to more robust and better-informed outputs.

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REGENERATIVE MEDICINE

ORGANIZATIONAL SPECIFICS

Standards Organizations:	Standards Coordinating Body (SCB)
Technical Committees:	
Other Partnering Organizations:	Various
Government Organizations:	DHS, NIST, FDA
Industry Sector(s) / Technology:	Regenerative Medicine
Program / Activity Website URL(s):	www.standardscoordinatingbody.org/organization

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The Standards Coordinating Body (SCB) began as an initiative of the Alliance for Regenerative Medicine (ARM) and other regenerative medicine stakeholders and industry to facilitate the development of standards for the nascent regenerative medicine industry. The first of advanced therapies, including cellular and gene therapies, are on the cusp of approval and standards are urgently needed to manufacture and test these new therapies.

PPP Goals:

The primary goal of this PPP is to coordinate the accelerated advancement and improved awareness of the standards and best practices that address the rapidly evolving needs of the global regenerative medicine advanced therapy community.

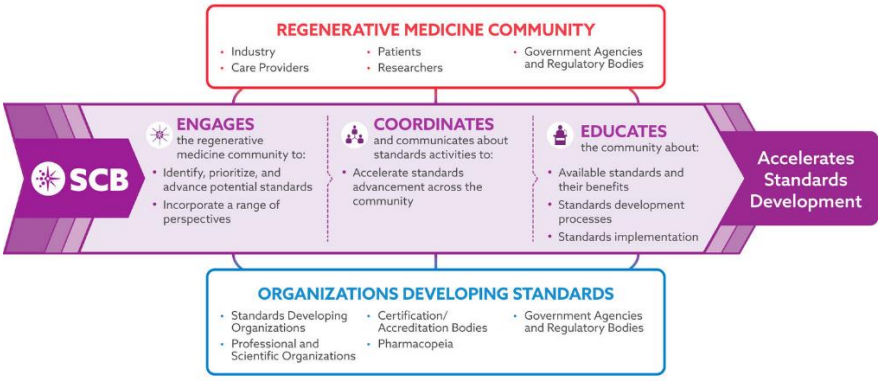
Public Sector Role & Participation:

In September 2016, the National Institute of Standards and Technology (NIST) and SCB established a Memorandum of Understanding (MOU), forming a partnership to jointly advance standards for the regenerative medicine community's needs. This MOU provides a mechanism for more cooperation with other U.S. agencies to work with industry, standards development organizations, and other stakeholders.

- The NIST laboratory programs provide supporting measurement science and data to support the development of innovative science-based standards and technology in support of the bio-economy. NIST scientists collaborate with industry, academia, and other entities through both formal and informal arrangements. NIST works with other government agencies including the U.S. Food and Drug Administration (U.S. FDA) on research collaborations, workshops, and standards development activities. NIST administers the US Mirror Committee to ISO/TC 276: Biotechnologies, which is developing standards relevant to cell and gene therapies. Lastly, NIST sits on the SCB Board of Directors as liaisons.

Formally launched in January 2017, SCB is now a fully independent, functioning non-profit organization. During the same year, FDA awarded a one-year contract to Nexight Group and SCB to engage with experts to recommend processes and outline a strategic plan for developing standards in regenerative medicine and advanced therapies. This work has helped to lay the foundation for standards development in regenerative medicine research and product development.

Following the initial contract, FDA has continued to provide Nexight Group and the SCB with funding to increase and accelerate the number of regenerative medicine standards being advanced in the field. These activities are intended to continue supporting the vision of the 21st Century Cures Act of 2016.



Implementation Methods:

SCB operates through project working groups, which are collaborative forums in which volunteers from the regenerative medicine community discuss and address standards needs.

Measurement of Success:

Since its inception, SCB has been successful at significantly reducing the time required to advance standards and standards drafts. In particular, SCB, in partnership with Nexight Group, has increased the efficiency of working with the broad regenerative medicine community to identify needed standards, prioritize those needs that will have the greatest impact on the field, and assess the feasibility of developing and implementing standards in these areas.

With SCB the average rate of a standard's development timeframe has decreased three-fold, significantly shortening the time from the establishment of need to the completed consensus standard from over 12 years to less than four. The most significant time savings occurs at the first steps of standards development, which involve coalescing generalized needs to a small set of finite problems that can be addressed by consensus standards. According to the SCB website, without a coordinating body like SCB, these pre-development steps can take up to six years; however, with SCB's support, these steps take only six months to one year.

