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Twenty-Sixth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment

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NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
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Abstract

In FY 2022, the 22 federal agencies that reported did not add or rescind any GUS in lieu of VCS, leaving a total of 80 previously reported GUS in lieu of VCS still in use. This analysis does not reflect the use of standards by the Department of Defense (DoD) or the National Aeronautics and Space Administration (NASA) as they report their use of GUS on a categorical basis via a different reporting mechanism. Agencies demonstrate the effectiveness of the NTTAA and Circular A-119 by their continuous review of opportunities to rescind GUS in favor of using VCS, and their involvement with the private sector through the VCS process. These activities suggest that federal agencies are cognizant of the benefits of meeting their mission needs by actively seeking to use VCS developed by the private sector.

Keywords

Agency use of standards, government unique standards, NTTAA, voluntary consensus standards.

Twenty-Sixth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment

Annually since 1997, the U.S. Department of Commerce (DOC) provides a report to the Office of Management and Budget (OMB) summarizing federal agency use of government unique standards (GUS) used in lieu of voluntary consensus standards (VCS) during the previous fiscal year (FY) as required by Section 12(d)(3) of Public Law 104-113, the "*National Technology Transfer and Advancement Act of 1995*" (NTTAA). By implementing the NTTAA and OMB Circular A-119 "*Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*" (Circular A-119), agencies minimize their reliance on GUS by using VCS whenever possible and thus help to achieve the following goals:

- reduce costs and regulatory burdens,
- provide incentives and opportunities that encourage growth of U.S. enterprises,
- realize benefits from public-private collaboration in standards setting.

This FY 2022 summary, prepared by the National Institute of Standards and Technology (NIST), compiles annual reports provided by the 22 agencies listed in Appendix A. For these reports, agencies were asked to document any new use of GUS in lieu of VCS during FY 2022 and provide a rationale for each new use. Agencies additionally were asked to list any rescinded GUS in lieu of VCS during the past fiscal year, and to briefly describe their activities undertaken to carry out provisions described in Circular A-119. The two questions are listed in Appendix B. Individual agency reports may be found at https://www.nist.gov/standardsgov/nttaa-reports.

VCS are defined in OMB Circular A-119 Sections 2d-e as standards developed via a process incorporating openness, balance, due process, an appeals process, and a consensus process. GUS, defined in OMB Circular A-119 Section 2c, are standards developed by and for use by the Federal Government that do not follow the process used in developing VCS.

For FY 2022, federal agencies did not report any new GUS used in lieu of VCS, nor did federal agencies rescind any GUS used in lieu of VCS.

Summary

In FY 2022, the 22 federal agencies that reported did not add or rescind any GUS in lieu of VCS, leaving a total of 80 previously reported GUS in lieu of VCS still in use. This analysis does not reflect the use of standards by the Department of Defense (DoD) or the National Aeronautics and Space Administration (NASA) as they report their use of GUS on a categorical basis via a different reporting mechanism. Agencies demonstrate the effectiveness of the NTTAA and Circular A-119 by their continuous review of opportunities to rescind GUS in favor of using VCS, and their involvement with the private sector through the VCS process. These activities suggest that federal agencies are cognizant of the benefits of meeting their mission needs by actively seeking to use VCS developed by the private sector.

In accordance with its coordination role as defined in the NTTAA and OMB A-119, NIST continues to assist federal agencies and their stakeholders by providing standards and conformity assessment information, program support, and guidance. NIST hosts http://standards.gov, which offers ongoing practical guidance and information needed by agencies to implement the NTTAA successfully and report standards activities as required by the NTTAA and OMB Circular A-119. This report fulfills the annual reporting requirements of both the NTTAA and OMB Circular A-119.

Appendix A: FY 2022 Federal Agencies Reporting per OMB Circular A-119

Access Board (ACCESS)

Consumer Product Safety Commission (CPSC)

Department of Agriculture (USDA)

Department of Commerce (DOC)

Department of Defense (DoD)*

Department of Energy (DOE)

Department of Health and Human Services (HHS)

Department of Homeland Security (DHS)

Department of Housing and Urban Development (HUD)

Department of the Interior (DOI)

Department of Justice (DOJ)

Department of Labor (DOL)

Department of State (DOS)

Department of Transportation (DOT)

Environmental Protection Agency (EPA)

Federal Communications Commission (FCC)

Federal Trade Commission (FTC)

General Services Administration (GSA)

Government Publishing Office (GPO)

National Aeronautics and Space Administration (NASA)*

National Archives and Records Administration (NARA)

Nuclear Regulatory Commission (NRC)

* Agencies reporting on a categorical basis per OMB Circular A-119, Section 11.

Appendix B: NTTAA Annual Reporting Survey

Instructions provided to each agency:

Per the NTTAA and the revised OMB Circular A-119, your agency is requested to report on the following two questions:

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 20XX. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Process:

Attached is a Word (.docx) file with Question 1 and Question 2. Please complete, finalize, and send to NIST.

1. Question 1 is for reporting on your agency's activities in standards and conformity assessment during FY2022. As a reference, we have included the greyed-out response from last year and instructions on completing.
2. Question 2 is for reporting on GUS used in lieu VCS and includes previously reported GUS. Please update by adding any new and removing any rescinded GUS.

We will post your agency's NTTAA Agency report on our website in pdf format.

Please do not hesitate to give feedback, ask questions, provide comments, etc. on this process.

Access Board (ACCESS) Fiscal Year 2022 Agency Report

1. **Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.**

Please note that your agency's report from last year is provided below in grey text. Please either delete and add this year's report or convert the grey text to black and update the year if nothing has changed. Please send this to NIST along with ACCESS FY2022 Q2.

The U.S. Access Board is an independent federal agency that promotes equality for people with disabilities through leadership in accessible design and the development of accessibility guidelines and standards. We are responsible for developing, or assisting in the development of, accessibility standards and guidelines under several federal statutes, including: the Americans with Disabilities Act (buildings and facilities, and transportation vehicles), Architectural Barriers Act (federal buildings and facilities); Communications Act (telecommunications equipment); Rehabilitation Act (information and communication technology used or procured by federal agencies); Patient Protection and Affordable Care Act (medical diagnostic equipment); Food and Drug Administration Safety and Innovation Act (prescription drug labels); and Help America Vote Act (voluntary voting system guidelines).

In FY 2022, as in previous reporting years, the Access Board relied heavily on voluntary consensus standards to fulfill its regulatory mission. While we did not publish any new or revised substantive (technical) regulations during this fiscal year, our existing guidelines and standards continue to incorporate by reference about 25 voluntary consensus standards, ranging from web content accessibility guidelines to specifications that relate to the determination of playground surface accessibility.

The Access Board also has a long history of working with standards development organizations (SDOs) on the development of consensus standards relating to accessible design. In FY 2022, Access Board staff served on numerous SDO committees, technical working groups, and cooperative research panels to ensure that the agency's technical expertise and perspective were brought to bear on the development (or revision) of model codes and standards that affect accessibility in a wide range of settings.

For example, agency staff served on, or provided technical assistance to, the following model code groups, SDOs, and research cooperatives:

- American Society of Mechanical Engineers, A18 Platform Lift and Stairway Chair Lift Committee;
- American Society of Testing and Materials, Committee on Sports Equipment, Playing Surfaces, and Facilities;
- International Code Council, Consensus Committee on Accessible and Usable Buildings and Facilities (ASC A117);
- National Committee on Uniform Traffic Control Devices;
- National Cooperative Highway Research Panel (sponsored by the Transportation Research Board

(TRB:);

- Transportation Cooperative Research Panel (sponsored by TRB);
- Rehabilitation Engineering and Assistive Tech. Society of North America, Standards Comm. on Cognitive Accessibility;
- TRB Standing Committee on Innovative Public Transportation Services and Technologies;
- RESNA Standards Committee for Assistive Technology for Air Travel; and
- World Wide Web Consortium Web Accessibility Initiative - Accessibility Guidelines Working Group,

Two Access Board members serve as statutory representatives on the Election Assistance Commission (EAC) Board of Advisors and Technical Guidelines Development Committee (TGDC). The TGDC, chaired by the NIST director, is responsible for drafting and recommending versions of the Voluntary Voting System Guidelines (VVSG). The Board of Advisors reviews the VVSG, best practice recommendations, and follows other EAC activities. For FY 2022, the EAC Board of Advisors and TGDC meetings were held virtually and focused on supplemental materials supporting and advancing adoption of VVSG 2.0. In addition to the formal Board of Advisors and TGDC meetings, Access Board members and staff also attend or participant in other EAC public-facing activities.

Additional information about the Access Board's accessibility standards and guidelines can be found at: https://www.access-board.gov (see "Guidelines & Standards" tab).

2. **Please keep track changes on to record or rescind any new government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2022. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.**

Start by reviewing Table 1: Current Government Unique Standards FY2021. If no changes, record the number of GUS in FY2022, save the file, and send to nrioux@nist.gov.

To add a new GUS, please go to Table 2: Government Unique Standards Added in FY2022 and use the template provided to add the GUS, VCS, and rationale. If more than one GUS is being added, please follow the template in listing any new GUS.

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please cut the rescinded standard and paste in Table 3: Government Unique Standards Rescinded in FY2022. Please add a 'Rationale for Rescinding' explaining why the standard was rescinded.

Please record below the total number of GUS currently in use (previous years and new as of this FY). This number should include the previous total plus any new GUS added, and minus any GUS rescinded:

Number of GUS in FY2022: 0 + (new) - (rescinded) = 0

Consumer Product Safety Commission (CPSC) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

From October 1, 2021 to September 30, 2022, CPSC staff provided technical support or was otherwise engaged in the development of voluntary safety standards for 83 different products, product areas, or hazards. Voluntary standards activities are handled by various standards developing organizations (SDOs) that are accredited by the American National Standards Institute (ANSI). The majority of the standards where staff was involved are developed by either ASTM International (ASTM) or Underwriters Laboratories Inc. (UL). The standards provide safety provisions addressing potential hazards associated with consumer products found in homes, schools, and recreation areas. Twice a year, the CPSC staff issues a Voluntary Standards Tracking and Access Report, otherwise known as the VSTAR Report. This report shows, among other things, product, product areas, or hazards associated with voluntary standards work, the name of the U.S. Consumer Product Safety Commission (CPSC or Commission) employee leading each activity, the name(s) and designation(s) of the standards associated with the product, the purpose of staff's involvement, any associated mandatory standard or regulation, the activity by staff during the reporting period, and staff's next actions associated with the voluntary standard. The VSTAR report is issued bi-annually in the form of: (1) a Mid-Year Report, covering the period from October 1 through March 31, and (2) an Annual Report of the CPSC fiscal year, which covers the period from October 1 to September 30. More about this report and other voluntary standards activity at the CPSC can be found at the following: https://www.cpsc.gov/Regulations-Laws-- Standards/Voluntary-Standards.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 2

(1) Government Unique Standard

16 CFR 1500.17(a)(13), Metal-Cored Candlewicks Containing Lead and Candles With Such Wicks [Incorporated: 2003]

Voluntary Standard

Voices of Safety International (VOSI) standard on lead in candle wicks

Rationale

The U.S. Consumer Product Safety Commission found that the VOSI standard is technically unsound, and thus would not result in the elimination or adequate reduction of the risk, and that substantial compliance with it is unlikely. See 68 Fed. Reg. 19145-6, paragraph H2, Voluntary Standards for further information on this finding.

(2) Government Unique Standard

CPSC 16 CFR Parts 1213, 1500, and 1513 for Bunk Beds [Incorporated: 2000]

Voluntary Standard

ASTM F1427-96 Standard Consumer Safety Specification for Bunk Beds

Rationale

The CPSC rules go beyond the provisions of the ASTM voluntary standard to provide increased protection to children from the risk of death and serious injury from entrapment.

Department of Agriculture (USDA) Fiscal Year 2022 Agency Report

1. **Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.**

The Agricultural Marketing Service (AMS) provides grading services, and price and volume reporting for a range of commodities including cotton, dairy, fruits and vegetables, livestock, poultry, seed, tobacco, and grain. AMS supports these services by maintaining commodity quality standards on its website at https://www.ams.usda.gov/. The grade standards provide a common language of trade between buyers and sellers and are voluntarily used by the supply chain to promote orderly and efficient trade of agricultural products. AMS grading services certify products according to these standards or to contract terms. In addition, AMS purchases a variety of food products for Federal nutrition assistance and international food aid programs. These purchases provide food to those in need and help stabilize agricultural commodity prices by balancing supply and demand. Fresh and processed food purchased under these programs includes fruits and vegetables, beef and pork, poultry and egg products, fish, dairy products, grain products, and oilseed products. To support the procurement process, AMS maintains a series of purchase specifications on its website at https://www.ams.usda.gov/commodity-procurement that are used by contractors to produce and deliver food products and by graders and inspectors within the U.S. Department of Agriculture (USDA) to determine product acceptability. If purchase specifications require laboratory analyses, only official standard analytical methods are used.

USDA also offers voluntary, independent food safety audits of fruit and vegetable suppliers throughout the production and supply chain. USDA's Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audits verify that fresh fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial food safety hazards. USDA GAP and GHP audits verify adherence to the recommendation in the U.S. Food and Drug Administration's (FDA) Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables and industry-recognized food safety practices. In FY 2022, USDA's Specialty Crops Program (SCP) and its licensed auditors performed 3,281 food safety audits (primarily GAP and GHP audits) on more than 100 different commodities in all 50 states, Puerto Rico and Canada.

Other USDA audit services focus on Good Manufacturing Practice (GMP), which verify adherence to FDA's GMP regulations: current (CFR Title 21 Part 110) and staggered effective dates from 2016 to 2018 (CFR Title 21 Part 117); Hazard Analysis Critical Control Points (HACCP), based on FDA's Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables and the HACCP principles established by the National Advisory Committee On Microbiological Criteria for Foods; food defense protocols, based on FDA's Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance; and traceability procedures.

The USDA Specialty Crops Program (SCP) serves as the United States representative on multiple Codex Alimentarius Commission (Codex) committees. Codex standards help ensure fair trade practices in the food trade and the trading of safe food internationally. SCP activities relating to CAC include:

- Committee on Processed Fruits and Vegetables (CCPFV): SCP chairs this committee. In FY 2022, though the CCPFV is adjourned, proposals were made to develop new standards and to review an existing one.

- Committee on Fresh Fruits and Vegetables (CCFFV): In FY 2022, SCP participated in the 22nd Session of the CCFFV at which three new standards were completed, one revised and proposals to develop two new CCFFV standards were agreed to. CCFFV accepted the Glossary of Terms Used in the Layout for Codex Standards for Fresh Fruits and Vegetables and Amendments to the CCFFV Standard Layout prepared by the delegations of the United States and Ghana.

- Codex Committee on Spices and Culinary Herbs (CCSCH): In FY 2022, SCP participated in the 6th Session of the CCSCH at which three new standards were completed, two undergoing development and three new ones approved for development.

- Codex International Outreach: SCP continuously undertakes outreach activities to maintain technical relationships on Codex standards and issues with foreign countries. In all three Codex commodity committees, SCP leads the working groups that select the priority commodities to be standardized.

SCP serves as the United States representative on multiple United Nations Economic Commission for Europe (UNECE) committees. UNECE is a voluntary international standards development organization. SCP activities relating to UNECE include:

- UNECE Specialized Section on Standardization of Fresh Fruits and Vegetables (SSSFFV): In FY 2022, SCP participated in the SSSFFV meeting where four existing standards and an explanatory brochure (inspection manual) were revised. Work commenced on two new standards.

- UNECE Specialized Section on Standardization of Dry and Dried Produce (SSSDDP): SCP chairs and heads the U.S. delegation to the annual meeting. In FY 2022, three new standards were completed, two new standards are being evaluated prior to final adoption, and two explanatory posters are ongoing development.

- UNECE Outreach: SCP conducted international outreach to government and industry officials to build support for U.S. positions related to fresh, dry, and dried produce standards being addressed by the UNECE.

The USDA National Organic Program (NOP) did not use any Government Unique Standards In lieu of Voluntary Consensus Standards in FY 2022. NOP also did not participate in any Voluntary Consensus Standards Activities during FY 2022.

The program continues to use the following Voluntary Consensus Standards. These are incorporated by reference in the USDA organic regulations 7 CFR Part 205.3:

1. ASTM D5988-12 (“ASTM D5988”), “Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil,” approved May 1, 2012.

2. ASTM D6400-12 (“ASTM D6400”), “Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved May 15, 2012.

3. ASTM D6866-12 ("ASTM D6866"), "Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis," approved April 1, 2012.

4. ASTM D6868-11 ("ASTM D6868"), "Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates

Designed to be Aerobically Composted in Municipal or Industrial Facilities," approved February 1, 2011.

5. EN 13432:2000: E ("EN 13432"), September 2000, "Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging."

6. EN 14995:2006: E ("EN 14995"), December 2006, "Plastics - Evaluation of compostability - Test scheme and specifications."

7. ISO 17088:2012(E), ("ISO 17088"), "Specifications for compostable plastics," June 1, 2012.

8. ISO 17556:2012(E) ("ISO 17556"), "Plastics—Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved," August 15, 2012.

USDA's Cotton & Tobacco Program utilizes ASTM environmental and laboratory cotton fiber testing standards to provide the methodology for the cotton classification process. In addition, physical and descriptive cotton classification standards for visual and instrument grading serve as the reference for all cotton classification measurements. The applicable websites are listed below:

https://www.astm.org/
https://www.ams.usda.gov/grades-standards/cotton

https://www.astm.org/get-involved/technical-committees/committee-d13/subcommittee-d13#

USDA's Dairy Program (DP) is accredited by the American National Standards Institute (ANSI) as Administrator of the U.S. Technical Advisory Group (TAG) to the International Organization for Standardization (ISO) Technical Committee 34, Subcommittee 5 for Milk and Milk Products (TC34/SC5). ANSI, the U.S. member body to ISO, relies on U.S. TAGs as national mirror committees to support the development of voluntary, consensus-based international standards used in the global marketplace. DP concurrently engages in and facilitates TC34/SC5 U.S. TAG activities to determine consensus positions from members representing all sectors of the U.S. dairy industry in the development, approval, reaffirmation, revision, and withdrawal of international ISO standards. Since the TAG was accredited in November 2019, it has provided the U.S. consensus position for approximately 120 voting events for ISO standards at various stages of development. DP as the TAG Administrator, organizes the U.S. delegation for ISO meeting attendance and oversees the nomination of experts to represent the U.S. on ISO technical committees. In November of 2022, members of the TAG representing the U.S. delegation participated in the 6th ISO TC34/SC5 meeting. Moreover, the TAG has nominated 11 U.S. experts to 11 technical working groups developing and/or revising ISO standards for the evaluation of milk and milk products.

Another part of DP's commitment to building and using voluntary consensus standards, is participation in U.S. TAGs associated with TC34/SC5, including the U.S. TAG for TC34 for Food Products and the U.S. TAG for TC34/SC9 for Microbiology. Participation and facilitation of U.S. TAG activities in support of international standards allows DP to have a direct role in the development and use of voluntary consensus standards.

Although the Codex Committee on Milk and Milk Products is adjourned *sine die*, DP was very engaged and active in participating in multiple Codex committees impacting the trade of milk and milk products including the following: Codex Committee on Fats and Oils (CCFO), Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), Codex Committee on Food Additives (CCFA) and Codex Committee on Methods of Analysis and Sampling (CCMAS).

Relevant Websites:

- ISO: https://www.iso.org/about-us.html
- ANSI Accredited U.S. TAG Listing: https://www.ansi.org/iso/ansi-activities/us-tags
- ISO TC34/SC5 for Milk and Milk Products: https://www.iso.org/committee/47878.html
- ISO TC34 for Food Products: https://www.iso.org/committee/47858.html
- ISO TC34/SC9 for Microbiology: https://www.iso.org/committee/47920.html

USDA's Livestock and Poultry Program's (LP) mission ensures that accurate and precise information is generated and available for the producers of U.S. meat and poultry products with respect to quality grading and marketing standards in support of both domestic and international trade. LP continues to coordinate its conformity assessment activities between the public and private sector with participation in consensus standard development bodies. LP still consistently uses government unique standards for the USDA grading and conformity system but continues to expand these into the voluntary consensus space with involvement of U.S. and international standard development organizations to promote efficiency and competitiveness for American farmers, producers, processors, handlers, wholesalers, warehousing companies, and retailers. In the U.S. there are over 400 meat, poultry and egg plants relying on LP for quality assessment. LP maintains several hundred in-house standards for this purpose and for coordinated product certification. Some of them have been in use for more than seventy-five years. LP also maintains Commercial Item Descriptions for hundreds of products that are procured through federal commodity purchase programs.