Key Takeaways:

- SCB has significantly shortened the time from the establishment of need to the completed consensus standard.
- By engaging and coordinating with stakeholders, SCB leverages expert experience and knowledge to identify and establish consensus standards that provide benefits to the regenerative medicine and advanced therapies community.

Advice for Others:

Establish a solid partnership through mutual support, shared goals, regular check-ins, and clearly defined roles and responsibilities.

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ANSI UNMANNED AIRCRAFT SYSTEM STANDARDS COLLABORATIVE (UASSC)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	Various
Technical Committees:	Various
Other Partnering Organizations:	ANSI
Government Organizations:	U. S. DOT, U.S. FAA, U.S. DHS Science and Technology Directorate
Industry Sector(s) / Technology:	Aviation
Program / Activity Website URL(s):	www.ansi.org/uassc

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

In 2017, the unmanned aircraft systems (UAS) users and the aviation sector engaged with several standards development organizations (SDOs) for the development of both application and UAS specific standards. At the time, it was difficult for the public and private sector to identify what efforts were being supported by the various organizations and left the impression that duplication of efforts was creating confusion in the marketplace. UAS certification and operations are regulated by the U.S. Federal Aviation Administration (FAA). The Association for Uncrewed Vehicle Systems International (AUVSI), a trade association who represented UAS stakeholders, and FAA requested ANSI explore the need for a UAS standards collaborative to help increase awareness about existing standards efforts and identify future standard's needs. ANSI engaged stakeholders to explore the need and support for increased coordination through two stakeholder meetings in 2017 which resulted in the formation of the UAS standards collaborative.

PPP Goals:

The UASSC's mission is to coordinate and accelerate the development of the standards and conformity assessment programs needed to facilitate the safe integration of unmanned aircraft systems (UAS), or drones, into the national airspace system. The collaborative also focuses on international coordination and adaptability, with the goal of fostering the growth of the UAS market, particularly related to civil, commercial, and public safety applications. Work of the UASSC resulted in standards landscapes, standards roadmaps, several gaps progress reports, and technical events. Gaps progress reports are typically issued twice per year after the publication of a full roadmap. The UASSC does not develop standards.

Public Sector Role & Participation:

More than 400 individuals from 250 public-and private-sector organizations supported the development of the UASSC roadmap, including representatives of the Federal Aviation Administration (FAA), other U.S. federal government agencies, standards developing organizations (SDOs), industry, academia, and others. Over the term of UASSC's existence it has been co-chaired by FAA and industry associations (HAI/VAI and AUVSI).

From its formation onward, all UASSC members offered their technical knowledge about issues, existing standardization activities, regulatory and policy activities, and R&D needs. There was no distinction between the roles of the public versus private sector. Some representatives engaged in UASSC as a member and others served in leadership roles. However, outreach efforts always targeted and advocated for both private and public sector engagement. Participation is open to UAS stakeholders that have operations in the U.S. Membership in ANSI is not a prerequisite and there is no fee to participate.

The UASSC efforts are primarily funded by the FAA but have also been supported through sponsorships from ASTM International, National Fire Protection Association (NFPA), and the U.S. Department of Homeland Security (DHS).

Implementation Methods:

Before forming the UASSC, ANSI hosted two stakeholder workshops to explore the needs for collaboration, identify stakeholders, and once there was a consensus regarding the need, ANSI established a structure for the UASSC.

To maximize the effectiveness and relevance of the UASSC work, a Steering Committee (SC) was established. The SC membership included the working groups chairs as well as standards organizations, government, consortia, and others to give balance to the SC. The SC offered guidance and strategic direction as well as leveraged their networks to ensure the technical expertise in the WG was sufficient to ensure technical and market relevance. The SC continues to meet twice a year to discuss results reported in the gaps progress reports, to increase awareness about key UAS issues and initiatives, and evaluate the need for future roadmaps.

To develop the roadmap, the UASSC established four working groups that typically held online meetings twice a month:

- WG1 covering airworthiness
- WG2 covering general flight operations, personnel training, qualifications, and certification
- WG3 covering flight operations for critical infrastructure inspections, environmental applications, commercial services, and workplace safety
- WG4 covering flight operations for public safety

The roadmap evolved from version 1 to version 2 based on the needs and applicability that UAS had at any given point. During the initial years of UASSC, more face-to-face events (with hybrid capabilities) were facilitated. Face to face events served more as plenary meetings. WG meetings took place more often and as web-based meetings.

Measurement of Success:

The roadmap and gaps progress reports continue increase awareness about research and standards to support UAS. They also highlight existing and needed standardization efforts, aimed at accelerating standards development and adoption. Feedback from the DOT, FAA and industry has emphasized how the roadmapping efforts, during development and after publication, have helped inform resource allocation (experts time in various standards activities), avoid duplication, and identify priorities.

The UASSC efforts alone have demonstrated success in completing the work they were chartered to carry out. The UASSC released version 1.0 of its standardization roadmap in December 2018, and version 2.0 in June 2020. Like its predecessor, version 2.0 of the roadmap identifies existing standards and standards in development, defines where gaps exist, and makes recommendations for priority areas where there is a perceived need for additional standardization including pre-standardization research and development (R&D). The roadmap includes proposed timelines for completion of the work and lists organizations that potentially can perform the work. The document also includes brief overviews of the UAS activities of the FAA, other U.S. federal government agencies, standards developing organizations (SDOs), and various industry groups. The roadmap covers issues such as:

- Airworthiness
- Flight Operations
- Personnel Training, Qualifications, and Certification
- Infrastructure Inspections
- Environmental Applications
- Commercial Services
- Workplace Safety

- Public Safety Operations

UASSC Roadmap 2.0 describes 71 gaps where no published standard currently exists to respond to a particular industry need. When a standards developer or other organization initiates or completes work in a specific area identified in one of those gaps, an update is made to the Gaps Progress Report. The most recent Gaps Progress Report was published in March 2024 and the next is expected in fall 2024.

Key Takeaways:

4. A clear scope of what technical areas should be addressed as a whole, as well as the WG level, is important in order to not overwhelm or slow efforts.
5. A balanced representation of expertise in each of the technical working groups is necessary to ensure market relevance and unbiased recommendations.
6. Allowing for public review of drafts prior to publications helps ensure broader input from directly and indirectly impacted stakeholders.

Advice for Others:

Standards roadmap development requires significant investment of resources – both expertise and time – of stakeholders. It is important to have alignment on the scope and timeline. As standards are always evolving, theoretically a roadmap is out of date by the time of publication and is best described as a living document. Participants should focus on the priorities and high-level descriptions and not solving the issues. Development of the standards will take a place as a result, as a separate initiative, from the roadmap development. Updates on standards work can be provided post-roadmap (gaps progress reports or workshops) and future versions can be developed to maintain visibility of current work and needs over time.

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APPENDIX E GENERAL PUBLIC-PRIVATE PARTNERSHIP EXAMPLES

The following three examples are considered general public-private partnerships and not standards-driven. During ANSI's literature review and interviews, these were identified. While they are not consider SD-PPP uses cases, they are provided as examples of general PPPs.

MANUFACTURING EXTENSION PARTNERSHIP (MEP)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	
Technical Committees:	
Other Partnering Organizations:	Hollings Manufacturing Extension Partnership (group within NIST)
Government Organizations:	NIST
Industry Sector(s) / Technology:	Manufacturing
Program / Activity Website URL(s):	www.nist.gov/mep

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

Manufacturing Extension Partnership (MEP) was founded on the premise that partnerships among the National Institute of Standards and Technology (NIST) MEP and other public-private entities increase the efficiency and effectiveness of the National Network of manufacturing extension services. MEP's ability to foster, develop, and leverage these relationships permits MEP Centers to expand the reach and value of the program to the manufacturing industry. For almost three decades, MEP has focused on accelerating the growth of the U.S. manufacturing base by improving the competitiveness of U.S.-based manufacturers, reducing company operating costs, growing company profits, and encouraging technology deployment. Last year, MEP Centers interacted with more than 36,000 manufacturers, leading to $16.2 billion in sales, $2.9 billion in cost savings, $4.8 billion in new client investments, and helped create or retain more than 107,100 jobs.

There are three public laws that dictate and govern the Hollings Manufacturing Extension Partnership Program and activities. Links to each can be found below.