In 2022, the U.S. delegation to the UNECE Working Party on Agricultural Quality Standards, Specialized Section on the Standardization of Meat was led by LP staff members. UNECE's Specialized Section on Meat is a voluntary international standards development organization that focuses on developing global standards for egg, meat, and poultry products. The 2022 meeting of the Specialized Section was held in both in-person and virtual formats to optimize participation and provide opportunities to strengthen relations. In attendance were delegations from Australia, Czech Republic, Germany, Mongolia, Morocco, Panama, Philippines, Poland, and the U.S., as well as representatives from non-government organizations. These proceedings covered topics of discussion on the fat content of meat, new technological developments for assessing marbling in beef, an update from the working group assigned to review the marbling requirements in the current version of the UN porcine standard, recent developments from research on the eating quality of meat, an update on capacity building and promotional activities, an outline of future work, and the election of officers. An AMS staff person was elected as the vice chairperson of this organization during the meeting session.

ISO technical committee 34 Food Products/subcommittee 16 Horizontal methods for molecular biomarker analysis (TC 34/SC 16) was established by the USDA AMS LP Agricultural Analytics Division with collaboration from the American Oil Chemist's Society (AOCS) in 2008 in anticipation of the need to support international regulatory requirements for the trade and marketing of bioengineered food products. LP provided collaborative agreement funding for the establishment of TC 34/SC 16 providing international

standardization of biomolecular testing methods applied to foods, feeds, seeds and other propagules of food and feed crops, variety identification and detection of plant pathogens. Deliverables in the form of ISO standards, technical specifications and technical reports from this committee now provide methods, requirements, and specifications for GMO testing, including citations and recommendations in the U.S. National Bioengineered Food Disclosure Standard. AOCS, an ANSI member took over funding of TC 34/SC 16 in 2013, however an LP staff person serves as the volunteer *pro bono* international executive committee manager and technical expert. The LP staff member leads all business operations for this committee. There are currently 8 working groups in TC 34/SC 16 covering meat speciation, subsampling of seeds and grains, rapid nucleic acid amplification methods, biobanking for agriculture and food production, molecular biomarkers of agricultural fibers, microarray detection, genetically engineered content detection and quantification, and single laboratory validation of qualitative real time PCR methods. The committee has published 34 international standards and with five under development. The committee is made up of delegations from 24 participating countries and 22 observing countries.

In 2022, TC 34/SC 16 published five new standards: ISO 16577:2022 Molecular biomarker analysis — Vocabulary for molecular biomarker analytical methods in agriculture and food production; ISO 22942-1:2022 Molecular biomarker analysis — Isothermal polymerase chain reaction (isoPCR) methods — Part 1: General requirements; ISO/TS 20224-8:2022 Molecular biomarker analysis — Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR — Part 8: Turkey DNA detection method; ISO/TS 20224-9:2022 Molecular biomarker analysis — Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR — Part 9: Goose DNA detection method; ISO 16578:2022 Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences and ISO TS 21569-7 Horizontal methods for molecular biomarker analysis — Methods of analysis for the detection of genetically modified organisms and derived products — Part 7: Real-time PCR based methods for the detection of CaMV and Agrobacterium Ti-plasmid derived DNA sequences. Standards under development in ISO TC 34/SC 16 include ISO/NP 20224-10 Molecular biomarker analysis — Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR — Part 10: Duck DNA detection method; ISO/NP 20224-11 Molecular biomarker analysis — Detection of animal- derived materials in foodstuffs and feedstuffs by real-time PCR — Part 11: Pigeon DNA detection method; ISO/NP TS 21569-8 Molecular biomarker analysis — Methods of analysis for the detection of genetically modified organisms and derived products — Part 8: DNA extraction from alfalfa seeds and real-time PCR based event-specific detection methods for genetically modified alfalfa lines J101, J163 and KK179; ISO/CD 5354-1 Molecular biomarkers — Detection of specific DNA sequences in textiles derived from cotton — Part 1: Extraction of DNA from cotton and cotton-derived textile materials; ISO/CD TS 5354-2 Molecular biomarkers — Detection of specific DNA sequences in textiles derived from cotton — Part 2: Overview of target sequences for use in PCR-based detection methods for cotton GM events; ISO/NP TS 21569-9 Molecular biomarker analysis — Methods of analysis for the detection of genetically modified organisms and derived products — Part 9: Construct-specific real-time PCR based screening method for the detection of the P-35S-nptII DNA—sequences; ISO/Approved Work Item (AWI) 16677-1 Biobanking — Biobanking genetic material for biodiversity and conservation of genetic material

— Part 1: Agricultural animal species; ISO/WD 11781 CEN Foodstuffs — General guidelines for single-laboratory validation of qualitative real-time PCR methods and ISO/NP 17174 CEN Food authenticity — DNA barcoding of fish and fish products using defined mitochondrial cytochrome b and cytochrome c oxidase I gene segments.

LP served on the drafting committee for ISO 23418:2022 Microbiology of the food chain — Whole genome sequencing for typing and genomic characterization of bacteria — General requirements and guidance which was published in 2022 and provided a proposal at the ISO TC 34 Food Products/SC 9

Microbiology of the Food Chain plenary meeting in 2022 for the development of new work on a One Health approach to the biomolecular identification of antimicrobial resistance in microbial pathogens. This work will be chaired by a member of the U.S. Food and Drug Administration. LP currently serves as a committee liaison for ISO committees in meat testing, dairy testing, health informatics, statistics, and genomic DNA data compression.

LP represents the USDA on the ISO Technical Management Board Strategic Advisory Group on Smart Farming (ISO TMB SAG SF). Smart farming refers to the modern use of information and communication technologies (ICT) in agriculture. According to ISO's overview of the SAG on smart farming, apart from the challenges of climate change and food security for the world's population, there are a range of technological challenges, foremost among which is the issue of interconnectivity across the entire value chain of the food industry. The ISO TMB SAG SF will provide a roadmap to potential ISO standardization in smart farming. The LP staff member currently chairs the ISO TMB SAG SF subgroup on semantics and terminology and is working on semantic and syntactic interoperability and capability development for the ISO TMB SAG SF which is due to be published in March of 2023.

LP continued to provide international expertise in each of the five ISO TC 276 Biotechnology working groups: WG 1 terminology; WG 2 biobanking, WG 3 analytical methods, WG 4 bioprocessing and as both an expert and the U.S. technical convener for ISO TC 276 Biotechnology/working group 5 Data programming and integration. LP served on the drafting committees and provided technical advice and input for the following standards that were published in 2022: ISO 20691:2022 Biotechnology — Requirements for data formatting and description in the life sciences; ISO/TR 3985:2021 — Data publication — Preliminary considerations and concepts; ISO 24088-1:2022 Biotechnology — Biobanking of microorganisms — Part 1: Bacteria and archaea.

LP was a member of the drafting committee for ISO 35001:2019 Biorisk management for laboratories and other related organizations produced by ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems/ working group 5 Laboratory biorisk management. ISO 35001:2019 is currently used in the U.S. and throughout the world. LP continues to work in this working group on two other projects.

LP chaired the AOAC International Stakeholder Program on Agent Detection Assays (SPADA) Working Group (WG) III Next Generation DNA sequencing Standards for Validation Criteria for Databases and *in silico* Processes. In this capacity LP developed validation criteria and confidence parameters for reference genome databases. The SPADA partnership between the U.S. Department of Defense and the AOAC includes scientists from the U.S. Department of Defense, U.S. Environmental Protection Agency,

U.S. Health and Human Services, U.S. Centers for Disease Control, U.S. Food and Drug Administration, the USDA, and others. The standard developed by LP entitled, Standard Requirements for Nucleotide Sequences used in Biothreat Agent Detection, Identification, and Quantification: Verified Next Generation Sequences (VNGS) is now ready for consensus balloting by the SPADA community and all who have a material interest in this work. It is expected to be published in 2023.

DP and LP staff represented the USDA at the two Interagency Committee on standards policy (ICSP) meetings and participated in the annual ANSI ISO Forum meetings.

USDA's Fair Trade Practices Program (FTPP), Packers and Stockyards Division (PSD) participated in Voluntary Consensus Standards Activities during FY 2022.

PSD enforces regulation 201.71(a) promulgated under the Packers and Stockyards Act. The regulation includes Section 5.59, "Electronic Livestock, Meat, and Poultry Evaluation Systems and/or Devices," of the National Institute of Standards and Technology (NIST) Handbook 44 (2013). The rule became effective and enforceable on June 30, 2014. No amendments to the regulations have been made since this date.

Handbook 44 references consensus standards established by ASTM International Committee F10 on Livestock, Meat, and Poultry Evaluation Systems, a committee made up of members representing industry associations, packing companies, instrument manufacturers, academia and government agencies.

ASTM Committee F10 on Livestock, Meat and Poultry Evaluation was formed in 2001. The ASTM Committee, with a membership of approximately 50, currently has jurisdiction over five standards, published in the Annual Book of ASTM Standards, Volume 15.12. F10 has five technical subcommittees that maintain jurisdiction over these standards.

REFERENCE DOCUMENTS

1. Electronic Livestock, Meat, and Poultry Evaluation Systems and/or Devices Section 5.59. *Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices*. NIST Handbook 44, 2013.
2. Standard Practice for User Requirements for Livestock, Meat, and Poultry Evaluation Devices or Systems. American Society for Testing Materials (ASTM) International Standard F 2341.
3. Standard Specification for Design and Construction of Composition or Quality Constituent Measuring Devices or Systems. ASTM International Standard F 2342.
4. Standard Test Method for Livestock, Meat, and Poultry Evaluation Devices. ASTM International Standard F 2343.

NOTE: Standards can be obtained by contacting www.ASTM.org .

USDA AMS FTPP Food Disclosure and Labeling Division (FDLD) encourages regulated entities to comply with the National Bioengineered Food Disclosure Standard (the Standard). The program uses the following Voluntary Consensus Standards that are incorporated by reference as part of the 2020 Guidance Documents related to testing and validation of refinement processes of the Standard. These recommendations are:

1. ISO/TS 16393:2019, "Molecular biomarker analysis — Determination of the performance characteristics of qualitative measurement methods and validation of methods," published February 2019.
2. ISO/IEC 17025:2017, "Testing and Calibration Laboratories," corrected version published in March 2018.
3. ISO/ 24276:2006, "Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions," published in February 2006; last reviewed and confirmed in 2020.
4. ISO 21568:2003, "Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products," published in February 2003.
5. ISO 21569:2005, "Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid-based methods," published June 2005; last reviewed and confirmed in 2020.
6. ISO 21570:2005, "Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid-based methods," published November 2005; last reviewed and confirmed in 2020.

7. ISO 21571:2005, “Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction,” published February 2005; last reviewed and confirmed in 2020.
8. CXG 74-2010, Codex Alimentarius, CAC/GL74-2010, “Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods”, adopted in 2011.
9. CGX 72-2009, Codex Alimentarius, CAC/GL 72-20009, Guidelines on Analytical Terminology, adopted in 2009.

The Federal Grain Inspection Service (FGIS) works in cooperation with National Conference of Weights and Measures (NCWM) by serving as the testing laboratory for grain analyzers seeking National Type Evaluation Program (NTEP) certification. The FGIS laboratory is located at the National Grain Center in Kansas City, Missouri and serves as the sole NTEP laboratory for evaluation of grain analyzer devices. These devices are evaluated for measurements of moisture, protein, oil, and test weight per bushel according to the requirements outlined in NCWM Publication 14. Other device types evaluated under the NTEP program include a range of weighing and measuring instruments that include, but are not limited to, scales, grain analyzers, liquid-measuring devices, dry volume containers, odometers, taximeters, and timing devices. Specifications, tolerances, and requirements for each device can be found in the NIST Handbook 44.

The NTEP is a verification program administered by the NCWM to ensure measurement devices are manufactured in accordance with U.S. standards. Standards, policies, and test procedures are developed by industry and technical experts who meet annually to maintain consensus. Devices maintaining an active NTEP Certificate of Conformance are deemed metrologically equivalent according to these standards and are authorized for establishing cost in commercial trade applications.

Authorization is dependent on individual state laws and can vary across U.S. states. Related

Websites:

https://www.ncwm.com/ntep-about

https://www.ncwm.com/grain-sector

2. **Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):**

Current total GUS: 1

(1) Government Unique Standard

WILDLAND FIRE FOAM: GUS Number: 5100-307a; June 2007. Title: Specification for Fire Suppressant Foam for Wildland Firefighting (Class A Foam). [Incorporated: 2010]

Voluntary Standard

NFPA 1150 - Standard on Fire-Fighting Foam Chemicals for Class A Fuels in Rural, Suburban, and Vegetated Areas.

Rationale

Foam fire suppressants contain foaming and wetting agents. The foaming agents affect the accuracy of an aerial drop, how fast the water drains from the foam and how well the product clings to the fuel surfaces. The wetting agents increase the ability of the drained water to penetrate fuels. Foam fire suppressants are supplied as wet concentrates. This standard was developed with international cooperation for Class A Foam used in wildland fire suppression situations and equipment. Standard was created by the USDA Forest Service in cooperation with the Department of Interior (DOI), the State of California, Department of Forestry and Fire Protection and the Canadian Interagency Forest Fire Center. The Forest Service has not chosen to utilize NFPA 1150 as it is designed specifically for application by municipal fire agencies in the wildland-urban interface, utilizing apparatus and situations that they are likely to encounter. The Forest Service's GUS for foam products is specific to use by wildland fire equipment and situations that are unique, e.g. helicopter use of foams, remote storage situations, and varied quality of water sources in the wildland settings. The agency feels this standard more accurately reflects the needs and mission of the federal wildland fire suppression agencies.

Department of Commerce (DOC) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The Department of Commerce's (DOC) mission is to create the conditions for economic growth and opportunity for all communities. Through its 13 bureaus, DOC works to drive the United States (U.S.) economic competitiveness, strengthen domestic industry, and spur the growth of quality jobs in all communities across the country. DOC serves as the voice of business in the federal government, and at the same time, touches and serves every American every day.

DOC fosters the innovation and invention that underpin the U.S. comparative advantage. Its scientists and engineers research emerging technologies and actively provide their knowledge to the voluntary standards development process. Data collected and analyzed by DOC is used by federal and local governments as well as by businesses. Companies benefit from DOC laboratories in conducting research and development (R&D) and in scientific and technical leadership. DOC advances R&D of the commercial space industry and climate science and uses intellectual property (IP) protections to ensure American innovators profit from their work.

Together with other branches of DOC, the five branches listed in this report support the strategic goals of enhancing U.S. leadership, accelerating job creation, strengthening U.S. economic and national security, fulfilling constitutional requirements, and delivering excellent customer service. The following report compiles information about how these organizations used their engagement in voluntary consensus standards and conformity assessment activities during FY2022 to support these critical mission areas in fulfillment of the Office of Management and Budget (OMB) and the National Technology Transfer and Advancement Act (NTTAA) reporting requirements.

The U.S. Census Bureau (Census Bureau)

The Census Bureau applies voluntary consensus standards from organizations such as the International Organization for Standardization (ISO), the American National Standards Institute (ANSI), the Open Geospatial Consortium (OGC), and the Federal Geographic Data Committee (FGDC) to all the Census Bureau statistical surveys, economic analysis, geographic programs, and products.

The 2022 Census Bureau geographic products include: the most current legal, statistical, and administrative boundaries and names for urban areas, congressional districts, and State Legislative Districts (Upper and Lower Chambers) as collected by the Census Bureau are available as TIGER/Line Shapefiles. Harvesting the metadata to the GeoPlatform.gov and Data.gov using ISO metadata standards is a requirement of the Geospatial Data Act (GDA) of 2018 for the Census Bureau's NGDAs

The Census Bureau led the development of ISO 19160-3, Addressing – Part 3: Quality management for address data and is actively involved in the development of ISO 19160-2, Addressing - Part 2: Assigning and maintaining addresses for objects in the physical world (see item 9 below). These standards and programs, in addition to ongoing research and innovation activities, were designed to improve public access, discoverability, integration, data sharing, and to support the open government initiative and the provisions of OMB Circular A-119.

Standards Development and Policies: In 2022, the following activities exemplified the Census Bureau's direct application of standards policies, membership in standards bodies, ISO standards licensing, and continued development of voluntary consensus standards to implement within the GSP and its geospatial data products.

1. Commerce continues to provide leadership to the United Nations Committee of Experts on Global Geospatial Information Management (UN-GGIM), helping to promote innovation, leadership, frameworks, and partnerships to enhance geospatial information management globally. The Census Bureau is the appointed head of the U.S. Delegation to the UN-GGIM and Co-Chair for the High-level Group on the Integrated Geospatial Information Framework (IGIF).

2. In 2021, the Commerce Geospatial Working Group (CGWG) published the Commerce Geospatial Strategy (2021-2024) and the associated Commerce Geospatial Strategic Action Plan. In 2022, DOC made significant progress in meeting the GDA requirements, including monthly reporting to DOC's Chief Data Officer and DOC's Data Governance Board on key Commerce Geospatial Strategic Action Plan milestones and accomplishments. These documents refer to open international standards, standards initiatives, metadata standards implementation, and standards development to support enhanced interoperability and equitable access to all DOC geospatial data users. In FY21, DOC established terms of Reference and a Membership List for the Commerce Geospatial Standards Users' Group (CGSUG) to leverage geospatial expertise and innovation in standards.

3. During FY22, the CGWG supported the continuation of the CGSUG to raise awareness on critical geospatial topics and activities pertaining to standards. The CGSUG has established a core team dedicated to metadata and standards with members from the Census Bureau, the National Oceanic and Atmospheric Administration (NOAA), and the National Institute of Standards and Technology (NIST). The CGDUG has developed a library to hold metadata and standards documentation, participated in voluntary consensus standards development, collaborated with the OGC, and attended training on metadata standards and compliance.

4. The Census Bureau recently published the U.S. Census Bureau - Strategic Plan-Fiscal Year 2022 Through Fiscal Year 2026 (January 2022) and the GSP Program Strategic Plan, Fiscal Year 2022 Through Fiscal Year 2026 (August 2022). Both plans emphasize the importance of a nationwide geographic database with boundary information for legal, statistical, and administrative areas to support the Census Bureau's programs and activities. Methodological and technical advances in the global statistical and geographic communities reflect in the geographic data production and the development of tools, applications, and standards shared with international organizations such as the UN-GGIM and the Pan American Institute of Geography and History. The GSP operates within the constraints of U.S.C. Title 13, U.S.C. Title 15, and U.S.C Title 26 and federal geographic, address, and statistical standards.

5. Census Bureau staff are leading address standards development through the International Committee for Information Technology Standards (INCITS) Technical Committee L1 - Geographic Information Systems (INCITS-L1) and the U.S. Technical Advisory Group to the ISO Technical Committee 211 Geographic information/Geomatics (TC 211).

6. As a requirement of the GDA, the Census Bureau staff participated in the DOC Office of the Inspector General's GDA Audit in FY22 and completed initial deliveries of the FGDC

Covered Agency Report and Lead Covered Agency reports to provide information on their use of the ISO standards for all geospatial data, including 34 NGDAs.

7. The Census Bureau's NGDA datasets represent a portfolio of geospatial datasets derived from the MAF/TIGER System. The Census Bureau's TIGER/Line shapefiles for these NGDAs are accessible by the public and discoverable on Census.gov, GeoPlatform.gov, and Data.gov. Each year, Census NGDAs are harvested to these open data portals using metadata standards INCITS/ISO 19115-2:2019 (2019) Geographic information - Metadata - Part 2: Extensions for acquisition and processing, INCITS/ISO/TS 19139-2:2012 (2017) Geographic information - Metadata XML schema implementation - Part 2: Extensions for imagery and gridded data, and adherence to FAIR principles (Findable, Accessible, Interoperable, Reusable).

8. Census Bureau Geospatial Standards Working Group (CBGSWG) facilitates monthly meetings relating to implementing geospatial standards for Census Bureau products and services. In FY22, the CBGSWG documented metadata creation, quality control, and harvesting activities for the Census Bureau's NGDAs, produced a geospatial product inventory, and developed a road map for future standards activities.

9. The Census Bureau submitted responses, to the FGDC, for the NGDA Baseline Standards Inventory Survey in October 2020 and has renewed licensed subscriptions to twenty-three ISO standards through the American National Standards Institute (ANSI):

   - INCITS 31-2009 (R2019) Information Technology - Codes for the Identification of Counties and Equivalent Areas of the United States, Puerto Rico, and the Insular Areas.
   - INCITS 38-2009 (R2019) Information Technology - Codes for the Identification of the States and Equivalent Areas within the United States, Puerto Rico, and the Insular Areas.
   - INCITS 446-2008 (R2018) Information Technology - Identifying Attributes for Named Physical and Cultural Geographic Features (Except Roads and Highways) of the United States, Territories, Outlying Areas, and Freely Associated Areas, and the Waters of the Same to the Limit of the Twelve-Mile Statutory Zone.
   - INCITS 454-2009 (R2019) Information Technology - Codes for the Identification of Metropolitan and Micropolitan Statistical Areas and Related Statistical Areas of the United States and Puerto Rico.
   - INCITS 455-2009 (R2019) Information Technology - Codes for the Identification of Congressional Districts and Equivalent Areas of the United States, Puerto Rico, and the Insular Areas.
   - INCITS/ISO 19110:2016 (2018) Geographic information - Methodology for feature cataloging.
   - INCITS/ISO 19111:2007 [R2012] Geographic information - Spatial referencing by coordinates.
   - INCITS/ISO 19115-1:2014 (R2019) Geographic information - Metadata- Part 1: Fundamentals.

- INCITS/ISO 19115-2:2019 (2019) Geographic information - Metadata - Part 2: Extensions for acquisition and processing.
- INCITS/ISO TS 19139:2007 [2015] Geographic information - Metadata XML schema implementation.
- INCITS/ISO/TS 19139-2:2012 (2017) Geographic information - Metadata XML schema implementation - Part 2: Extensions for imagery and gridded data.
- INCITS/ISO 19157:2013 (R2019) Geographic information - Data Quality.
- INCITS/ISO 19115-2003 Geographic information - Metadata.
- INCITS 453-2009 [R2014] Information Technology - North American Profile of ISO 19115:2003 - Geographic Information - Metadata (NAP - Metadata).
- INCITS/ISO/TS 19115-3:2016 (2017) Geographic information – Metadata – Part 3: SML Schema Implementation for Fundamental Concepts.
- INCITS/ISO/IEC 19757-3:2016 (2018) Information technology - Document Schema Definition Languages (DSDL) - Part 3: Rule-based validation – Schematron.
- INCITS/TR-47-2012 (R2017) INCITS Technical Report for Information Technology - Fibre Channel - Simplified Configuration and Management Specification (FC-SCM).
- ISO/IEC 19757-3:2020 Information technology - Document Schema Definition Languages (DSDL) - Part 3: Rule-based validation using Schematron.
- ISO 19115-2:2009 Geographic information - Metadata - Part 2: Extensions for imagery and gridded data.
- ISO 3166-1:2020 Codes for the representation of names of countries and their subdivisions - Part 1: Country code.
- ISO 3166-2:2020 Codes for the representation of names of countries and their subdivisions - Part 2: Country subdivision code.
- ISO 3166-3:2020 Codes for the representation of names of countries and their subdivisions - Part 3: Code for formerly used names of countries.
- ISO/IEC 10646:2020 Information technology - Universal coded character set (UCS).

10. ISO 19160-2: The Census Bureau continued active involvement in the development of ISO 19160-2, Addressing - Part 2: Assigning and maintaining addresses for objects in the physical world. This standard specifies how to plan, implement, and maintain addresses and corresponding address data to gain maximum benefits for governance and society. While the Census Bureau does not assign addresses within local communities, it has extensive experience in national address data management and an understanding of the principles and requirements necessary to create an address maintenance system. This standard will be valuable to stakeholders embarking on new addressing systems (e.g., developing countries, communities planning or considering a re-addressing initiative) and those that want to

enhance their existing systems. Through participation in the development of ISO 19160-2, the Census Bureau gains valuable knowledge about how other nations maintain their data. This project also has the potential to help the Census Bureau's partners improve their address assignment and maintenance systems, which in turn will benefit the Census Bureau and other federal agencies seeking to obtain current, complete, and accurate address data. Expect ISO 19160-2 to publish in early 2023.

International Trade Administration (ITA)

ITA strengthens the competitiveness of U.S. industry, promotes trade and investment, and ensures fair trade through the support of rigorous enforcement of U.S. trade laws and agreements. Through its participation on U.S. delegations addressing global standards development and trade-related standards issues, ITA works to improve the global business environment and helps U.S. organizations compete at home and abroad. Information on ITA's work on standards can be found at: https://www.trade.gov/standards-information-and-resources.

In FY2022, ITA participated in a variety of trade-related international standards activities including standards development along with engaging in policy dialogues and capacity building efforts. ITA experts participated in the U.S. Technical Advisory Group (TAG) to ISO/TC293, Feed Machinery to support U.S industry's engagement through ITA's Market Development Cooperator Program (MDCP). ITA representatives also joined the virtual TAG for the recently formed ISO Special Advisory Group on Smart Farming (SAG SF), tasked with developing a gap analysis and standardization road map for smart farming applications.

ITA regularly notifies relevant U.S. stakeholders about opportunities to participate in new standards development activities that might have trade implications with the aim of preventing future market access issues for U.S. exporters. In FY2022 ITA also worked with NIST, the National Telecommunications and Information Administration (NTIA) and the Department of State to publish a monthly newsletter highlighting international standards development activities in critical and emerging areas where U.S. engagement could benefit commercial goals.

During FY2022, three U.S. Commercial Service officials from the U.S. Embassy in Mexico City and the U.S. Consulate General in Guadalajara participated in the working group for Mexican technical regulation NOM-194 on safety devices for passenger vehicles, convened to review public comments on the draft technical regulation.

ITA participates in the ANSI Unmanned Aircraft Systems Standards Collaborative. An ITA specialist continues to participate in the Smart Textiles Subcommittee of ASTM Committee D13 on Textiles and a staff member of the Commercial Section in the U.S. Embassy in Mexico City participates in the monthly sessions of Mexico's National Textile Standards Committee to monitor standards that could impact U.S. textiles and apparel exporters.

In FY2022 ITA was represented on interagency teams addressing standards policy and development in the International Civil Aviation Organization (ICAO), the World Health Organization (WHO) and in Codex Alimentarius. ITA worked on standards capacity building in the Asia-Pacific Economic Cooperation (APEC) Forum and the Association of Southeast Asian Nations (ASEAN) in areas including food safety, medical devices, cybersecurity, autonomous and electric vehicles, and conformity assessment. ITA engaged on standards issues with the ASEAN Consultative Committee on Standards and Quality

(ACCSQ), including organizing workshops and discussions on advanced manufacturing and digital trade standards – particularly those related to cybersecurity and promoting digital trust - and work on standards for critical and emerging technologies through the Quad (Australia, India, Japan, and U.S.) including on Artificial Intelligence (AI) and advanced communications.

Bilateral engagement on standards issues was ongoing with various trading partners including through the U.S.-Brazil Commercial Dialogue, the U.S.-Singapore Partnership for Growth and Innovation, and the U.S.-European Union (EU) Trade and Technology Council (TTC), among others. ITA maintained Standards Attaches in Beijing, Brussels, Johannesburg, Mexico City, and Sao Paulo.

ITA staff serve as part of the U.S. delegation headed by the Office of the U.S. Trade Representative (USTR) to the World Trade Organization's (WTO's) Committee on Technical Barriers to Trade (TBT) that addresses specific standards-related trade concerns. ITA, in coordination with USTR, pursued standards and conformity assessment-related trade concerns on the floor of the WTO TBT Committee against a number of countries in FY2022, including but not limited to China, India, Indonesia, the European Union, and Saudi Arabia. During FY2022, ITA also participated as part of the USG delegation for negotiations with Uruguay on a good regulatory practices (GRP) annex under the U.S-Uruguay Trade and Investment Framework Agreement (TIFA), in GRP negotiations with Taiwan, towards development of a GRP declaration under the Summit of the Americas, and in collaborative discussions with Kenya on TBT and standards. ITA regularly works with U.S. industry to address issues of non-compliance with trade agreement commitments found in the WTO TBT Agreement and respective Free Trade Agreement (FTA) TBT chapters.

Finally, ITA co-manages the Industry Technical Advisory Committee on Standards and Technical Trade Barriers (ITAC 15) with USTR which provides input to the Secretary of Commerce and USTR on standards-related policy matters.

National Institute of Standards and Technology (NIST)

NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve the quality of life. Below are a few of NIST's activities in several high priority areas addressing practical aspects of critical and emerging technologies and fundamental research illuminating potential new areas of interest for manufacturers.

As specified in the NTTAA, in authorizing legislation, and in OMB Circular A-119, NIST, through its Standards Coordination Office (SCO), assists and guides federal agencies in leveraging voluntary consensus standards and private sector conformity assessment mechanisms in their programs, procurement, and regulatory activities. SCO chairs the Interagency Committee on Standards Policy (ICSP) and works closely with federal agencies to reduce unnecessary duplication and complexity in standards and conformity assessment practices. The ICSP created two new working groups on Artificial Intelligence and Advanced Communications Technologies to advance interagency standards coordination in these critical areas. SCO provides consultation and advice to other Federal agencies in implementing conformity assessment programs, and holds leadership roles in ANSI governance, policy, and program oversight committees. SCO also hosts www.Standards.gov to serve as a standards and conformity assessment related resource for Federal agencies, industry, and the public.

5G Network Security

Through participation in 5G security-focused standards setting groups, NIST provides contributions and impact specifications relevant to our various areas of cybersecurity expertise. Some of these areas include cybersecurity risk management, identity and access management, and cryptography, including quantum safe cryptography. NIST participates actively in 3rd Generation Partnership Project (3GPP)'s Service and System Aspects – Security (SA3) working group.

Artificial Intelligence

NIST chaired the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Joint Technical Committee 1 Subcommittee (JTC 1 SC) 42 (Artificial Intelligence) working group (WG) 2 on AI and Data. The efforts of WG 2 advanced and matured ISO/IEC 5259 - Parts 1-5 Data Quality for Analytics and Machine Learning. NIST has been very active in ISO/IEC JTC 1 SC 27 Information security, cybersecurity, and privacy protection. SC 27 initiated an approved work item (AWI) project, ISO/IEC AWI 27090 *Cybersecurity — Artificial Intelligence — Guidance for addressing security threats and failures in artificial intelligence systems*. ISO/IEC AWI 27090 in its final form, will provide guidance for organizations to address security threats and failures in artificial intelligence (AI) systems.

Automotive Industry

NIST leads the U.S. TAG to ISO/IEC TC 22 SC 32 WG 12 Software Update for Road Vehicles and published the first international standard on updates to vehicles *ISO 24089:2023 – Software update engineering for road vehicles.* NIST staff served as the co-chair for the Cybersecurity Assurance Levels (CAL)/Targeted Attack Feasibility (TAF) project group that is working on follow-up work to the first international standard on automotive cybersecurity under the Joint Working Group for ISO and Society of Automotive Engineers (SAE) International.

Biometrics

NIST served as the chair of ISO/IEC JTC 1 SC 37 on Biometrics and contributed to the activities of multiple working groups under SC 37 focused on image quality for both face and fingerprint and demographic variations in performance. NIST actively engaged in the drafting of ISO/IEC 29794- 5 *Information Technology – Biometric sample quality – Part 5: Face Image Data* and ISO/IEC CD 19795-10 *Information Technology – Biometric performance testing and reporting – Part 10: Quantifying biometric system performance variation across demographic groups*. NIST staff were also heavily involved with preparing updates to ISO/IEC 29794-4 I*nformation technology – Biometric sample quality – Part 4: Finger image data*. NIST has also supported cross-cutting work on new terminology for use in evolving voice biometric standards with the aim of facilitating a uniform understanding of voice biometrics across U.S. government agencies.

Biotechnology

NIST manages the U.S. TAG to ISO TC 276 on Biotechnology. ISO TC 276 develops standards and reports addressing biobanks and bioresources, analytical methods, bioprocessing, data processing, and metrology related to biotechnology. NIST also serves as the chair of ISO TC 276 WG3 on analytical methods. TC 276 published 8 standards in FY 2022 and has 18 standards documents under development. NIST actively participates in all projects developed under this technical committee.

Blockchain

NIST actively participates in the activities of ISO TC 307 on Blockchain and Distributed Ledger Technologies and its U.S. mirror committee. NIST has contributed to ISO 22739 - *Blockchain and distributed ledger technologies — Vocabulary* and several other projects on identity, security, and interoperability, including a collaboration on digital currencies that is synchronized with interagency colleagues active in ISO TC 68 on Financial Services.

Biomedical

NIST served as a member of the Bioimaging North America (BINA) Quality Control and Data Management Working Group, with a focus on building a metrology suitcase for calibrating fluorescent microscopes and on image quality metrics. NIST also served as a member of the Quality Assessment and

Reproducibility for Instruments & Images in Light Microscopy (QUAREP-LiMi), Image Quality WG 10 and Stage Control WG 6. In addition, NIST engaged in the Data Management WG focused on uploading, storing, and downloading large microscopy datasets. The group aims to prepare a white paper that discusses funding the infrastructure for biomedical research.

Cyber Infrastructure

NIST played key leadership roles in support of cyber infrastructure standardization. A NIST representative served as the INCITS Subcommittee Vice Chair for ISO/IEC JTC 1 SC 38, the WG 3 Ad-Hoc Chair within SC 38, and the SC 38 Advisory Group Stakeholder Engagement Chair. NIST served as Chair of the Industry Internet of Things (IoT) (II) Consortium Architecture Task Group and various draft standards within the II Consortium. In addition, NIST actively participated in ISO/IEC JTC 1 SC 41 (IoT and Digital Twins) WG 3 activities, served as lead architect on ISO/IEC 30141 Internet of Things Reference Architecture ed2, and served on Advisory Group 8, also within ISO JTC 1, on Meta Reference Architecture and Reference Architecture for Systems Integration.

Cybersecurity

NIST contributes to various international standards development efforts related to cybersecurity risk management. The latest revision of ISO/IEC 27002 information security controls was published in February 2022 and contains attributes and concepts that align with the functions of the NIST Cybersecurity Framework. NIST serves as editor for a project (ISO/IEC 27028) developing guidance on using these attributes in ISO/IEC 27002 and will remain active within ISO/IEC JTC 1 SC 27 to help promote alignment between ISO standards and NIST resources, including the transition to the NIST Cybersecurity Framework Version 2.0. NIST also served as co-editor of recently published ISO/IEC 27070 - *Security techniques — Requirements for establishing virtualized roots of trust*. NIST participated in revisions to ISO/IEC 27017 - *Security techniques — Code of practice for information security controls based on ISO/IEC 27002 for cloud services*.

Cryptography and Post-Quantum Cryptography

NIST has made contributions to the revision of ISO/IEC 18031 *Information technology — Security techniques — Random bit generation* to facilitate alignment with NIST Special Publication (SP) 800-90. NIST also contributed to ISO/IEC14888-4 *Information security – Digital signatures with appendix – Part 4: Stateful hash-based mechanisms* to facilitate alignment with the stateful hash-based signatures specified in NIST SP 800-208. NIST staff has served as a co- editor on ISO/IEC preliminary work item (PWI) 19541 -- *Inclusion of key encapsulation mechanisms for Post-Quantum Cryptography*.

Cryptographic Module Validation

The Cryptographic Module Validation Program (CMVP) is the validation authority for Federal Information Processing Standards (FIPS) 140-3. FIPS 140-3 “Security Requirements for Cryptographic Modules” and NIST SP 800-140 “FIPS 140-3 Derived Test Requirements (DTR): CMVP Validation Authority Updates to ISO/IEC 24759” align with the following ISO/IEC standards: ISO/IEC 19790 and ISO/IEC 24759, respectively. Two NIST staff members participated in ISO/IEC JTC 1 SC 27 WG 3 activities to develop both standards.

Digital Evidence and Forensic Science

NIST served as Liaison to the Scientific Working Group on Digital Evidence (SWGDE) Executive Committee and as Project Lead on Quality Management for SWGDE. NIST also served as Vice Chair for

the Organization of Scientific Area Committees Digital Evidence Sub-Committee and participated in the (American Society for Testing and Materials) ASTM E.30 on Forensic Sciences.

Identity Management and Authentication

NIST participates in several committees and standardization initiatives related to identity management and authentication, including ISO/IEC 24760 series - *A framework for identity management*, ISO/IEC 23220 - *Building blocks for identity management via mobile devices* series, ISO/IEC 18013 Part 5 - *Mobile driving license (mDL) application* and Part 7 - *Mobile driving license (mDL) add-on functions*.

Interoperable Health Information

NIST held leadership positions as the Health Level 7 (HL7) Conformance Work Group Co-chair, HL7 v2 Management Board Member, and HL7 Healthcare Device Work Group Co-chair. A NIST representative also served as the test lead for Integrating Healthcare Enterprise (IHE) devices and participated in IHE-DEV technical and planning committees. NIST contributed to various activities within the HL7 V2 Management Working Group (V2MG) and the HL7 Terminology Services Management Working Group.

Internet of Things (IoT)

NIST is actively engaged within JTC1 SC 27 WG 4 on IoT Security activities, including significant contributions to ISO/IEC 27404 - *Cybersecurity labelling framework for consumer IoT* and ISO/IEC 27402 - *IoT security and privacy - Device baseline requirements.* Within IETF, NIST co-chairs the Software Updates for Internet of Things (SUIT) working group focused on designing a firmware update solution suitable for tiny IoT devices.

Privacy

NIST provided extensive technical contributions to ISO/IEC 27557 - *Application of ISO 31000:2018 for organizational privacy risk management*. This standard offers a framework for assessing organizational privacy risk, with consideration of the privacy impacts on individuals as a component of overall organizational risk. NIST also engaged on ISO/IEC 31700 - *Privacy-by- design for Consumer Goods and Services*, a multi-part publication focused on supporting consumer trust in the digital economy. NIST contributed to Part 1 on high-level requirements, and Part 2 on use cases. NIST contributions for both documents promoted alignment with NIST privacy risk management and privacy engineering guidance. NIST also serves as project editor for the revision of ISO/IEC 27018 – *Security Techniques —Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors,* which is updating privacy controls for use by cloud service providers.

Usability

NIST contributed to standards on the testing of usability-related information. As experts in Joint Working Group 28 of ISO/IEC JTC 1 SC 7 on software and systems engineering, NIST participated in writing the ISO/IEC TC 159 SC 4 and ISO 2506x series of standards on Common Industry Formats (CIF) for Usability Reports. NIST also worked on revisions for the following documents: ISO/Technical Report (ISO/TR) 25060 – *General framework for usability-related information*; ISO 25062 – *Reporting usability evaluations* and ISO 25066 – *Evaluation report*.

International Cooperation

NIST co-chairs the 1) U.S.-EU Trade and Technology Council, Technical Standards Working Group with ITA and 2) The QUAD Critical and Emerging Technology Working Group's Technology Standards Sub-Group with the Department of State. These efforts identify areas of standards cooperation aligned with

technology leadership and trade facilitation and are focused on cooperative work in areas such as artificial intelligence and advanced communications technology.

National Oceanic and Aeronautic Administration (NOAA)

NOAA's mission hinges on the effective sharing of its data for use by the public, industry, and academia. That sharing is underpinned by standardization of data acquisition and data management practices. NOAA seeks to establish and use voluntary standards with selected industrial associations, academia, and national organizations of state and local governments (e.g., the American Association of State Climatologists), as well as through participation in professional societies (e.g., American Meteorological Society (AMS)) and Standards Development Organizations (e.g., Open Geospatial Consortium (OGC)) as well as international organizations (e.g., United Nations (numerous committees) and International Hydrographic Organization (IHO)). All NOAA line organizations participate in standards development activities, which are coordinated through NOAA's Data Governance Committee (DGC), which is chaired by the NOAA Chief Data Officer.