- Hollings Manufacturing Extension Partnership Program: 15 USC 278k
- Competitive Awards Program: 15 USC 278k-1
- Expansion Awards Pilot Program: 15 USC 278k-2

PPP Goals:

The overall objectives of the MEP program are to enhance competitiveness, productivity, and technological performance in U.S. manufacturing through:

(1) the transfer of manufacturing technology and techniques developed at the Institute to Centers and, through them, to manufacturing companies throughout the United States;
(2) the participation of individuals from industry, institutions of higher education, state governments, other federal agencies, and, when appropriate, the Institute in cooperative technology transfer activities;
(3) efforts to make new manufacturing technology and processes usable by U.S.-based small and medium-sized companies;

(4) the active dissemination of scientific, engineering, technical, and management information about manufacturing to United States-based industrial firms, including small and medium-sized manufacturing companies;
(5) the utilization, when appropriate, of the expertise and capability that exists in federal agencies, other than the Institute, and federally-sponsored laboratories;
(6) the provision to secondary schools, community colleges, and area career and technical education schools, including those in underserved and rural communities, of information about the job skills needed in manufacturing companies, including small and medium-sized manufacturing businesses in the regions they serve;
(7) the promotion and expansion of certification systems offered through industry, associations, local secondary schools and local colleges, including historically black colleges and universities, tribal colleges or universities, minority-serving institutions, community colleges, and secondary schools and colleges in underserved and rural communities, when appropriate, including efforts such as facilitating training, supporting new or existing apprenticeships or other applied learning opportunities, and providing access to information and experts, to address workforce needs and skills gaps in order to assist small- and medium-sized manufacturing businesses; and
(8) the growth in employment and wages at U.S.-based small and medium-sized companies.

Public Sector Role & Participation:

Each MEP is designed from inception as a cost-share program. Federal appropriations pay one-half, with the balance for each center funded by state/local governments and/or private entities, plus client fees. This cost-share model contributes to MEP's success. Public funding allows smaller manufacturers to afford services.

The MEP National Network, with more than 1,440 trusted advisors and experts at approximately 460 MEP service locations located in all 50 states and Puerto Rico, connects manufacturers with their local ecosystem. Partners include:

- State and local governments
- Other federal government agencies, departments, programs, and laboratories (see partnership agreements)
- Universities, community colleges, and technical schools
- Trade associations
- Professional societies
- Industry leaders and think tanks
- Economic development organizations
- The private sector including consulting firms as well as the manufacturers across the nation

The Network and the program's foundation is built on partnership and its success depends on these partners and building new partnerships.

Implementation Methods:

Manufacturing and the ecosystems that support the industry, are diverse. Manufacturing is apparel, chemicals, and advanced materials; it is also electronics, glass, medical devices, food, and transportation equipment. Manufacturing is rural and urban. Manufacturing is large and small companies. As such, each MEP center is tasked to outreach to SMEs in their state to identify what local companies want and/or need to tailor the programs. A listing of the programs can be found at MEP National Network.

Measurement of Success:

The MEP has identified a number of success stories on their website. MEP also tracks the number of clients served quarterly, and the total number of projects completed by Centers. This collection also includes project type, duration, and client characteristics. In addition, through an annual client impact survey, MEP tracks the impacts of Center

assistance on several major firm-level indicators (sales, investments, cost savings, jobs). As a set, these indicators suggest the presence of business changes that are positively associated with productivity growth.

Key Takeaways:

This cost-share model contributes to MEP's success. A GAO study found that because client fees give manufacturers a higher stake in the outcome of services, the positive impact on their businesses is greater. At the same time, public funding allows smaller manufacturers to afford services.

Advice for Others:

The MEP evaluation system is very rigorous and there are high costs associated with that; however, most centers are willing to participate this way because of the partnership program and they're able to use the evaluation system to further promote their success. It was noted that it is important to agree on the goals (and evaluation of those goals) up front for the partnership to be successful for all involved.