Standards used in many NOAA activities are established in conjunction with other Federal agencies either through joint participation in national (e.g., Federal Geographic Data Committee (FGDC)) and international (e.g., United Nations committee of experts on Global Geospatial Information Management (UN-GGIM)) organizations or by means of bilateral and multilateral agreements with other nations.

The following presents highlights examples of the ways that NOAA actively engages in not only the adoption of but also the development of voluntary consensus standards:

- NOAA is an active leader, participant, and contributor to the FGDC, the lead entity (established by Geospatial Data Act of 2018 (GDA)) for the development, implementation, and review of policies, practices, and standards relating to geospatial data across the Federal government and the National Spatial Data Infrastructure (NSDI), which per Executive Order 12906 (Coordinating Geographic Data Acquisition and Access) is the technology, policies, standards, and human resources necessary to acquire, process, store, distribute, and improve utilization of geospatial data. NOAA leads four NSDI data themes and contributes to many others.
    - NOAA and Census co-led the Department of Commerce's response to the recently completed 2022 Department of Commerce Inspector General's GDA Audit. NOAA's Chief Data Officer is the Senior Agency Official for Geospatial Information. NOAA and Census co-developed an action plan to address the Audit's five recommendations.
- NOAA leads the Integrated Ocean Observing System (IOOS), a part of the Global Earth Observing System of Systems (GEOSS), which ascribes to the GEOSS data sharing principles as a core capacity. The U.S. IOOS Program Office is organized into two divisions that implement policies, protocols, and standards to implement IOOS and oversee the daily operations and coordination of the System. For more information on IOOS standards, visit the IOOS Data Standards and Requirements webpage.
- NOAA's National Geodetic Survey (NGS) represents the U.S. on the UN-GGIM's Subcommittee on Geodesy (UN SCoG), which developed the Global Geodetic Reference Frame (GGRF). The GGRF includes information on infrastructure, education, training, governance, and the adoption of internationally accepted standards.

- NOAA’s Center for Operational Oceanographic Products and Services (CO-OPS) represents the U.S. on the Global Sea Level Observing System Group of Experts (GLOSS GE), a component of the IOC/Global Ocean Observing System (GOOS), whose efforts are focused on e establishing high quality, global water level data sets to support a broad research and operational user base. GLOSS's main work is to establish and disseminate best practices and standards for operating water level stations and support international data centers.

- NOAA's Office of Coast Survey (OCS) and CO-OPS represent the U.S. in the IHO, an international organization that coordinates the activities of national hydrographic offices, promotes uniformity in nautical charts and documents, and issues survey best practices, provides guidelines to maximize the use of hydrographic survey data and develops hydrographic capabilities in Member States. OCS is also active in several regional hydrographic commissions.

- NOAA has strengthened its long-standing relationship with the Open Geospatial Consortium (OGC) by becoming a Strategic member and continues championing open standards and innovation at OGC. As a Strategic Member, NOAA supports the consortium's OGC applicable programming interface (API) and cloud-native geospatial modernization efforts by championing the standards applicable to Findable, Accessible, Interoperable and Reusable (FAIR) environmental data (such as OGC API - Environmental Data Retrieval), and benefit from, and contribute to, the OGC Community's collective problem solving via the OGC Innovation Program. For more information on OGC's efforts to ensure geospatial information interoperability, visit the OGC Standards webpage.

- NOAA contributes U.S. expertise to help the global community deal with the meteorological, climatological and hydrological threats via its membership in and engagement with the World Meteorological Organization (WMO), an agency of the United Nations (UN) that serves as the international standardization organization in the fields of meteorology, hydrology, climatology and related environmental disciplines. The WMO's standards and best practices include Technical Regulations, an international framework for standardization and interoperability, which consists of standard and recommended practices and procedures adopted by World Meteorological Congress for universal application by all members, as well as Guides, which describe practices, procedures and specifications which members are invited to follow or implement in order to achieve compliance.

- NOAA participates in national standards organizations ANSI and INCITS and the international standards organization ISO TC211.

- NOAA applies environmental management standards set by ISO to NOAA data. Examples of ISO standards in use in NOAA include:

    - ISO 14721: "Open Archival Information System (OAIS)" which defines the reference model for an OAIS. This standard is the basis for archival activities supporting NOAA environmental data.

    - ISO 26324: "Information and documentation - Digital object identifier system" which specifies the syntax, description and resolution functional components of the digital object identifier system. NOAA assigns unique, resolvable, and persistent identifiers to archival datasets and technical reports. Building upon this standard, NOAA recently developed a report on digital object identifiers (DOI) recommendations for use across NOAA and is in the process of updating its Public Access to Research Results (PARR) Plan to also address DOIs.

    - ISO 19115: "Geographic information – Metadata" which defines the schema required for describing geographic information and services by means of metadata. NOAA participates in the ISO TC211, a committee that focuses on

standardization in the field of digital geographic information and maintains standards for Geographic information/Geomatics.

    - ISO 19139: "Geographic information — XML schema implementation" which defines XML based encoding rules for conceptual schemas specifying types that describe geographic resources. The encoding rules support the unified modeling language (UML) profile as used in the UML models commonly used in the standards developed by ISO/TC 211.

- NOAA National Weather Service (NWS) meteorological data and reports comply with WMO Standards. NOAA serves as one of the WMO Information System (WIS) Global Information System Centres (GISC) and provides a portal to search all WMO Region IV data center metadata. Additionally, NOAA operates several WMO-recognized global centers, including the Aviation Weather Center (AWC), the Space Weather Prediction Center (SWPC), the National Hurricane Center (NHC), and the Ocean Prediction Center (OPC). For more information on the NWS role in support of the WMO, visit the NWS' WMO webpage.

- U.S. marine fisheries are scientifically monitored, regionally managed, and legally enforced under a number of requirements, including ten national standards, that taken together provide principles that must be followed in any fishery management plan to ensure sustainable and responsible fishery management. As mandated by the Magnuson-Stevens Fishery Conservation and Management Act, NOAA Fisheries has developed guidelines for each national standard. For more information on the standards, visit the NOAA Fisheries Standards webpage.

- NOAA's National Centers for Environmental Information (NCEI) is the Nation's leading authority for environmental data and manages one of the largest archives of atmospheric, coastal, geophysical, and oceanic research in the world. In this role, NCEI follows and implements the ISO metadata standard to facilitate data search and discovery. Metadata at NOAA can be represented in number of different standards and formats including Directory Interchange Format (DIF), Ecological Metadata Language (EML), Sensor Model Language (SensorML), Climate Science Modeling Language (CSML), and NetCDF Markup Language (NcML). NCEI uses the ISO 14721 OAIS Reference Model standard as the basis for archival activities supporting NOAA environmental data. NCEI also provides distributed data access via the Open source Project for a Network Data Access Protocol (OPeNDAP) compliant THREDDS and ERDDAP data servers.

National Telecommunications and Information Administration (NTIA)

NTIA contributes to the development and application of national and international telecommunication standards by leading, participating in, making technical contributions to, and collaborating with various voluntary national and international telecommunication standards committees, such as the 3GPP, International Telecommunication Union (ITU-R, ITU-T), the Institute of Electrical and Electronics Engineers (IEEE) Standards Association, Radio Technical Commission for Aeronautics (RTCA), and Alliance for Telecommunications Industry Solutions (ATIS).

In addition, NTIA's Institute for Telecommunication Sciences (NTIA-ITS) established and continues to play a significant role in the Video Quality Expert Group (VQEG), which performs technical validation that is a prerequisite to standardization. VQEG is currently focused on collaborative efforts to develop new and improved methods for subjective and objective video quality assessment. VQEG contributes

these updated methods to the ITU, where ITU Recommendations are modified to accommodate rapid changes in video technologies.

In FY 2022, NTIA staff held 88 positions in 9 standards bodies, including 18 Chair/Co-Chair/Vice-Chair positions.

- NTIA staff filled key leadership positions in the ITU-T, including Head of the U.S. Delegation to Study Group (SG) 11 (Signaling requirements, protocols, test specifications and combating counterfeit products), Chair of the Telecommunication Standardization Advisory Group (TSAG) Rapporteur Group on Restructuring, and Vice-Chair of Q1/17 (Security standardization strategy and coordination).

- NTIA staff also filled key leadership positions in the ITU-R, including Head of the U.S. Delegation to SG1 (Spectrum management) and SG3 (Radiowave Propagation); Head of Delegation to SG1 Working Party (WP) 1A; Head of Delegation to SG5 (Terrestrial services) WP 5B and 5C; International Chair of SG5 WP 5C and 5D; Deputy Head of Delegation to SG7 (Science services) and SG7 WP 7C; International Chair and U.S. Chair of SG3 WP 3K; U.S. Chair of Working Parties 3J and 3L; and Chair of Correspondence Groups CG-3L-7 (Radio Noise), CG-3J-11 (Reference Standard Atmospheres), and CG-3K-3M-9 (Aeronautical Propagation).

- Within the Inter-American Telecommunications Commission (CITEL), NTIA holds Vice-Chair position within the Permanent Consultative Committee I for Telecommunications/Information and Communications Technology (PCC.I) Working Group for the Preparation and Follow-up of the World Telecommunication Standardization Assembly (WTSA), World Conference on International Telecommunications (WCIT), and World Telecommunication Development Conference (WTDC); Deputy Head of Delegation to the Permanent Consultative Committee II (PCC.II) for Radiocommunications; and International Working Group Chair of the CITEL PCC.II Working Group relative to CITEL's Preparation for World Radiocommunication Conferences.

International Telecommunications Union (ITU)

NTIA-ITS leads U.S. efforts at the ITU-R Study Group 3 (SG3), the technical group that focuses exclusively on radio wave propagation. At SG3, NTIA-ITS contributes inputs and ensures the technical accuracy and correctness of international radio wave propagation standards. SG3 Recommendations on radio wave propagation are treaty-level agreements and play a role in international agreements on spectrum allocations and sharing scenarios, such as the on-going discussions of 5G mid-band spectrum and mmWave spectrum.

In FY 2022, three of the 14 U.S. technical contributions to Study Group 3 were authored or coauthored by NTIA-ITS. NTIA-ITS submitted a proposal to replace the software GRWAVE with the ITS-developed LFMF-SmoothEarth for Recommendation ITU-R P.368 (Ground-wave propagation curves for frequencies between 10 kHz and 30 MHz), which is used to support broadcast services. NTIA-ITS chairs three Study Group 3 Correspondence Groups. Correspondence Group CG-3K-3M-9 (aeronautical propagation) is working towards improvements in Recommendation ITU-R P.528 as well as a new site-specific aeronautical propagation Recommendation. Correspondence Group CG-3L-7 (radio noise) continued its work on improving prediction of radio noise and produced editorial amendments to Recommendation ITU-R P.372 which corrected a few figures and improved software usability. Lastly, Correspondence

Group CG-3J-11 (reference standard atmospheres) continued to analyze and process the 2021 release of the European Centre for Medium-Range Weather Forecasts (ECMWF) Reanalysis data (ERA5), aiming to create a model for a single, global, reference standard atmosphere.

NTIA's Office of International Affairs (OIA) followed and/or provided inputs to various ITU-T Sector Study Groups, which consider "Recommendations" on such diverse subjects as M2M/IoT (Machine to Machine/Internet of Things) traffic, OTT (Over the Top), Distributed Ledger Technology (DLT), Revised Internet Network Architecture proposals (e.g., New IP, Polymorphic Networking), facial recognition, Security by Design and Cybersecurity testing, and IoT/Smart Cities. In addition to these topics, OIA, with technical support from NTIA-ITS, has been participating heavily in ITU-T Study Groups 11 and 13 to counter regional adversary efforts to develop alternate Internet Protocol standards in the ITU rather than in more appropriate SDOs; NTIA-ITS led the U.S. delegation in those study groups. NTIA's work in ITU-T focuses on industry-led, bottom-up, consensus-based standards and appropriately working with

U.S. government colleagues to help ensure the ITU-T avoids duplication of efforts with other standards development organizations such as 3GPP and Internet Engineering Task Force (IETF). NTIA-OIA also provides U.S. leadership in the ITU-T Telecommunications Specification Advisory Group (TSAG) to assure that the rules of operation to create ITU-T Recommendations do not disadvantage U.S. industry.

NTIA's Office of Spectrum Management (NTIA-OSM), International Spectrum Policy Division (ISPD) participated in and/or led delegations to several ITU-R working party and study group meetings. Specifically, ISPD staff led delegations for ITU-R Study Group 1 (Spectrum Management), WP 1A (Spectrum Engineering Techniques), and participated in WP 1B (Spectrum Management Methodologies and Economic Strategies) and WP 1C (Spectrum Monitoring). ISPD staff supported NTIA-ITS activities in ITU-R SG3 and followed all activities in ITU-R SG6 (Broadcasting services) which has four separate working parties related to end-to-end broadcasting over terrestrial systems.

NTIA-OSM ISPD staff co-led SG 4 (Satellite Systems) participation for the U.S. and participated in and helped manage U.S. participation in WP 4A (Fixed Satellite Service (FSS) and Broadcasting Satellite Service (BSS) systems) and WP 4B (Technical aspects for FSS, BSS, and Mobile Satellite Service (MSS)). ISPD Staff also participated in WP 4C (Orbit/spectrum utilization for MSS and Radio Determination Satellite Service (RDSS)) and SG 5 (Terrestrial Systems), where they served as international vice chair and led U.S. delegations to WP 5B (Maritime, Radar, and Aeronautical systems) and WP 5C (Fixed Systems). In addition, ISPD staff participated in WP 5A (Mobile Systems) and WP 5D (International Mobile Telecommunications (IMT) - broadband systems, i.e., 3G/4G/5G/6G) where they hold lead positions for specific sub-groups both internationally and for the U.S. delegations.

ISPD staff also participated in the Task Group 6/1 which is addressing broadcasting/broadband sharing in the 470-960 MHz band in Region 1 (Europe, Middle East, Africa). ISPD staff participated in the SG 7 (Space Sciences) meetings and participated and supported federal government leads for WP 7A (Time Signals and Frequency Standard Emissions), WP 7B (Space Radiocommunication Applications), 7C (Remote Sensing Systems) and 7D (Radio Astronomy).

ISPD staff also participated in the ITU Coordination Committee for Vocabulary which works on non-regulatory definitions commonly utilized within the ITU (all three sectors). ISPD staff participate in International Civil Aviation Authority (ICAO) meetings which develop international procedures for civil aviation; International Maritime Organization (IMO), a treaty level organization for development of requirements for commercial maritime operations including safety of ships and ports; and North Atlantic Treaty Organization (NATO) spectrum management committees which develop positions and recommendations for World Radio Conferences (WRCs). Finally, ISPD staff participate in the CITEL

PCC.II (Radiocommunication and Broadcasting) meetings to develop regional positions for WRC and to develop recommendations and reports on spectrum management throughout the Americas.

3rd Generation Partnership Project (3GPP)

Direct participation by NTIA in 3GPP, the dominant cellular communications standards development organization, allows NTIA to advance U.S. commercial, economic, and government interests by providing technical input to promote strong unbiased standards that support fair competition in next generation/5G cellular technologies. NTIA-ITS is currently engaged in 3GPP Technical Specification Groups (TSG) for Radio Access Networks (RAN) and Services & Systems Aspects (SA) and attends the RAN Plenary meetings. NTIA-ITS participates in 3GPP Working Groups for Services (SA WG1), System Architecture and Services (SA WG2), and Security and Privacy (SA WG3), as well as RAN WG1, focused on the physical layer for LTE and 5G. Additionally, NTIA-OIA participates in TSGs SA and RAN at a Plenary level.

In FY 2022, NTIA-ITS continued to provide other U.S. Government stakeholders a comprehensive understanding of the 3GPP New Radio (5G NR—the global standard for the air interface of 5G networks) capabilities, the services 5G NR was built to deliver, and deployment scenarios in both licensed and unlicensed spectrum for the evolution to 5G. ITS provided briefings to other agencies (under interagency agreements) on agency-specific concerns with regard to standardization developments with respect to spectrum sharing, vehicle-to-everything communication, non-terrestrial networks, unmanned aerial vehicle and cyber security topics relative to security vulnerabilities in 4G and 5G systems architecture.

NTIA-OSM attends 3GPP Technical Specification Group RAN 1 and RAN 4. NTIA-OSM's goals are to: gain a more in-depth understanding of 3GPP standards and models used in compatibility studies; monitor 3GPP proposals that have a potential to impact federal operations; identify 3GPP spectrum standards that could be adopted for federal systems; and verify that 3GPP standards are being properly used in domestic and international spectrum sharing studies.

Internet Engineering Task Force (IETF)

In FY 2022, OIA scaled back its engagement with the IETF compared to prior years but continues to monitor IETF work.

O-RAN ALLIANCE

The Open Radio Access Network (O-RAN) ALLIANCE was founded in 2018 by a number of large mobile broadband network operators to develop technical specifications for Open RAN, or O-RAN architecture. The O-RAN ALLIANCE initially discouraged membership by governmental entities, but after extensive discussion in 2022, governmental agencies are now permitted to join as members. NTIA is currently in the process of obtaining internal clearance and approval for O-RAN alliance membership. Pending approval, NTIA-ITS and NTIA's Office of Policy Analysis and Development (OPAD) will send members to participate in and observe O-RAN Alliance work. In FY 2022, NTIA-ITS carried out the first of two 5G Challenge competitions focused on accelerating the adoption of open interfaces, interoperable subsystems, and modular, multi-vendor solutions. During the first-year event, 5G Challenge Event: RAN Subsystem Interoperability, NTIA-ITS executed a first-of-its-kind independent, objective interoperability testing event that assessed how vendor products adhere to 3GPP standards and O-RAN ALLIANCE specifications in multi-vendor networks.

Wireless Innovation Forum (WInnForum)

NTIA-ITS participates as a member of WInnForum. Following the 2015 Federal Communications Commission (FCC) allocation of the 3550-3700 MHz spectrum band for the Citizens Broadband Radio Service (CBRS) through a three-tiered access system that includes Environmental Sensing Capability (ESC) sensors and Spectrum Access System (SAS) databases, NTIA-ITS participated in the development of the underlying standards for this three-tiered access system and, in collaboration with the FCC and industry Cooperative Research and Development Agreement (CRADA) partners, developed the certification test requirements to assess compliance with the standards. The final certification test system for ensuring SAS conformance with Part 96 of the FCC's rules, which includes the test harness component developed through WInnForum, will be delivered to the FCC in FY 2023.

Radio Technical Commission for Aeronautics (RTCA)

RTCA is the standards body for aircraft manufacturers and operators. The NTIA-OSM is a paid member of RTCA and has worked over the past year to help develop technical documentation of the future capabilities for radio altimeters and will continue supporting the work in development of a new RTCA standard (Minimum Operating Performance Standard – MOPS) for radio altimeters operating in the 4.2-

4.4 GHz band.

Video Quality Experts Group (VQEG)

Since its creation in 1997, NTIA-ITS has supported VQEG with leadership and electronic working methods. In FY 2022, NTIA-ITS contributed to discussions to create a new video quality metadata standard. Many video quality encoders produce quality assessments that are discarded due to the lack of a standard mechanism to propagate the quality assessments in video streams. The VQEG solution will enable intelligent industry responses to quality of experience (QoE) problems in various video transmission and streaming services. VQEG conducts open meetings, which enables broad international participation from industry, academia, and governments. This idea will be forwarded to ITU-T, the Motion Picture Experts Group (MPEG), and the Alliance for Open Media (AOMedia) in FY2023.

United States Patent and Trademark Office (USPTO)

USPTO contributes to the development of international standards for patent and trademark information and documentation primarily through participation of USPTO scientific and technical experts to the Committee on WIPO Standards (CWS) of the World Intellectual Property Organization (WIPO). The standards developed are used by the USPTO and other international intellectual property organizations around the world to harmonize intellectual property information practices. The standards harmonize practices regarding electronic data processing procedures with respect to filing, examination, and publication of intellectual property data. The standards facilitate the exchange, sharing, dissemination, access and retrieval of intellectual property data and documents. USPTO staff also participate in standardization activities of the International Patent Classification (IPC) Union. The IPC provides a hierarchical system for the classification of patents according to different areas of technology. The worldwide access to patent and trademark data and documents supports U.S. industry and

organizations' knowledge of national and international intellectual property.
https://www.uspto.gov/patents-application-process/patent-search/understanding-patent-classifications/international.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2020. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY): 0

Department of Defense (DoD) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The primary goal of the Department of Defense (DoD) is to support our nations warfighter in the most efficient, effective, and cost-conscious manner possible while meeting mission objectives. Standards and standardization are essential elements to ensuring cost containment and operational effectiveness are achieved during the development and continued maintenance of DoD systems and subsystems. More information on the Defense Standardization Program can be found at https://www.dsp.dla.mil.

DoD relies on voluntary consensus standards (VCS) to gain access to cutting edge technologies within the global marketplace while reducing total acquisition costs. Currently, DoD has adopted 8,123 VCS approved for use within the Department of Defense. Each of these 8,123 VCS is cataloged with an adoption notice in the ASSIST database (https://assist.dla.mil), which gives visibility of the VCS so that others within DoD may use that standard in implementing their own systems or programs. Each adoption notice provides contact information for the adopting activity should any potential DoD users have questions regarding the technical content, or how to get a copy of the document. To promote the use of VCS by DoD, publishing an adoption notice is highly encouraged, but it is not a mandatory prerequisite for their use.

Therefore, the number of adoption notices for VCS is only a partial representation of their use in DoD. Many additional VCS documents are called out in DoD acquisitions and used in defense systems. Over 2500 VCS are cited as normative references in DoD standardization documents. Similarly, normative references to VCS are found in International Standardization Agreements and are used by DoD in the implementation of U.S.-ratified International Standardization Agreements. The extensive use of VCS allows DoD to gain access to cutting edge technologies and to be interoperable with our allies and partners.

In Fiscal Year 2022, DoD adopted 35 VCS in several areas, including: Construction Building Materials; Hardware and Abrasives; Paints, Dopes, Sealants and Adhesives; Non-Metallic Fabricated Materials; Electrical and Electronic Equipment Components; Electrical Connectors; Engine, Turbines, and Components; Pipe, Tubing, Hose and Fittings; Pumps and Compressors; Firefighting Equipment; and Glass Fabricated Materials. DoD also canceled 200 military unique documents and replaced 14 of them with VCS.

While DoD continues to support and use VCS for many different purposes, there are times where military unique requirements cannot be satisfied by VCS, and as such, DoD must continue to develop GUS to carry out its defense mission and meet warfighter needs. In FY 22, 34 documents were created based on military unique needs. These documents call out requirements for items used in weapon systems and other tactical military grade equipment that are unique to the department and not covered by VCS or available in the commercial marketplace. Wherever possible, DoD implements the

requirement to use VCS to avoid duplication. The Department actively encourages DoD to personnel participate in VCS bodies at all levels from policy to technical committees as means for adopting and referencing best practices and inserting technological innovation in weapon systems where practicable.

The Department continues to participate with other Federal Government Agencies in working to implement policies and procedures related to standardization and in particular the use of VCS. In addition, DoD has taken an active role by leading various sub-committees and panels looking into policy issues surrounding participation and use of VCS.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

This agency reports voluntary consensus standards usage on a categorical basis.

Department of Energy (DOE) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

In 2022, as in previous reporting years, the Department of Energy (DOE) relied heavily on voluntary consensus standards (VCSs) to fulfill its mission and has a long history of working with the VCS community to develop standards that help DOE achieve its missions. DOE supports federal and contractor participation on appropriate VCS committees and writing bodies and tracks participation. Appropriate VCSs are referenced or invoked in our directives or contracts to meet our specific requirements.

The DOE Technical Standards Program has a detailed set of procedures called Technical Standards Program Procedures (TSPPs), which include the requirement to perform a mandatory search for existing VCSs prior to initiating a DOE Standard development or revision project. The Department has a robust project justification process which demands that a potential DOE Standard developer perform searches for existing VCSs and document not only the results of those searches, but also the methods used to perform the searches. In September 2021 the DOE acquired an online subscription to VCS access. This subscription is managed through the DOE Technical Standards Program. Having this subscription enables Department standards developers to conduct more efficient searches for VCS which could be used in lieu of developing, revising, or reaffirming DOE Technical Standards documents. In 2022, the scope of the subscription service was further expanded in response to an increased demand for VCS access. The Department recognizes that new VCSs are always being developed and approved.

Therefore, the project justification process includes the requirement to perform VCS searches when revising DOE Standards as well as when developing new DOE Standards. Lastly, DOE Standards can also be reaffirmed, meaning that the DOE Standard does not require technical changes to remain appropriate for use. The next revision of the TSPPs is scheduled to take place in CY-2023 and will include a VCS search requirement for reaffirmation. This requirement will make it mandatory to perform searches for any newly approved VCSs which could be used in lieu of reaffirming a DOE Standard.

DOE does not have a conformity assessment program, and therefore does not track conformity assessment activities regarding VCSs.

DOE Technical Standards Program Internet Link:

https://www.standards.doe.gov/

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years currently in use (previous years and new as of this FY): Current total GUS: 0

Department of Health and Human Services (HHS) Fiscal Year 2022 Agency Report

1. **Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.**

Agency for Healthcare Research and Quality (AHRQ)

The mission of AHRQ is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. AHRQ uses voluntary consensus standards in our national Medical Expenditure Panel Survey, in our Healthcare Costs and Utilization Project, and in our Quality Indicators. AHRQ supports the U.S. standards developing organizations (SDOs) through participation in relevant workgroups. By improving the uniformity, accuracy, validity, and digitization of health data used for research and decision making, AHRQ increases the robustness of its research findings and the usability of tools developed based on these findings.

Centers for Disease Control and Prevention (CDC)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

CDC Centers, Divisions, and Programs work in consensus with partners in a voluntary manner to develop, evaluate, and apply standards for data capture and dissemination. Below is a summary of significant standards for communications, messaging, data structuring and transport. CDC endeavors to follow industry or community agreed upon standards with subtle content level modifications to accommodate the complex and varied demands of public health whenever possible. During the development process, CDC works with local public health departments, academia, non-profits, and healthcare industry and information technology partners to collaboratively achieve consensus.

Type / Domain Document Transaction Standard(s) Used Status

- Communications and Directory HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US

- Cancer Reporting:

(Stage 3 MU) HL7 CDA Published

Communications and Directory Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries (March 2014)

- Cancer Reporting:

(Stage 2 MU) HL7 CDA Published

Communications and Directory Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries (August 2012)

- Cancer Reporting

(Stage 2 MU) HL7 CDA Published

Communications and Directory PHIN Communication and Alerting (PCA) Guide Version 1.3 (April 27, 2010) Public Health Alerting EDXL V 1.0

CAP V1.1 Published

Communications and Directory PHIN Directory Exchange Implementation Guide Version 1.0 (May 16, 2007)

Public Health Directory Exchange DSML 1.0 Published

- ELR HL7 Version 2.5.1 Implementation Guide:Electronic Laboratory Reporting to Public Health (US Realm), Release 2, HL7 Informative Document (May 2014)

(HL7 account required) Electronic Laboratory Reporting to Public Health HL7 2.5.1 Published

- NNDSS https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html Specific Notifiable Disease Reporting to Public Health (Final Guides) HL7 2.5.1 Published Syndromic Surveillance (HL7 Standard for Trial Use) Syndromic Surveillance Message Mapping Guides

Syndromic surveillance transmissions from healthcare providers to public health HL7 Version 2.5.1, ICD-10-CM,

SNOMED-CT, LOINC,

Rx Norm, UCUM,

CPT4 HL7 Standard for Trial Use v.1. Available on the HL7 website (membership required.) Syndromic Surveillance PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 (April 2015)

- Erratum to the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings ADT Messages A01, A03, A04 and A08 Optional ORU^R01 Message Notation for Laboratory Data HL7 Version 2.5.1 (Version 2.3.1 Compatible) Release 2.0 April 21, 2015pdf icon

PHIN 2.0 Implementation Guide Meaningful Use Clarifying Document (PDF available on NIST Website)external icon

Sending data from emergency department, urgent, ambulatory care and inpatient settings to public health authorities

- Certifying 2014 Edition Meaningful Use electronic health record technology HL7 2.5.1 Published as CDC version 2.0

Center for State, Tribal, Local, and Territorial Support (CSTLTS)

The Centers for Disease Control and Prevention (CDC) Center for State, Tribal, Local, and Territorial Support (CSTLTS) has been a key supporter in the development, launch and support of the voluntary accreditation program for public health departments. A non-profit accrediting body, The Public Health Accreditation Board (PHAB), leads the accreditation program which launched in September 2011. Until the establishment of PHAB, there had been no national accreditation program for public health departments. The initial national consensus standards were released in July 2011 (Version 1.0), an update (Version 1.5) was released in 2014, and PHAB released the Version 2022 Standards and Measures in FY22 with support from CDC to produce and vet the new standards. CDC has been involved as a partner and funder of this initiative to provide support to PHAB's accreditation and continuous improvement activities as evidenced through its accreditation page at (https://www.cdc.gov/publichealthgateway/accreditation/). The first cohorts of health departments were accredited in early 2013. As of the end of FY 2022:

- PHAB has accredited 427 health departments—40 states, six tribes, and 381 local health departments (including 314 individually accredited local health departments and 67 county health departments through a centralized state application).

- 91% of the U.S. population is served by an accredited health department (HD).

- PHAB began reaccrediting sites in 2018; 81 sites have been reaccredited.
- 497 HDs, including 42 SHDs, are formally in the accreditation process (applied or accredited) and are demonstrating how they meet the national standards.

All documents related to the accreditation program (the standards, assessment process guidance, glossary, etc.) are available at www.phaboard.org. Annual evaluation findings consistently report short- and long-term benefits to participating in accreditation. June 2022 evaluation data indicate that the program has stimulated quality improvement (95% of accredited health departments agree), improved accountability and transparency (89%), improved the capacity of the department to provide high quality programs and services (82%), and improved collaboration across units within the health department (88%) one year after accreditation. Four years after accreditation, accredited health departments report that the program has helped health departments use health equity as a lens for identifying and addressing health priorities (74%) and strengthened the utilization of resources (65%). More information about the accreditation program can be found at (http://www.phaboard.org) and aggregate accreditation data about health department capacity, searchable by PHAB domain, theme, and health department characteristics, can be found at the PHAB data portal at (www.phabdata.org).

Division of Cancer Prevention and Control (DCPC)

CDC's National Program of Cancer Registries (NPCR) works to measure progress in preventing and treating cancer, a leading cause of death in the United States. Established by Congress through the Cancer Registries Amendment in 1992, NPCR collects data on cancer occurrence (including the type, extent, and location of the cancer), the type of initial treatment, and outcomes. Today, through NPCR, CDC supports central cancer registries in 46 states, the District of Columbia, Puerto Rico, the U.S. Pacific Island Jurisdictions, and the U.S. Virgin Islands. These data represent 97% of the U.S. population. NPCR follows the data collection and quality standards in the North American Association of Central Cancer Registries (NAACCR) consensus documents. Annually, these data are evaluated for quality, completeness, and timeliness according to the National Data Quality Standard for 23-month data and the Advanced National Data Quality Standard for 12-month data. Data also are evaluated according to the USCS Publication Standard before publication. NPCR standards can be found here.

National Center for Health Statistics (NCHS)

The National Center for Health Statistics (NCHS) participates in health data standards activities providing public health representation in the development, maintenance, and implementation of national healthcare standards. These activities support the divisions within NCHS and have included standards and implementation projects within the Division of Vital Statistics (DVS) and the Division of Health Care Surveys (DHCS). The Classification and Public Health Data Standards Staff (CPHDSS) supports the development of national standards for the center and has worked with NCHS divisions in representing their standards development work at national level standards development organizations. In support of the agency wide data modernization initiative, divisions mentioned below are actively working on standards development efforts to provide a mechanism utilizing information obtained from health IT systems for public health reporting.

Division of Vital Statistics (DVS)

The Division of Vital Statistics (DVS) in collaboration with CPHDSS is working with HL7 to maintain and create mortality and natality national reporting standards. The mortality standards include the continued maintenance and updates of the Vital Records Death Reporting (VRDR) FHIR implementation guide (IG). Over the course of 2021 and beyond, the VRDR FHIR IG is being updated to include the inter-jurisdictional exchange content that jurisdictions utilize to exchange data among each other and with NCHS. This work will include substantial changes to this specification and these updates will be tested in May 2022. Related to natality reporting the Birth and Fetal Death (BFDR) FHIR standard was balloted through HL7 in January in 2021 and has been published as a standard for trial use. It is also being utilized by two state pilot projects who are currently creating a SMART on FHIR application to test data quality in receiving medical birth information from an EMR. Listings of the aforementioned published HL7 standards can be found here: (http://www.fhir.org/guides/registry/). Lastly, recent development of a

Medicolegal Death Investigation (MDI) FHIR standard is underway and will balloted through HL7 in May 2022. This standards development project will aim to support the Medical Examiner and Coroner (ME/C) community in helping improve the timeliness of these types of data. An initiative to support these development efforts is known as the National Vital Statistics System (NVSS) Community of Practice. The NVSS CoP not only supports the development of national standards but also provides resources to jurisdictions on the modernization of their electronic registration systems.

Further information on jurisdictional participation for vital records offices can be found here: (https://www.cdc.gov/nchs/nvss/modernization/cop.htm)

Division of Health Care Statistics (DHCS)

The Division of Health Care Statistics in collaboration with CPHDSS is working with HL7 to maintain the existing CDA National Health Care Surveys Standards (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=385). To that end NCHS has worked with the HL7 Public Health Working Group to resolve comments on STU Releases 1.2 and 3.0 of the National Health Care Surveys CDA Standards and work is in progress to ballot two "dot releases" of these standards which are expected to result in the new National Health Care Surveys CDA Standards Releases 2.1 and 3.1 in January 2022.

While maintaining its CDA healthcare interoperability standards, DHCS--in collaboration with CPHDSS and CDC CSELS colleagues--is developing new HL7 FHIR standards as part of the Making EHR Data More Available for Research and Public Health (MedMorph) Project, a PCOR Trust Fund funded project. DHCS's National Health Care Surveys are one of the three core public health use cases in the MedMorph Project. In January 2021 MedMorph successfully balloted a HL7 MedMorph Reference Architecture (RA) Implementation Guide (IG). This MedMorph RA IG establishes a common framework (e.g., FHIR resources, FHIR APIs, FHIR operations, security mechanisms) that will be leveraged by multiple public health and research use cases. On December 10, 2020, the Health Care Surveys Content Implementation Guide Standard for Trial Use (STU) ballot process was started. (http://hl7.org/fhir/us/health-care-surveys- reporting/2022Jan/index.html) This Content IG is designed to work "hand in glove" with the MedMorph RA IG to allow a low burden way for health care providers to use their EHR's FHIR APIs to submit National Health Care Surveys to NCHS. The content that the Health Care Surveys Content IG specifies is highly aligned with the United States Core Data for Interoperability (USCDI) which is operationalized in the IG vi HL7 US Core Resource Profiles. It is anticipated that the CDA National Health Care Surveys IG Releases will remain in use for the next several years as the Health Care Survey FHIR Content IG is piloted in 2022 and then more fully adopted in 2023 and beyond.

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Division for Heart Disease and Stroke Prevention (DHDSP)

As much as possible, DHDSP works to follow existing standards in public health activities and surveillance. A current project leverages existing CMS eClinical Quality Measures (http://hl7.org/fhir/us/cqfmeasures/) to develop use cases for public health surveillance of hypertension control (CMS165) and diabetes control (CMS122) from EHR data, using electronic case reporting technology (http://build.fhir.org/ig/HL7/case-reporting/) aligned with the FHIR reference architecture known as Making EHR Data More Available for Research and Public Health (MedMorph). MedMorph refers to a common framework (including FHIR resources, FHIR APIs, FHIR operations, and security mechanisms) that can be used in many public health use cases.

CDC Diabetes Prevention Recognition Program (DPRP)

The Centers for Disease Control and Prevention established the CDC Diabetes Prevention Recognition Program (https://www.cdc.gov/diabetes/prevention/lifestyleprogram/index.html) as part of the National Diabetes Prevention Program (National DPP) (https://www.cdc.gov/diabetes/prevention/index.html). The DPRP is the quality assurance arm of the National DPP. It provides information about the location and performance of type 2 diabetes prevention programs across the US. This includes organizations delivering the National DPP lifestyle change program in-

person, online, via distance learning, and through a combination of these delivery modes. The purpose of the DPRP is to recognize organizations that have demonstrated their ability to effectively deliver a proven type 2 diabetes prevention lifestyle change program.

The DPRP assures the quality of recognized organizations and provides standardized reporting on their performance. The original 2012 DPRP Quality Standards were based on successful efficacy and effectiveness studies. In one such efficacy study, the US Diabetes Prevention Program research trial (DPP), participants in the lifestyle intervention losing 5-7% of their bodyweight experienced a 58% lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention (https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-preventionprogram- dpp/Documents/DPP_508.pdf). CDC updates the DPRP Standards every 3 years based on new information available in the scientific literature, insights gained through analysis of DPRP data, lessons learned from best practices in the field, and public comment.

The DPRP has three key objectives:

- Assure program quality, fidelity to scientific evidence, and broad use of an effective type 2 diabetes prevention lifestyle change program throughout the United States
- Develop and maintain a registry of organizations that are recognized for their ability to deliver the National DPP lifestyle change program to people at high risk
- Provide technical assistance to organizations to assist staff in effective program delivery and in problem-solving to achieve and maintain recognition status.

Program delivery organizations must also track results and send data to CDC every 6 months based on requirements in the DPRP Standards CDC reviews these data and provides feedback to each organization. DPRP evaluation data to date show evaluated participants attended an average of 18 core sessions (organizations are required to offer a minimum 22 core sessions) and 9 core maintenance sessions (organizations are required to offer a minimum 6 core maintenance sessions) in the National DPP lifestyle change program. Participant risk reduction, determined using outcomes associated with weight, physical activity minutes, and HbA1c, was seen in 52.4% of all evaluated participants. This risk reduction included 48.4% who achieved at least a 5% weight loss; 34.8% who achieved at least a 4% weight loss combined with at least 150 min/week on average, of physical activity; and 2% to date who had at least a 0.2% reduction in HbA1c (of those who submitted HbA1c information*). As of January 6, 2023, there are 2,140 CDC-recognized organizations that have collectively enrolled 666,374 participants nationwide since the program's inception.

*Note: The DPRP Standards were revised in 2021, to include HbA1c as a new, optional outcome variable. As a result, limited data are currently available on this new variable.

The CDC Diabetes Prevention Recognition Program Standards and Operating Procedures describe in detail the DPRP requirements and explain how an organization may apply for, earn, and maintain CDC recognition (https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf) to offer the National DPP lifestyle change program.

National Institute for Occupational Safety and Health (NIOSH)

The National Institute for Occupational Safety and Health (NIOSH) encourages its employees with relevant expertise to participate as approved representatives in the development of national and international standards activities as part of voluntary consensus standards committees. NIOSH currently has 45 staff contributing their expertise to approximately 24 major committee organizations (e.g., ANSI, ISO, ASTM, NFPA). Participation by NIOSH staff on such committees affords the Institute an opportunity to ensure standards are established using sound evidence-based science, as well as to help facilitate the transfer of NIOSH research findings into improved occupationally-related health and safety practices, procedures, and policies. A list of NIOSH-approved participation

in established voluntary consensus standards committees can be found at: (http://od.niosh.cdc.gov/Consensus-Standards/Consensus-Standards.html).