MOBILITY INNOVATION CENTER

ORGANIZATIONAL SPECIFICS

Standards Organizations:	n/a
Technical Committees:	n/a
Other Partnering Organizations:	Mobility Innovation Center, University of Washington, Challenge Seattle
Government Organizations:	State of Washington, Seattle Department of Transportation, King County Metro System
Industry Sector(s) / Technology:	Transportation
Program / Activity Website URL(s):	https://mic.comotion.uw.edu/; https://mic.comotion.uw.edu/wp-content/uploads/2023/11/Charging-Forward_FINAL-Nov-2023_Bart-Treece.pdf

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The University of Washington and Challenge Seattle partnered to establish the Mobility Innovation Center. This multidisciplinary Center brings together the transportation industry's leading expertise from local business, government, non-profit, and academia to help develop new technologies and explore creative solutions that have the potential to change the way we move people, information, and goods across our transportation network.

Charging Forward is a report that details a specific project done by the Mobility Innovation Center to identify various PPP models to support King County Metro's transition to a zero-emissions fleet.

PPP Goals:

The goal of the Center is to leverage the power of collaborative innovation to improve the Puget Sound region's transportation system. This includes examining how technology, policies, and infrastructure can support the needs of a growing population. The Mobility Innovation Center also helps partners scope near-term transportation projects that have the ability to address critical challenges through data-based insights, creative ideation, and applied research. It is a resource for the local government to engage directly with various businesses and academics to solve and or share the costs for potential innovation.

The goal of Charging Forward specifically was to investigate if King County Metro could use a PPP to help with the transition to a zero-emissions fleet and research existing PPPs already using this project delivery method as potential models. King County Metro was specifically interested in working with the Center as their team can quickly bring together researchers and partitioners to deliver the report titled *Charging Forward: Evaluating Public-Private Partnerships for Electric Bus Base Conversion to Support A Zero-Emission Fleet* in a six-month timeframe.

Public Sector Role & Participation:

In general, the Mobility Innovation Center, as part of the University of Washington, strives to enable cutting-edge multidisciplinary work and support the student experience and has:

- 19 academic departments
- 167 collaborating partners
- 30 projects launched

For the Charging Forward project, King County Metro provided funding for a three-person team to develop the report. The team consisted of the Director, Mobility Innovation Center at the University of Washington and two academic researchers from the University of Washington Department of Construction Management.

Implementation Methods:

The Mobility Innovation Center relies on a number of implementation methods depending on the goal of the work. These include:

- Joint funding
- In-kind contributions for equipment and technology resources from private sector partners
- Staff time from partnering organizations

For Charging Forward the team used the following methods:

- Conducted researching interviews
- Literature review of published journals and public policies in states and local jurisdictions
- Review of public agency procurement contracts
- Workshop to deliver the 2023 report, highlight the key focus areas for King County Metro, and present additional factors that they discovered during the research

Measurement of Success:

The Mobility Innovation Center has a portfolio of projects to discover how multidisciplinary research and innovation have been harnessed to solve today's most pressing transportation challenges.

For Charging Forward, the report confirmed that King County Metro could use a PPP as a tool to transition to a zero-emissions fleet. They also identified existing PPPs already in use in other cities around the country that King County could use as a model. King County Metro is currently reviewing the report to determine next steps. Updates on the transition are published on their website.

Key Takeaways:

- Investment in the process and outcomes: By committing resources such as staff time, funding, or in-kind contributions, partners are committed to the project that will help address their issues and challenges.
- De-risking innovation: The university serves as a convener to provide a venue for collaboration and a trusted third-party evaluator.
- Leveraging unique contributions: Successful partnerships rely on each entity bringing something to the project.

Advice for Others:

- Clearly define success and value for participation: Identify the goal, the "why" and the "shared win" for involvement must be clear to each partner.
- Build trust and a "no surprises" culture: These projects and efforts often are different than what partners may accustomed to and there will be challenges. Good communication is essential to troubleshoot and overcome obstacles.
- Share, tell, and tag: Success must be shared widely and those involved acknowledged in appropriate venues.
- Make it actionable: Clear next steps are essential to build off the work accomplished.