The Office of Laboratory Science and Safety (OLSS)

The Office of Laboratory Science and Safety encourages its employees with relevant expertise to participate as approved representatives in the development of national and international standards activities as part of voluntary consensus standards committees. OLSS currently has 1 staff contributing their expertise to the US Technical Advisory Group (TAG) for ISO/TC 212 (https://clsi.org/about/clsi-and-international-standards- development/iso-committees/us-tag-to-isotc-212/). This committee is administered by the Clinical Laboratory Standards Institute (CLSI), is accredited by the American National Standards Institute (ANSI) and operates in compliance with applicable ANSI requirements. Participation by OLSS staff on such committees affords an opportunity to ensure standards are established using sound scientific and management expertise, as well as to help facilitate awareness of internationally recognized technical laboratory standards in OLSS's mission to promote excellence in scientific research, safety practices, procedures, and policies. Specific outputs from the ISO/TC 212 in 2022 included the finalization and publication of a new edition of voluntary international standard ISO 15189: 2022 (https://clsi.org/standards/products/iso-documents/documents/iso-15189-2022/)— Medical laboratories— Requirements for quality and competence. This voluntary international standard is applicable to medical laboratories developing quality management systems, assessing laboratory competence and for confirming or recognizing the competence of medical laboratories by laboratory users, regulatory authorities, and accreditation bodies. ISO 15189: 2022 is also pertinent to point-of-care testing (POCT). In 2022, CDC also announced its new Laboratory Quality Plan (https://www.cdc.gov/labs/quality-activities.html). The Laboratory Quality Plan sets a framework that encourages continuous quality improvement, while providing the quality assurance checks that ensure excellent test results. This narrative refers to ongoing participation and recent outputs in US Technical Advisory Group (TAG) for ISO/TC 212 (https://clsi.org/about/clsi-and-international-standards-development/iso-committees/us- tag-to-isotc-212/). This committee is administered by the Clinical Laboratory Standards Institute (CLSI), is accredited by the American National Standards Institute (ANSI) and operates in compliance with applicable ANSI requirements.

National Center for HIV, Viral Hepatitis, STD, and TB Prevention

The Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) is a supporter in the development and recommendations to standardize pregnancy status reporting. NCHHSTP subject matter experts (SMEs) participated as members of the Council of State and Territorial Epidemiologist workgroup on pregnancy status reporting, including contributing to recommendations created by this workgroup.

Division of Sexual Transmitted Disease Prevention (DSTDP)

DSTDP is developing a standards-based syphilis and congenital syphilis registry model leveraging Fast Healthcare Interoperability Resources (FHIR). FHIR is a standard describing data formats and elements and an application programming interface (API) for exchanging electronic health records (EHR). To date, FHIR has been used to enhance electronic case reports, specifically obtaining data on patient diagnoses, symptoms, medications, and demographics.

Division of Tuberculosis Elimination (DTE)

DTE's Clinical Research Branch (CRB), through the Tuberculosis Trials Consortium (TBTC), conducts programmatically relevant clinical trials to improve treatment options and outcomes for tuberculosis disease and latent tuberculosis infection. CRB serves as the sponsor for these clinical studies, and, as such, has the regulatory responsibility to submit trial data to the US Food and Drug Administration conforming to Clinical Data Interchange Standards Consortium (CDISC) standards. Data for all TBTC studies are collected in Clinical Data Acquisition Standards Harmonization (CDASH) format and transformed to the Study Data Tabulation Model (SDTM) for submission to FDA.

Centers for Medicare and Medicaid Services (CMS)

The National Standards Group (NSG) within the Office of Burden Reduction & Health Informatics at the Centers for Medicare & Medicaid Services (CMS) is responsible for adopting and enforcing national standards and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification provisions to increase the electronic exchange of health information between covered entities. HIPAA covered entities include health plans, health care providers and health care clearinghouses, as defined in HIPAA. Representatives from NSG participate with several national standards development organizations as they develop and/or update the standards and operating rules in preparation for the next version to be considered for adoption. NSG is committed to enforcing adoption of electronic standards by all covered entities, including those organizations in the private and public sector, as electronic transaction standards will increase efficiency in health care.

The specific transactions (for business operations) developed by these organizations include enrollment, eligibility, claims, claim status, electronic funds transfer, remittance advice, prior authorization, and attachments. NSG staff participate in workgroups of the standards setting organizations listed below:

- Health Level 7 (HL7): (www.HL7.org)
- National Council for Prescription Drug Programs (NCPDP): (www.ncpdp.org)
- American Dental Association: (www.ada.org)
- American Medical Association: (www.ama-assn.org)
- Accredited Standards Organization, Insurance (X12N): (www.x12.org)
- Council for Affordable Quality Healthcare (CAQH) Committee for Operating Rules for Information Exchange (CORE) CAQHCORE: (www.caqh.org)
- NACHA (the Electronic Payments Association): (https://www.nacha.org/)

NSG consults with numerous other stakeholder groups, such as the NUCC, NUBC, WEDI, and regularly engages with the National Committee on Vital and Health Statistics, advisory body to the Secretary.

The Quality Measurement and Value-Based Incentives Group (QMVIG) in the Centers for Clinical Standards and Quality (CCSQ) at CMS selects performance measures for use within its various quality initiatives including healthcare provider public reporting and value-based purchasing programs. CMS prefers selecting performance measures (https://www.cms.gov/medicare/quality-initiatives-patient- assessment-instruments/qualitymeasures?redirect=/qualitymeasures) that have been reviewed through a consensus process, and can be considered consensus-based standards. National Quality Forum (NQF), a not-for-profit, nonpartisan, membership-based organization, meets the NTTAA definition of a consensus-based organization. CMS currently contracts NQF to execute a public and transparent consensus development process to endorse and maintain performance measures. NQF's consensus development process (CDP) (https://www.qualityforum.org/Measuring_Performance/Consensus_Development_Process.aspx) includes an open call for candidate consensus standards (i.e., performance measures); multi- stakeholder review of scientific and statistical evidence against NQF-endorsement criteria; discussion and evaluation of measures by multi-stakeholder experts including patient and caregiver advisors; and opportunities for stakeholder feedback and public comments throughout the process. The CDP also includes a process for stakeholders and the public to object to measures after they receive NQF- endorsement. NQF's processes are consistent with the NTTAA and OMB Circular A-119.

1) CMS Quality Measures: (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualitymeasures)

2) National Quality Forum: (http://www.qualityforum.org/)

Food and Drug Administration (FDA)

FDA is responsible for protecting public health by helping to bring safe and effective medical products and foods to the U.S. public; and advancing public health by ensuring the public has the most accurate, science-based information they need to use medicines and foods to improve and maintain their health. Standards help to ensure data and process consistency and enable use of advanced technology and analytics in FDA's performance of its mission.

Where feasible, FDA participates in the development of, and uses voluntary consensus standards to help facilitate consistent and predictable product manufacturing and assessment, regulatory testing, clinical trial data exchange, and product labeling, just to name a few examples. Information exchange with our stakeholders promotes efficiency and awareness in the standards setting processes. The Agency looks for the appropriate time, process, and forum by which we can engage with standard development organizations. By doing so, FDA can facilitate standard setting activities and not hinder or duplicate efforts that are already underway in complementary bilateral or multilateral discussions. The use of voluntary consensus standards can increase predictability, streamline premarket review, and facilitate market entry for safe and effective products, including products of emerging technologies, under FDA regulatory authority.

In addition, FDA participates actively in the standard setting process of the Codex Alimentarius, which for over 50 years has provided governments with a venue for adoption of food standards to facilitate safety and fair-trade practices. Codex is a joint body of the Food and Agricultural Organization of the United Nations and of the World Health Organization, and the standards developed through this body are recognized by the World Trade Organization. FDA supports Codex through the participation of experts and delegates representing the United States and through hosting meetings, along with the (The U.S. Department of Agriculture's (USDA) USDA Food Safety and Inspection Service. While FDA is not obligated to adopt the standards, Codex provides greater assurances of the safety of food imports, as many countries that export to the United States will adopt Codex standards.

Standards developed through interactions with various standard development bodies, including VCS organizations and/ or industry consortia, can provide benefit to both the Agency and our stakeholders in multiple ways such as:

- Standards can assist regulatory reviewers with assessment of products and product applications;
- Standards can assist industry with methodologies they can adopt for the assessment of their products;
- Standards often result in better utilization of limited internal resources;
- International standards can be used by multiple regulatory regions that can facilitate global harmonization, to the extent feasible;
- Direct participation by a broad group of stakeholders in development of standards can result in consensus among users, practitioners, manufacturers, and government regulators on safety and effective use of regulated products;
- Reduction in the costs and in transcription errors resulting from manual data entry such as for registrations and listing and adverse event reporting; and
- Reduction in the cost for incorporating new electronic processes such as electronic food and device labeling by leveraging existing exchange standards, business processes and information technology (IT) systems.

FDA policy is to help develop and use voluntary consensus standards wherever possible in the management of products FDA regulates. FDA supports the letter and spirit of the National Technology Transfer and Advancement Act (NTTAA) and the Office of Management and Budget (OMB) Directive. For more information about FDA's policies and procedures related to standards management, please see our Staff Manual Guide 9100.1 at: (https://www.fda.gov/media/79684/download)

For more information about FDA data standards and the FDA Data Standards Advisory Board, please see: (http://www.fda.gov/ForIndustry/DataStandards/default.htm)

Center for Devices and Radiological Health (CDRH)

CDRH gained additional authority under the 21st Century Cures Act to enhance its Standards Recognition Program. A final guidance titled Recognition and Withdrawal of Voluntary Consensus Standards published on September 15, 2020 notes that FDA will publish its rationales about recognition decisions, respond to recognition requests within 60 days and establish transition times to revised recognized standards (when appropriate). Finally, the guidance reflects FDA's commitment to periodically update the Recognized Standards Database with pending recognitions. This means that once FDA conveys its intention to recognize a standard it will appear in the standards recognition database. Manufacturers may cite it in premarket submissions and will no longer need to wait for the publication of a *Federal Register* notice.

During FY2022, in accordance with section 514(c), 21 U.S.C. 360d(c), FDA/CDRH published the following notices to the Federal Register to announce the addition, withdrawal, correction, and/or revision of certain consensus standards the Agency will recognize for use towards a declaration of conformity in premarket submissions and other requirements for medical devices:

Publications in the Federal Register related to Modifications to the List of Recognized Standards is available at (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm)

Standards recognitions published during FY 2022:

Date Federal Register Notice

December 9, 2021 FR Notice (List #56) [Docket No. FDA-2004-N-0451] (https://www.govinfo.gov/content/pkg/FR-2021-12-09/pdf/2021-26635.pdf)

April 22, 2022 FR Notice (List #57) [Docket No. FDA-2004-N-0451] (https://www.govinfo.gov/content/pkg/FR-2022-04-22/pdf/2022-08571.pdf)

August 10, 2022 FR Notice (List #58) [Docket No. FDA-2004-N-0451] (https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-17150.pdf)

Access to the current FDA List of Recognized Consensus Standards, as published and updated in the Federal Register, can be found at (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm)

Conformity Assessment

In general, conformity assessment activities for FDA-regulated products are conducted under applicable regulations and guidance that are informed by our standards development efforts described above. Standards may become part of conformance activities as they may provide an acceptable approach to ensure compliance with applicable laws and regulations.

CDRH's Standards and Conformity Assessment Program (S-CAP) has launched a voluntary pilot called the 'Accreditation Scheme for Conformity Assessment,' or ASCA. Conceptualized to promote a least burdensome approach to medical device review, ASCA was developed in conjunction with the device manufacturing industry, standards development organizations and conformity assessment entities. The ASCA Pilot relies upon international consensus standards (ISO/IEC 17011 and ISO/IEC 17025) augmented by additional ASCA specifications and is designed to increase FDA's confidence in testing methods and results from ASCA-accredited testing laboratories. Ultimately the ASCA Pilot is expected to make device review more efficient, ensuring patients have access to safe and effective medical devices without unnecessary delay. The final guidances outlining program specifications can be found on the ASCA Pilot web page and listed below:

- **ASCA Pilot program guidance:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance* (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-programsessment-asca-pilot- program)

- **Basic Safety and Essential Performance standards-specific guidance:** *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* (https://www.fda.gov/regulatory-information/search-fda- guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment- medical-electrical-systems-and)

- **Biocompatibility standards-specific guidance:** *Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* (https://www.fda.gov/regulatory-information/search-fda-guidance- documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation- scheme)

The docket number: for these guidances are under docket FDA-2019-D-3805U (https://www.regulations.gov/docket/FDA-2019-D-3805) published on September 25, 2020.

Under the ASCA Pilot, at the end of FY22, CDRH has provided ASCA recognition to 5 Accreditation Bodies and granted ASCA-accreditation to 91 testing laboratories under the scope of standards and methods included in the ASCA Pilot, adding 14 testing laboratories in FY 22.

Under the Medical Device User Fee Amendments 2022 (MDUFA V), section 2005 updated ASCA to advance from a Pilot to a permanent program as established under Section 514(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(d)). Under MDUFA V, CDRH is committed to improve ASCA through continued training of FDA staff and supervisors, testing laboratories and accreditation bodies. CDRH will continually report annually on the progress of the ASCA Program and work with stakeholders for further input on programmatic improvements and/or considerations for expansion.

Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)

The FDA Food Safety Modernization Act (FSMA) gives the Agency explicit authority to establish a program for accreditation of conformity assessment bodies (identified in the statute as third-party auditors) to conduct food safety audits and issue certifications of foreign food facilities for FDA- regulated food, which includes human food, pet food, and non-medicated animal feed. In 2015, FDA issued regulations (21 CFR Part 1 subpart M) establishing the Accredited Third-Party Certification Program (https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party- certification-program). The regulations describe the framework, procedures, and requirements for accreditation bodies seeking recognition by the FDA, as well as requirements for third-party certification bodies seeking accreditation, under the program. Accreditation bodies and third-party certification bodies may use documentation of their conformance with ISO/IEC 17011:2004, ISO/IEC 17021:2011, and ISO/IEC 17065:2012 in meeting the requirements of the regulations, supplemented as necessary (e.g., to meet the conflict of interest, reporting, and notification standards in section 808 of the FD&C Act). FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under the voluntary third-party certification program are contained in a guidance document entitled, "Third- Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff" (https://www.fda.gov/regulatory-information/search-fda- guidance-documents/guidance-industry-and-fda-staff-model-accreditation-standards-third-party- certification-body)

As part of these recommendations, FDA cited ISO/IEC 17021:2011 and ISO/IEC 17065:2012, which are voluntary consensus standards on accreditation that are widely used in determining the qualifications of third-party conformity assessment bodies that audit and certify the food industry. As of the end of FY22, the FDA has recognized 4 accreditation bodies which have accredited 13 certification bodies.

FDA maintains an online registry of accreditation bodies recognized, and certification bodies accredited, under this program (https://www.fda.gov/food/importing-food-products-united- states/accredited-third-party-certification-program-public-registry-recognized-accreditation-bodies).

FSMA also gives us express authority to establish a laboratory accreditation program for the analyses of human and animal foods. FDA issued a final rule in December 2021 establishing the Laboratory Accreditation for Analyses of Foods (LAAF) program (https://www.fda.gov/food/food-safety- modernization-act-fsma/fsma-final-rule-laboratory-accreditation-analyses-foods-laaf).

The final rule specifies the oversight, uniformity, and standards necessary to help ensure that the results of certain food testing of importance to public health are reliable and accurate. Under the LAAF program, FDA recognizes accreditation bodies that accredit laboratories to the standards established in the final rule ("LAAF accredit"); only LAAF-accredited laboratories may conduct the food testing covered by the final rule. The final rule incorporates by reference two voluntary consensus standards: ISO/IEC 17011:2017 forms the foundational requirement for accreditation bodies, and ISO/IEC 17025:2017 forms the foundational requirement for food testing laboratories. Although FDA only recently began implementing the LAAF program, as of the end of FY22 7 accreditation bodies have been recognized and are in the process of assessing testing laboratories that wish to participate. FDA maintains an online registry (https://datadashboard.fda.gov/ora/fd/laaf.htm) of accreditation bodies recognized under the LAAF program; once those accreditation bodies start conferring LAAF- accreditation on laboratories, the registry will list them as well.

FDA's Moffett Proficiency Testing Laboratory (Moffett PT), located within CFSAN's Office of Food Safety, Division of Food Processing Science and Technology and part of the Institute for Food Safety and Health (IFSH), has been an ISO/IEC 17043 accredited proficiency testing laboratory since February 2017 but has been in operation within FDA in varying capacities since the 1950s. This PT program's scope of work is expansive as it is the official PT provider for FDA's inter-/intra-agency programs (CVM Veterinary Laboratory Investigation and Response Network, Office of Regulatory Affairs (ORA) Office of Regulatory Science (ORS) Quality Assurance programs/dietary supplement adulteration, FDA/USDA Food Emergency Response Network) as well as regulatory and food safety programs for milk, shellfish, vitamins, and food microbiology. FDA's Moffett PT incorporates both food microbiological and chemical analytes and matrices based on the historical, current, and emerging food safety and defense requirements of the FDA. Microbiological PT schemes, for example, include bioterror agents such as *B. anthracis* (attenuated), *Y. pestis* (attenuated) or *F. tularensis* (attenuated strains) and food pathogens such as *Listeria*, *Salmonella*, *Vibrio* and others in a variety of food products. Chemical PT schemes include glyphosate, tetramine, thallium, aflatoxin B1, carbamates, ricin and other toxins in a variety of food products. In addition, FDA's Moffett PT schemes include detection for fraudulent weight loss and erectile dysfunction drugs in dietary supplements. Moffett PT's expansive ISO/IEC 17043 accredited scope of work has greatly contributed to the groundwork built by FSMA for model laboratory standards, accreditation, and capability building of the nation's food laboratory networks.

Office of Regulatory Affairs (ORA)

Through self-coordinated or collaborative method development & research to support regulatory testing, the ORA Office of Regulatory Science (ORS) laboratory network actively contributes to the repertoire of consensus analytical methods that are published in the AOAC's compendium of the Official Methods of Analysis. According to 21CFR2.19, the Official Methods of Analysis of the AOAC INTERNATIONAL are specified to be used in cases where a method of analysis is not prescribed in the regulation.

Within the framework of a current FDA-USP Cooperative Research and Development Agreement (CRADA) (https://www.fda.gov/science-research/cooperative-research-and-development-agreements- cradas/fda-cradas), ORA/ORS Laboratories also conduct analytical work aimed at updating USP pharmaceutical analysis monographs using USP reference materials.

ORA/ORS laboratories are accredited to ISO/IEC 17025:2017 standards. The FDA Forensic Chemistry Center (FCC), the ORS forensics specialized lab, is accredited to the standards of ANSI-ASQ National Accreditation Board (ANAB) in the field of Forensic Science Testing. ORA/ORS laboratories also conform to well established method validation and verification criteria such as ICH, USP, AOAC standards when qualifying their analytical methods. Each laboratory in the ORA/ORS network is audited by an ISO/IEC 17025:2017 accreditor.

Each laboratory conforms to the core requirements of a Quality Management System (QSM) which includes the design and maintenance of a proficiency testing and exercise schedule. This proficiency testing program of ORA/ORS laboratories is called the National Check Sample Program and aims to provide an assessment of laboratory proficiency in performance of analytical methods in the accreditation scope. Some proficiency tests utilized in the National Check Sample Program are internally generated sample panels prepared with third party vendor standard materials while other proficiency tests are obtained commercially.

ORA/ORS Laboratories are also active members of the Integrated Consortium of Laboratory Networks (ICLN) (https://www.icln.org/) and CODEX International (http://www.fao.org/fao-who- codexalimentarius/en/); and adopt consensus standards developed by these organizations that pertain to specialized testing areas such as veterinary drug residue testing, radiation testing, and pesticide testing.

ORA/ORS in coordination with CFSAN and CVM supports ISO/IEC 17025 accreditation of state food testing laboratories through the Manufactured Food Regulatory Program and the Flexible Funding Model. The program advances the nationally integrated food safety system (IFSS) specifically with regards to microbiological and chemical food analyses. This includes preparing state laboratories for accreditation enhancements. Data generated by awarded state laboratories will be available to inform FDA in its enforcement actions, surveillance, and response to foodborne outbreaks. These ISO accredited laboratories aid FDA with additional resources and exceptional data to maintain the safety of the food chain.

More detailed information on the Manufactured Food Regulatory Program and other standards- related programs managed by ORA can be accessed via the links below:

- Manufactured Food Regulatory Program Standards (https://www.fda.gov/federal-state-local- tribal-and-territorial-officials/regulatory-program-standards/manufactured-food-regulatory- program-standards-mfrps)
- Flexible Funding Model (https://www.fda.gov/federal-state-local-tribal-and-territorial- officials/grants-and-cooperative-agreements/flexible-funding-model-ffm-infrastructure- development-and-maintenance-state-manufactured-food)
- National Integrated Food Safety System – Laboratory Capacity Building (https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food- safety-system-ifss-programs-and-initiatives/laboratory-capacity-building)
- Voluntary National Retail Food Regulatory Program Standards (https://www.fda.gov/federal-state- local-tribal-and-territorial-officials/grants-and-cooperative-agreements/voluntary-national-retail- food-regulatory-program-standards-vnrfrps-cooperative-agreement-program)
- Animal Feed Regulatory Program Standards (https://www.fda.gov/federal-state-local-tribal-and- territorial-officials/regulatory-program-standards/animal-feed-regulatory-program-standards- afrps-and-preventive-controls-cooperative-agreement-program)

Center for Biologics Evaluation and Research (CBER)

In September of 2021, the Center for Biologics Evaluation and Research's (CBER) Division of Biological Standards and Quality Control (DBSQC), which is in the Office of Compliance and Biologics Quality, was audited for ISO 17025:2017: "General requirements for the Competence of Testing and Calibration Laboratories" for the biological and chemical testing for product lot release, and ISO 17034:2016: "General Requirements for the Competence of

Reference Material Producers." These reference materials included influenza antigens and sheep antisera for influenza vaccine potency testing, as well as tetanus and diphtheria antitoxin for flocculation for DTaP vaccines. No deficiencies were identified during the audit.

CBER's Laboratory of Immunobiochemistry (LIB), in the Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, was also audited for ISO 17025: 2017 in August 2021; no deficiencies were identified. The scope of accreditation for the LIB covers the "ELISA Competition Assay for Quantitative Determination of Relative Potency of Allergenic Extracts." Additionally, in October 2020 LIB released E7-Orchard Grass Reference and in August 2021 released C14-Cat Hair Reference.

CBER coordinates with CDER to implement data standards related to the following:

- Real World Data and Real World Evidence
- Identification of Medicinal Products
- CDISC standards for study data and terminologies (e.g., MedDRA, SNOMED, WHO Drug Global)
- HL7 v3 and FHIR for exchange of data for numerous use cases including labeling, drug registration and listing, and other use cases
- HL7 ICSR for adverse event data
- ICH eCTD v 4 for content of regulatory submissions
- For more information, see Study Data for Submission to CDER and CBER | FDA

The 21st Century Cures Act was signed into law in December 2016. Section 3036 directs the FDA to collaborate with the National Institute of Standards and Technology (NIST) and FDA stakeholders to coordinate and prioritize standards development for regenerative medicine and regenerative medicine advanced therapies. CBER awarded a contract to Nexight Group and the Standards Coordinating Body (SCB) in 2017 to establish a collaboration consisting of FDA, NIST, and stakeholders, to coordinate the development and implementation of the processes and criteria to identify and prioritize standards that have a high impact on the quality and safety of regenerative medicine products and determine whether the development of any specific standard is feasible. This contract has been extended to 2024 with deliverables to include the identification of needed standards, the conduct of feasibility assessments for needed standards, maintenance of the standards web portal that allows for stakeholders to search form standards under development and standards available, and stakeholder outreach to experts for input on standards under development.

To encourage the use of standards for regenerative medicine products, CBER published the draft guidance Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies on June 22, 2022 (https://www.fda.gov/media/159237/download). This guidance describes a standards recognition program for regenerative medicine therapies (SRP-RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. CBER encourages the use of appropriate standards in the development of CBER-regulated products. The use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. This program is modeled after the formal standards and conformity assessment program or S-CAP for medical devices. When the final version on the guidance is published, CBER will post a list of recognized standards on the regenerative medicine therapies portion of the FDA website https://www.fda.gov/vaccines-bloodbiologics/cellular-gene- therapy-products/framework-regulation-regenerative-medicineproducts.

Center for Drug Evaluation (CDER)

Section 3022 of the 21st Century Cures Act directs FDA to "establish a program to evaluate the potential use of Real World Evidence (1) to help to support the approval of a new indication for a drug approved under section 505(c); and (2) to help to support or satisfy post-approval study requirements." Real World Evidence (RWE) is generated from data sources other than those typical of clinical trials used for drug approval. RWE sources include, but are not limited to, healthcare records, insurance claims, or dedicated registries for drugs or diseases. The interest in using RWE stems from its potential to facilitate more timely and cost-effective demonstrations of efficacy, safety, and the ability to understand drug effects across a wider population than currently possible with traditional clinical trials, thus providing improved benefits to the public.

As part of the 21st Century Cures directives, FDA is to create a framework establishing the RWE program, along with Guidance documents for industry, informed by communications with stakeholders from industry and the public. To fulfil these mandates, in 2017 CDER established a committee and associated workgroups dedicated to this effort with participation from multiple FDA Centers. Throughout 2017 and 2018, these groups have (1) developed a draft RWE Framework that was published in December 2018; (2) established workgroups to develop Guidance on a range of topics pertinent to the use of this data; (3) reviewed the range of RWE already in use for FDA submission; (4) and engaged with stakeholders from industries and the public through participation in meetings and workshops focused on the use of RWE for clinical research and regulatory submissions. Meetings were facilitated by stakeholders including the Margolis Center for Health Policy at Duke University and the National Academies of Sciences.

Attending stakeholders at various meetings included a spectrum of representatives from the pharmaceutical industry, healthcare, academia, patient organizations, standards development organizations such as Health Level 7 (HL7) and Clinical Data Interchange Standards Consortium (CDISC), and other members of the general public. In 2019 the Center began examining the ability of current submission data standards to accommodate real-world data and develop a roadmap to optimizing these standards in the future for real-world data submission. As with other FDA data standards activity, consensus-based standards such as those from CDISC and HL7 are being explored. In 2020, FDA developed the draft guidance "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products" that was published in September 2021. Another draft guidance focusing on data standards considerations for submission of studies containing RWD was developed in 2021. In 2022, FDA has collated and addressed all public comments for the draft RWD guidance and is revising the document to prepare for publication of the final guidance. FDA further explored opportunities to adapt HL7 Fast Healthcare Interoperability Resources (FHIR) for Real World Data submissions through engagement with HL7 Vulcan Accelerator Track, resulting in the development of draft Implementation guides (IG) for two use cases (Acute Coronary Syndrome and Anti-TNFa Treatment in Patients with Crohn's Disease). FDA will continue to explore and evaluate approaches to standardize RWD for regulatory submission in 2022 and beyond.

FDA is also working to standardize submissions for the information submitted in Electronic Common Technical Document (eCTD) Module 3 covering Pharmaceutical Quality, Chemistry, Manufacturing, and Controls (PQ/CMC). In 2017, a Federal Register Notice was published documenting structured data and associated vocabularies for approximately one-third of Module 3 information. In 2019, development began for Phase 1 of the PQCMC effort by using HL7 FHIR as the exchange standard to represent an initiate set of eCTD Module 3 structured data for submissions. In 2020, the Center initiated Phase 2 of the development effort to standardize the remaining information for eCTD Module 3. Development continued into 2021 and a Federal Register Notice (FRN) detailing the FHIR mapping of all Phase 1 PQ/CMC data elements is in the clearance process. In 2022, FDA published a FRN requesting for comments on the Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Exchange, and later addressed public comments resulting in revisions to PQCMC Phase 1 data elements and the completion of the PQ/CMC Phase 1 Interim Implementation Guide. FDA has also initiated development of a draft FRN for publication in 2023 announcing new Phase 2 and KASA-specific Phase 1 data elements and to request for public comments.

ISO Identification of Medicinal Product (IDMP) is a suite of five related standards to identify and describe medicinal products and to exchange of product information between partners to support pharmacovigilance, product shortage, and other regulatory activities. The Integrity Product Domain and Global Substance Registration System

are built based on ISO 11615/ISO 11616 and ISO 11238 respectively to be the master repository for CDER regulated medicinal products and FDA regulated substances. To enable pharmacovigilance across multiple jurisdictions or at global level, FDA continues to participate in the revision and enhancement of IDMP standards with ISO TC 215, and to collaborate with other regulators for harmonized approach for IDMP development.

In 2022, FDA jointly established the Global IDMP Working Group (GIDWG) with WHO-UMC and EMA to conduct and report on projects leading to the establishment of a framework for the global implementation of the ISO IDMP standards and maintenance of global identifiers. The GIDWG is conducting 5 pilot projects to identify challenges and mitigation to establish common grounds, business rules, and processes to facilitate global IDMP implementation.

Indian Health Service (IHS)

The primary mission of the Indian Health Service (IHS) is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. Standards and conformity assessment activities are an integral part of the effective operations of the IHS in achieving its mission. There are health-related standards that are used for numerous purposes in the health industry. The IHS has used them for privacy/security, interoperability, compliance/accreditation, and certification.

Privacy and security standards are used throughout IHS and comply with Department of Homeland Security (DHS) requirements. Privacy and security standards are used for other purposes beyond those related to patient and employee data. The IHS also uses privacy and security standards to address communication of biomedical diagnostic and therapeutic information for digital imaging, telemedicine, national drug codes, energy-efficient and environmentally friendly construction, and for reporting medical services and procedures.

Interoperability is achieved within IHS through following standards from various development organizations, e.g. the use of Health Level Seven (HL7) schemas and International Classification of Disease, Tenth Edition (ICD-10) codes. The HL7 standard allows interoperability among health information systems both within and beyond the IHS healthcare environment, such as immunization data exchange (including COVID-19) to various state and federal partners. ICD-10 is a clinical cataloging system used by IHS and its providers, coders, information technology professionals in addition to insurance carriers, government agencies and others use to properly note diseases on health records, track epidemiological trends, and assist in medical reimbursement decisions. It brings interoperability among disparate systems for information sharing.

Accreditation is a process of review in which healthcare organizations participate to demonstrate the ability to meet predetermined criteria and standards of accreditation established by a professional accrediting agency. DirectTrust Agent accreditation recognizes excellence in health data processing and transactions. It ensures compliance with industry-established standards, HIPAA regulations and the Direct Project. Accreditation granted by the DirectTrust Agent Accreditation Program for Health Information Service Providers from the Electronic Healthcare Network Accreditation Commission (EHNAC) and DirectTrust is valid for a two-year period; thereafter, a re- accreditation process take place.

Certification is a process by which an accreditation body assess and verifies the attributes of a product in accordance with established requirements or standards. Over the past decade the IHS successfully achieved certification of its Electronic Health Record for both ambulatory and inpatient settings against the 2011, 2014, and 2015 Edition standards published by the Office of the National Coordinator for Health Information Technology (ONC). This has allowed IHS, Tribal and Urban Indian healthcare organization hospitals and providers to qualify for various Centers for Medicare and Medicaid Services (CMS) Meaningful Use incentives authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act and to participate in CMS Quality Payment Programs. IHS has certified to the requirements that were due in 2022 for the ONC 2015 Edition Cures Update per ONC's timeline in the Federal Register. The IHS is continuing work to comply with the requirements due in 2023 as well. The IHS has utilized and incorporated numerous information technology standards promulgated by development organizations and specified in the various ONC Final Rules to meet the rigorous certification requirements.

The IHS Office of Information Technology maintains a website that references a number of the standards and policies in use by the agency that can be found at: (https://www.ihs.gov/oit/standardspolicy/)

National Institutes of Health (NIH) National Cancer Institute (NCI)

The Nanotechnology Characterization Laboratory (NCL) (https://ncl.cancer.gov/) is part of the Frederick National Laboratory for Cancer Research operated by Leidos Biomedical Research (contractor) for the National Cancer Institute (NCI). The NCL is guided by the NCI's Alliance for Nanotechnology in Cancer, Cancer Imaging Program, the Division of Cancer Treatment and Diagnosis. The laboratory is dedicated to supporting the extramural research community.

The mission of the NCL is to advance the science of nanoparticle characterization. As part of these efforts, the NCL has developed 79 assays and 5 characterization guides for nanomaterial characterization, termed NCL's Assay Cascade. All NCL assays are published on the NCL website and free to download: (https://www.cancer.gov/nano/research/ncl/protocols-capabilities). Over 480 nanomaterial platform types have passed through the NCL Assay Cascade. The laboratory updates existing assays on a regular basis and develops and validates new assays to meet the needs of the nanotechnology research community. This year, one new protocol was added to our catalogue:

- PCC-22: Analysis of Residual Ethanol in Nanoformulations Using Headspace Gas Chromatography

In addition to these assays, NCL commonly applies the following voluntary standards and guides:

- ISO Standard: TR 10993-22:2017: Biological evaluation of medical devices — Part 22: Guidance on nanomaterials
- ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection Of Tests For Interactions With Blood
- USP <85> Bacterial Endotoxins Test, December 2012

NCL team members are also active participants of the standards organizations ASTM International and ISO, which develop voluntary consensus standards. NCL staff serve as subject matter experts in various nanotech-related working groups within these organizations. NCL has contributed to the development of ISO 29701:2010 "Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems — Limulus amebocyte lysate (LAL) test", and is currently working on a second ISO standard, "Nanotechnologies—Total and free drug quantitation in doxorubicin hydrochloride liposomal formulations."

NCL protocol ITA-8 was used as a foundation in the ASTM E3238-20 Standard Test Method For Quantitative Measurement Of The Chemoattractant Capacity Of A Nanoparticulate Material In Vitro. In 2022, the NCL has completed the revisions and renewal of three standard methods originally developed by the team in 2008:

- ASTM 2524-22: Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
- ASTM 2525-22: Standard Test Method for Analysis of Nanoparticle Effects on CFU-GM
- ASTM 2526-22: Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells.

This year, the FDA team finalized another ASTM standard, ASTM E3351-22 Standard Test Method for Detection of Nitric Oxide Production In Vitro, which is based on the NCL assay cascade protocol ITA- 7.

Efforts are also ongoing to bring 10 NCL protocols through ASTM as Standard Methods or Standard Guides. These efforts are continuing into 2023. The standards under development are:

- **WK76862** Guide for the Identification of Nanoparticles Ability to Induce Infusion Reactions

- **WK76861** Method for the In vivo analysis of nanoparticle-mediated physiological changes accompanying hypersensitivity reactions
- **WK76860** Method for the Preparation and Analysis of Culture Supernatants for the Presence of Cytokine Biomarkers by Nanoparticles in Human Whole Blood Cultures
- **WK76878** Method for the analysis of nanoparticle effects on human platelets in vitro
- **WK76821** Practice for the Synthesis and Assembly of Nucleic Acid Nanoparticles
- **WK76822** Method for the Preparation and Analysis of Culture Supernatants for the Presence of Cytokine Biomarkers by Nucleic Acid Nanoparticles in Human Peripheral Blood Mononuclear Cells
- **WK76823** Guide for the Evaluation of Immunostimulatory Properties of Nucleic Acid Nanoparticles (NANPs)

National Library of Medicine (NLM)

The National Library of Medicine (NLM) is a leader in biomedical informatics and computational health data science research, and the world's largest biomedical library. NLM leads innovation in the development of advanced tools for clinical data interpretation and decision-making through cutting- edge research, training programs, and information services. NLM is distinctive within the National Institutes of Health (NIH) because of its substantial investment in sustainable biomedical information systems that make scientific literature, genomic, clinical, and other types of biomedical data readily available to those who need it.

Bibliographic consensus standards

NLM is active at national and international levels in the creation, review, and ongoing maintenance of standards related to the basic functions of a library including interlibrary loan, collection preservation, bibliographic control, and database creation and access. NLM's goal is to ensure these standards are workable for the library community as a whole. NLM participates in the National Information Standards Organization (NISO). Because NISO decisions feed into the decision-making process of the American National Standards Institute (ANSI), the official U.S. representative to the International Organization for Standardization (ISO), NLM's activities extend to the development of standards at an international level. One example of an important NISO standard developed by NLM is the Journal Article Tag Suite (JATS), which is an outgrowth of NLM's work on the PubMed Central journal article archive.

Health data consensus standards

For more than five decades, NLM has conducted and supported groundbreaking research and development related to the representation, interpretation, and use of electronic biomedical data and information including clinical data.

NLM serves as the central coordinating body for clinical terminology standards within the Department of Health and Human Services (HHS)[1]. To fulfill its role, NLM works with standards development organizations (SDOs), other federal agencies, and implementers of standards.

NLM also participates in international consensus standards groups, including Health Level Seven International (HL7), Clinical Data Interchange Standards Consortium (CDISC) and the ISO Health Informatics Technical Committee Subcommittee 1 (ISO/TC 215/SC1). ISO/TC 215/SC1 provides advice at the national (ANSI) and international (ISO) levels concerning the "standardization of computable data, information, and knowledge, including their representation and metadata, for the application of omics, including but not limited to genomics, phenomics and proteomics, to support human health and clinical research."

Clinical terminology consensus standards supported or developed by NLM include:

- LOINC (Logical Observations Identifiers Names and Codes) – NLM supports and funds the ongoing development, maintenance, and free distribution of this standard with codes names and other information for reporting and ordering laboratory tests, measurements, survey instrument and other kinds of observations (accessible within the UMLS Metathesaurus and from the Regenstrief Institute). LOINC can be accessed worldwide via a web tool (SearchLOINC) which enables searches for tests and measures, their descriptions, units of measure, synonyms, and tests/measures. LOINC can also be downloaded as a whole or as its component parts including the LOINC tables, Hierarchy, Document Ontology, linguistic variations, mappings between RadLex

[1] Thompson TG (Secretary of Health and Human Services). letter to: Lumpkin J M.D. (Chair, National Committee on Vital and Health Statistics). 2004 September 22 [cited 2021 August 16]. Available from: https://ncvhs.hhs.gov/wp-content/uploads/2014/05/040922lt.pdf

(Radiology codes) and LOINC codes, and mappings between IEEE instrument codes and LOINC codes. LOINC content can be accessed programmatically via an HL7® FHIR® API.

- SNOMED CT – SNOMED CT is a comprehensive clinical terminology for clinical findings, anatomical structures, events, procedures, substances, etc. The terminology is owned and maintained by SNOMED International, a not-for-profit organization that has over 43 member countries as of 2022. NLM is the US representative to SNOMED International and as such pays an annual fee that enables free U.S.-wide use of SNOMED CT. NLM is also the National Release Center for SNOMED CT United States (US) Edition, which is the official version of SNOMED CT for use in US healthcare systems. The US Edition is a standalone release that combines the content of both the US Extension (unique terms) and the International releases of SNOMED CT. The US Edition is accessible both within the UMLS Metathesaurus and separately from NLM.

- RxNorm – NLM produces and distributes RxNorm, a terminology for clinical drugs. RxNorm provides normalized names for clinical drugs and links to many drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary. RxNorm is accessible both within the UMLS Metathesaurus and separately from NLM. NLM provides several application programming interfaces (APIs) for retrieving data from several drug sources including RxNorm API, RxTerms API, RxClass API, and Drug Interaction API. Another resource, RxNav, is a browser for several drug information sources, including RxNorm, RxTerms and MED-RT.

- UCUM (Unified Code for Units of Measure) – NLM funds development of UCUM, which is an international code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units.

- Mappings -- NLM develops and maintains authoritative mappings between standard clinical vocabularies, HIPAA code sets, and other key vocabularies used in federal health information systems. The mappings are intended to facilitate development and implementation by health care providers of EHRs that capture clinical data at the point of care and subsequently support generation of required HIPAA code set data for claims and other administrative transactions. Mappings maintained and distributed by NLM include:

    - SNOMED CT to ICD-10-CM – Based on the same tools and mapping principles used in the SNOMED CT to ICD-10 map, which is maintained by SNOMED International.

    - ICD-9-CM to SNOMED CT – Designed to further facilitate the transition from ICD-9-CM to SNOMED CT, NLM makes available maps from heavily used ICD-9-CM procedure codes to SNOMED CT as well as the map from heavily used ICD-9-CM diagnostic codes to SNOMED CT. Both maps are based on in-patient claims data obtained from the Centers for Medicare and Medicaid Services (CMS).