QUANTUM ECONOMIC DEVELOPMENT CONSORTIUM (QED-C)

ORGANIZATIONAL SPECIFICS

Standards Organizations:	IEEE, ISO, IEC
Technical Committees:	ISO/IEC JTC 3
Other Partnering Organizations:	Lead: SRI International, full list: https://quantumconsortium.org/members/
Government Organizations:	NIST, Commerce full list: https://quantumconsortium.org/members/
Industry Sector(s) / Technology:	Quantum technology
Program / Activity Website URL(s):	https://quantumconsortium.org/

STANDARDS-DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The Quantum Economic Development Consortium (QED-C) is a consortium of stakeholders that aims to enable and grow the quantum industry. QED-C was established with support from the National Institute of Standards and Technology (NIST) as part of the federal strategy for advancing quantum information science and as called for by the National Quantum Initiative Act enacted in 2018.

PPP Goals:

The Quantum Economic Development Consortium (QED-C®) is an industry-driven consortium managed by SRI International (SRI). The consortium seeks to enable and grow the quantum industry and associated supply chain. QED-C is supported by the National Institute of Standards and Technology (NIST) in the U.S. Department of Commerce and about 200 members, including component manufacturers and suppliers, software and hardware system developers, researchers, professional service providers, and end users. Consortium membership represents companies, universities, federally funded research and development centers, government, and other stakeholders. The main goal of the QED-C is to provide an industry voice by:

- Identifying high impact use cases and applications for quantum-based technologies
- Identifying gaps in enabling technologies, standards and performance metrics, and workforce that need to be filled to realize diverse applications
- Working with stakeholders in industry, academia, and government to fill technology, standards, and workforce gaps

A byproduct of the QED-C goals is highlighting how standards are involved and encourage development of standards and performance metrics. QED-C will connect members with relevant standards development organizations worldwide. Some discussions include how existing standards could be adapted for quantum.

Public Sector Role & Participation:

QED-C was initially set up by NIST, but today is managed by SRI International and has support from multiple agencies and a diverse set of industry, academic, and other stakeholders. Membership is available to corporations, academic and research institutions, and other entities related to the quantum industry and its supply chain headquartered in or with majority ownership/control in the following 39 countries:

Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Netherlands,

New Zealand, Norway, Poland, Portugal, Republic of Korea, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, and the United States.

Implementation Methods:

The QED-C is under an Other Transaction Agreements (OTA). OTAs relieve some of the contractual burdens typically placed on contractors working for federal clients, making it possible for non-traditional contractors such as small and emerging companies to participate in technology development. The QED-C holds plenary meetings for members and invited guests and organizes workshops to develop industry consensus on enabling technology needs and roadmaps for addressing those needs.

QED-C is organized into Technical Advisory Committees (TACs), which bring members together to address focus areas relevant to advancing the emerging quantum industry:

- Enabling Technologies - Identify enabling technologies – both quantum and classical – that need to be advanced to realize high economic impact applications and uses.
- Q4NS - A forum for government and industry to exchange information related to advancing QIST for national security applications. Topics cross-cut with other TACs, but with a national security focus.
- Quantum Law - A forum for government, industry, and academia to exchange information about legal and legal-adjacent issues and policies related to QIST. Topics of interest include international engagement, workforce diversity, intellectual property, and social/ethical matters of QIST applications. This group also discusses immigration and student visas and how it will impact workforce.
- Standards and Performance Metrics - Identify standard and metrics that can accelerate commercialization of quantum-based products and services. Connect members with relevant standards development organizations worldwide.
- Use Cases - Identify and assess applications and use cases of quantum-enabled technologies. The output will inform companies across the supply chain — from component suppliers to users — as well as policymakers, government program managers, and investors.
- Workforce - Identify education and workforce development needs to support the emerging quantum industry, working with universities and other educational institutions.

Individual TACs will take the lead on a topic or workshop. Other TACs may be involved depending on the topic. The topics are chosen based on the interests of the individuals populating the TAC.

Measurement of Success:

QED-C efforts to date have focused on identification of quantum needs, challenges and opportunities. Discussions among stakeholders have matured and the agreed to 2024 activities include:

- Repository documenting the landscape of standards development activities
- Interactive graphical visualization of the repository and other standards related information
- Development of application-oriented benchmarking for quantum computing
- Demonstrate interoperability among devices/software of different QED-C members
- Explore compatibility with classical networks
- Consider future quantum sensing standards needs
- Standards readiness and integrity assessments
- Standards education within QED-C
- Interactions and collaborations with other entities with standards-related activities and interests

Key Takeaways:

While this PPP does not specifically address standards, there is a lot of talk about standards in the TACs and potential opportunities to collaborate in the near future.

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