LOINC, SNOMED CT, RxNorm, and UCUM form a suite of key clinical terminology standards that have been designated for use in the U.S. healthcare system over the past 20 years. The current policy framework includes:

- The Office of the National Coordinator for Health Information Technology (ONC) Cures Act Final Rule (effective 6/30/2020) extended and expanded previous Health IT Certification Program requirements (2015) for the use of NLM-coordinated clinical terminologies to promote interoperability. It also establishes the United States Core Data for Interoperability (USCDI), a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. SNOMED CT, LOINC, RxNorm and UCUM are all required for use under the Cures Act Final Rule, for designated purposes.
- Since 2019, the National Institutes of Health (NIH) has promoted the use of Fast Healthcare Interoperability Resources® (FHIR®) to facilitate research involving the integration of clinical and observational data (for more information, see https://datascience.nih.gov/fhir-initiatives). NIH subsequently issued a notice to encourage NIH-supported clinical research programs and researchers to adopt and use USCDI data classes and associated vocabulary standards.

As a member of HL7, NLM staff participate in the support and development of messaging and exchange consensus standards relate to Health Level 7 (HL7) V2 and HL7® Fast Healthcare Interoperability Resources® (FHIR), such as:

- HL7 V2
  - Clinical Genomics Work Group. HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 2. 2014+ HL7 Informative Document. March 2013.
  - Clinical Genomics Work Group. HL7 Version 2.5.1 Implementation Guide: Clinical Genomics; fully LOINC-Qualified Cytogenetics Model, Release 1 – US Realm. July 2014.
  - Orders and Observation Group. HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 1, HL7 V STU Release 4 - US Realm, Chapter 4 Results for Newborn Dried Blood Spot (NDBS) Screening. HL7 Standard for Trial Use. HL7 International; 2018.
  - Orders and Observation Group. HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 1, HL7 V STU Release 4 - US Realm, Chapter 4 Clinical Genomics Results Reporting. HL7 Standard for Trial Use. HL7 International; 2018.
  - Orders and Observation Group. HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 2, HL7 STU Release 1.1 - US Realm, Chapter 4 Clinical Genomics Results Reporting. HL7 Standard for Trial Use. HL7 International; 2018.
  - Orders and Observation Group. HL7 Version 2.5.1 Implementation Guide: Lab Results Interface (LRI), Release 1, STU Release 4 - US Realm, Chapter 5. HL7 Standard for Trial Use Ballot. HL7 International; 2017.
- HL7 FHIR
  - Clinical Genomics Work Group. HL7 FHIR® Implementation Guide: Genomics Reporting Implementation Guide, v1.0.0. Standard Trial for Use 1 based on FHIR R4.
  - FHIR Implementation Work Group. HL7 FHIR® Implementation Guide: Structured Data Capture, v2.7.0. Standard Trial for Use 3 based on FHIR R4.
  - Demo available: https://lhcforms.nlm.nih.gov/sdc

- Implementable Technology Specifications Work Group. HL7 FHIR® Implementation Guide
- Software code library available via NPM/GitHub: https://github.com/hl7/fhirpath.js/

NLM participates in other measures and standards efforts, such as:

- LOINC In Vitro Diagnostic (LIVD) Test Code Mapping -- LIVD is a guidance document for instrument manufacturers to provide LOINC codes for their tests. Initially developed for SARS- CoV-2 Tests in 2020, LIVD uses LOINC, SNOMED CT, Unique Device Identifiers (UDI) and UCUM to identify and report SARS-CoV-2 test results in electronic reporting systems to facilitate timely and quality data reporting to state and federal public health agencies (https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html). In 2022, the CDC announced updated the guidance to include for Mpox testing in laboratory data reporting. LIVD is a collaboration between CDC, FDA, Regenstrief (LOINC), SNOMED International, APHL, NLM and the IVD industry connectivity consortium.

Genomic Data Standards:

- NLM, through its National Center for Biotechnology Information (NCBI), participates in international voluntary standards collaborations intended to assure the global consistency, integrity, and reusability of genomic and proteomic data. NLM both contributes genome- related vocabulary resources for common use and uses standards developed internationally. The NLM-maintained NCBI Taxonomy, which includes organism names and classifications for every sequence in the nucleotide and protein sequence databases of the International Nucleotide Sequence Database Collaboration, in which NLM participates, is used as a standard across the collaboration. ClinVar, NLM's freely accessible, public archive of reports of the relationships among human variations and phenotypes with supporting evidence, incorporates the international Human Genome Variation Society (HGVS) nomenclature standard. Developed under the auspices of the Human Genome Organisation (HUGO), the HGVS nomenclature is used world-wide, especially in human health and clinical diagnostics, to unambiguously and consistently describe changes in DNA, RNA and protein sequences, also called variants.
- NLM is a voluntary participant in the Global Alliance for Genomics and Health (GA4GH), an international, nonprofit alliance formed in 2013 to create frameworks and schemas to enable the responsible, voluntary, and secure sharing of genomic and health-related data. Data submitted to NLM's dbGaP Sequence Read Archive include file formats managed by GA4GH. NLM also engages in the development and review of GA4GH schemas, including evaluation as to their suitability for NLM purposes
- NLM is also engaged in efforts to coordinate standards development across groups, as a member of in Technical Committee 215 (ISO/TC215) for Health Informatics.
- NLM databases of genetic variants (e.g., ClinVar, dbSNP) are considered required coding systems for HL7 Version 2 and FHIR clinical genetic reporting. NLM's Lister Hill National Center for Biomedical Communications developed and maintains a web service to provide programmatic access to these NCBI genetic coding systems to facilitate their use in electronic health record systems via a FHIR API.

Tools and Resources

NLM provides tools and resources to make standards more accessible. These include:

- UMLS Metathesaurus – Produced by NLM, the Unified Medical Language System® (UMLS®) integrates and distributes key terminology, classification and coding standards, and associated resources to promote creation of more effective and interoperable biomedical information systems and services, including electronic health records. The UMLS Metathesaurus, the largest component of the UMLS, is a thesaurus organized by concept, or meaning -- set of files and software -- that brings together and identifies relationships between nearly 200 biomedical and health vocabularies and standards.

- Value Set Authority Center (VSAC) – Produced by NLM and released in 2013, in collaboration with CMS and ONC, VSAC is a repository and authoring tool for public value sets created by external programs. Its authoring tool allows users to create value sets in a collaborative environment. NLM continues working with CMS and ONC to enhance and expand VSAC to meet users' needs.
- AccessGUDID (Global Unique Device Identification Database) - NLM, in conjunction with the Food and Drug Administration (FDA), introduced AccessGUDID in FY2015. This web resource contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).
- Newborn Screening laboratory reporting - NLM, in collaboration with CDC, FDA, Health Resources and Services Administration (HRSA), and other NIH institutes and centers, as well as with the American Public Health Laboratory (APHL) and many state public health departments develop and maintain an HL7 v.2.5.1 laboratory reporting guide for newborn screening result reporting. The guide leverages LOINC, SNOMED CT, and HL7 messaging structures to support the timely communication of newborn screening results and conditions.
- Nursing Resources for Standards and Interoperability - a resource for anyone interested in nursing terminologies for systems development. The page describes the role of SNOMED CT and LOINC in implementing meaningful use, specifically for the nursing and care domain.
- NIH Common Data Elements (CDE) Repository - developed and maintained by NLM on behalf of NIH, the CDE repository provides access to structured human and machine-readable definitions of data elements that have been recommended or required by NIH for use in research and other purposes. The repository helps facilitate standardization by providing tooling (search, browse, compare) that can be used in the harmonization and de-duplication of data elements.
- MedlinePlus Connect - a free service that delivers consumer-oriented information about relevant conditions and disorders, health and wellness, and prescription and over-the-counter medications to patients, families, and health care providers via EHR systems. The system works by accepting specific requests from EHR systems and providing in response links to relevant consumer health information from NLM's MedlinePlus system. To facilitate the connection, NLM maps all MedlinePlus health topics pages to standard coding systems used in EHRs. Specifically, MedlinePlus Connect responds to requests for information based on diagnosis (problem) codes (SNOMED CT CORE Problem List Subset, ICD-9-CM, ICD-10-CM), procedure codes (SNOMED CT, CPT), medication codes (RxNorm, NDC), and lab test codes (LOINC). Code requests will then receive relevant health information from MedlinePlus, Genetics Home Reference, and other reliable health resources. MedlinePlus Connect supports requests for information in English or Spanish. It is intended for use within the United States health care system and cannot support coding systems not used in the United States.

NLM works closely with ONC to ensure NLM's vocabulary harmonization and standards efforts are consistent with those of ONC. NLM represents the HHS Secretary in ONC's external advisory committee, the Health Information Technology Advisory Committee (HITAC).

A complete list of NLM's activities relating to health information technology and health data standards is available from the NLM Website at http://www.nlm.nih.gov/healthit.html.

Office of the National Coordinator (ONC)

Standards are an integral component of ONC's mission to support the development of a nationwide health information technology (health IT) infrastructure that allows for electronic use and exchange of information in a scalable manner, promotes the adoption of interoperable health IT in a cost- effective manner, and provides leadership in the development, recognition, and implementation of standards and certification of health IT products.

The consistent use of health IT standards is a necessary requirement to achieve interoperability of health information, which is a central key to reducing health care costs.

One way in which ONC encourages the consistent use of health IT standards is through ONC's Health IT Certification Program which is composed of functional requirements known as “certification criteria.” Health IT standards are part of the certification criteria. Developers certify their Health IT Modules by demonstrating conformance to these certification criteria, using test procedures (that may have associated test tools and/or test data) approved by the National Coordinator. Additionally, ONC provides clarifications to certification criteria through Certification Companion Guides (CCG) designed to assist with health IT product development.

One of the standards used in certification criteria is the United States Core Data for Interoperability (USCDI) which is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. It establishes a baseline set of data that can be commonly exchanged across care settings for a wide range of uses. In 2020, ONC published USCDI Version 1 and created an annual process for updating the USCDI based on public input. In 2022, ONC published USCDI Version 3 after going through the annual process and is now working on developing USCDI Version 4. Additionally, ONC continues to use the Health Information Technology Advisory Committee (HITAC) to review proposed drafts of the USCDI as one means to get expert feedback before finalizing each version. The USCDI’s impact is not limited to health IT products certified under the ONC Health IT Certification Program. The ONC Cures Act Final Rule provisions related to “information blocking” also reference the USCDI as the initial scope of electronic health information (EHI) healthcare providers, health information networks and exchanges, and developers of certified health IT need to consider when it comes to the access, exchange, and use of EHI. Please see the USCDI v2 and the USCDI Fact Sheet for more information.

The Standards Version Advancement Process (SVAP) enables health IT developers to voluntarily incorporate newer versions of specific ONC-regulated standards and implementation specifications into their products under the ONC Health IT Certification Program, including future versions of the USCDI. The SVAP advances interoperability by permitting developers of certified health IT to implement newer versions of standards and specifications than currently adopted in regulation. In 2020, ONC established an annual public comment process for SVAP-eligible standards and implementation specifications. In 2022, ONC announced the “Approved Standards for 2022.” Please see the SVAP Approved Standards on the ONC Certification Program SVAP webpage.

ONC provides some funding and works with the standards development organization named the Regenstrief Institute, in their development of Logical Observations Identifiers, Names and Codes (LOINC), a health IT standard for reporting and ordering laboratory tests, measurements, and other observations.

Another standard development organization that ONC works closely with and provides funding to is Health Level Seven (HL7) to support the development and ongoing maintenance of Fast Healthcare Interoperability Resources (FHIR) standard and related implementation guides along with their Consolidated Clinical Document Architecture (CCDA) standard. These standards are referenced in ONC’s certification program and enables nationwide interoperability.

Additionally, ONC works with Integrating the Healthcare Enterprise (IHE) a non-profit organization that creates guidance, called “profiles”, by combining a variety of standards and documents how they work together in order to support a specific use case. ONC’s focus with IHE has largely been related to updating IHE profiles to use the HL7 FHIR standard.

Related Links

https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi https://www.healthit.gov/isa/standards-version-advancement-process https://www.healthit.gov/topic/standards-version-advancement-process-svap https://www.healthit.gov/topic/certification-ehrs/certification-health-it

Substance Abuse and Mental Health Services Administration (SAMHSA)

The Substance Abuse and Mental Health Services Administration (SAMHSA) is a member of the National Quality Forum (NQF), a voluntary consensus body for performance measurement. SAMHSA works with NQF, as well as public and private-sector partners, as part of NQF's Measure Application Partnership to recommend quality measures to the Department of Health and Human Services (HHS) for federal reporting.

Additionally, SAMHSA works with NQF, as well as private and public stakeholders, as part of the Medicaid and Children's Health Insurance Program Scorecard Workgroup that provides input to HHS on quality measures that will be included in the Centers for Medicare and Medicaid Services (CMS) public reporting efforts.

As a member of the NQF, SAMHSA collaborates with a number of federal partners, including, the office of the Assistant Secretary for Planning and Evaluation, and CMS, to develop behavioral health quality measures that address key gaps in the field related to substance use and mental health disorders. Some of these measures have been used in different stages of "Meaningful Use" and are now part of the Medicaid Adult and Child Core Sets of Measures and the Merit-based Incentive Payment System (MIPS).

These Adult Healthcare Quality measures can be found at: (https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child- health-care-quality-measures/adult-health-care-quality-measures/index.html)

2023 and 2024 Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set): (https://www.medicaid.gov/sites/default/files/2022-11/2023-adult-core-Set.pdf)

2023 and 2024 Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set): (https://www.medicaid.gov/sites/default/files/2022-11/2023-child-core-set.pdf)

The 2023 MIPS Quality Measures can be found at: (https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2217/2023%20MIPS%20Quality%20Measures%20List.xlsx)

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 1

Table 1: Current Government Unique Standards FY 2022

(1) Government Unique Standard

FDA Guidelines on Asceptic Processing (2004) [Incorporated: 2004]

Voluntary Standard

ISO 13408-1 Asceptic Processing of Health Care Products, Part 1, General Requirements

Rationale:

FDA is not using the ISO standard because the applicability of these requirements is limited to only portions of aseptically manufactured biologics and does not include filtration, freeze-drying, sterilization in place, cleaning in place, or barrier-isolator technology. There are also significant issues related to aseptically produced bulk drug substance that are not included in the document.

DHS's FY2022 NTTAA Agency Annual Report Component Responses

Department of Homeland Security (DHS) Fiscal Year 2022 Agency Report

1. ***Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.***

The Department of Homeland Security (DHS) standards policy was established as part of the Homeland Security Act of 2002, incorporating the National Technology Transfer and Advancement Act of 1995 and the Office of Management and Budget Circular A-119.
Implementation of the Circular was delegated to the Under Secretary for Science and Technology by the Secretary of Homeland Security.
A summary of DHS Components that were active in FY2021 in carrying out the provisions of OMB Circular A-119 include the Countering Weapons of Mass Destruction Office (CWMD), Federal Emergency Management Agency (FEMA), the U.S. Coast Guard (USCG), as well as the Science & Technology Directorate (S&T), which executes the duties of the Department's Standards Executive. For more information about DHS, see www.dhs.gov.
Component-level responses are summarized below:

- **USSS**

USSS uses several Voluntary Consensus Standards (ISO, ASTM, MIL SPEC, IBC Building Codes, etc.) to conduct the development, testing and procurement of equipment and technology and facilities. Furthermore, USSS does not have any USSS-specific standards.

USSS does not maintain a standards-specific website.

- **USCIS**

USCIS has developed and is implementing data standards in its technology systems, which are used to perform the mission. USCIS participates in the DHS Immigration Data Integration Initiative (IDII) to help promote consistent data standards across the department. USCIS standards are maintained locally and

made available via Reference Data as a Service and a DHS-hosted instance of Collibra. *https://ecn.uscis.dhs.gov/team/opq/OCDO/DSP/SitePages/default.aspx#standards*

- **CBP**

CBP utilizes consensus standards from the following groups:

  - AATCC - American Association of Textile Chemists and Colorists
  - ABC - American Board of Criminalistics
  - AIC - Arizona Identification Council (AIC)
  - ANAB - ANSI National Accreditation Board
  - ANSI - American National Standards Institute

- API - American Petroleum Institute
- API - American Petroleum Institute
- ASB - Auditing Standards Board (under American Institute of Certified Public Accountants)
- ASCP - American Society for Clinical Pathology)
- ASME - American Society of Mechanical Engineers
- ASTM - American Society of Testing and Materials
- ASTM- ASTM International (formerly American Society for Testing and Materials)
- CFTT - National Institute of Standards (NIST) Computer Forensics Tool Testing Program
- IACIS - International Association of Computer Forensic Examiners
- IAI - International Association for Identification
- ICUMSA - International Commission for Uniform Methods of Sugar Analysis
- IEEE - Institute of Electrical and Electronics Engineers Standards Association
- NAFTZ - National Association of Free Trade Zones
- NFPA - National Fire Protection Association
- OSAC - Organization of Scientific Area Committees For Forensic Science
- SAE - Society of Automotive Engineers
- SAFS - Southern Association of Forensic Scientists
- SANS - SANS Institute Best Practices (SysAdmin, Audit, Network and Security)
- SWAFS - Southwestern Association of Forensic Scientists
- SWGDE - Scientific Working Group on Digital Evidence
- TIC Council - Testing, Inspection, and Certification Council (formerly IFIA – International Federation of Inspection Agencies)

Government Standards:

- CISA – Cybersecurity and Infrastructure Security Agency
- EPA – Environmental Protection Agency

CBP is directly involved in the development of consensus standards for the following:
ASTM – American Society of Testing and Materials

- D02 Committee – Petroleum Products, Liquid Fuels, and Lubricants
- E30 Committee - Forensics

API – American Petroleum Institute

- COPM – Committee on Petroleum Measurement Standards Meeting

OSAC

- IAI representative to Forensic Science Standards Board; Affiliate, Footwear and Tire Subcommittee

AIC

- Member, Board of Directors

ASB

- Executive Secretary, Footwear and Tire Consensus Body

CBP uses our own agency-specific standards under the CBP Lab Methods (CBPL Method) that often "incorporate by reference" consensus standards from ASTM, ANSI, and other groups.

https://www.cbp.gov/about/labs-scientific-svcs/technical-documents/lab-methods

- **CWMD**

In 2022, CWMD continued activities in accordance with OMB Circular A-119 which directs that "agencies must consult with voluntary consensus standards bodies in the development of standards when consultation and participation is in the public interest and is compatible with their missions, authorities, priorities, and budgetary resources." To this end, CWMD continued to sponsor and participate in the development and maintenance of Institute of Electrical and Electronics Engineers (IEEE), American National Standards Institute (ANSI) and ASTM voluntary consensus standards for radiation and nuclear, and biological threat detection systems used in homeland security. In 2022 CWMD sponsored the publication of a revision to ANSI N42.41 American National Standard Performance Criteria for Active Interrogation Systems Used for Homeland Security and IEEE Standard N42.43 for Mobile Radiation Monitors Used for Homeland Security and of an amendment to ANSI N42.32a American National Standard Performance Criteria for Alarming Personal Radiation Detectors for Homeland Security. CWMD also participated with the U.S. Committee for International Electrotechnical Commission (IEC) international standards for radiation detection systems. In 2022 the IEC published IEC 61452: Standard for Calibration and Measurements using High Purity Germanium (HPGe) Detectors.
CWMD continued to sponsor IEEE Series N42 standards for radiation detection for homeland security that are available at:
https://ieeexplore.ieee.org/browse/standards/get-program/page

- **CISA**

The **Cybersecurity and Infrastructure Security Agency (CISA)** partners with standards organizations, consistent with CISA authorities, strategic intent, and DHS International Cybersecurity priorities, to drive policies and create standards to improve interoperability and automate cybersecurity operations, among other outcomes. CISA works with domestic and international partners and engages in standards development at the national and international levels. CISA participates in the following standards bodies: 3rd Generation Partnerships Project (3GPP), Institute of Electrical and Electronic Engineers (IEEE), International Telecommunication Union (ITU), Global Systems for Mobile Communication Alliance (GSMA), Internet Engineering Task Force (IETF), Alliance for Telecommunications Industry Standards (ATIS), Wi-Fi Alliance, O-RAN Alliance, Wireless Broadband Alliance, and OASIS Open. Within those bodies, CISA

participates to monitor, support, and influence standards development activities relevant to agency mission objectives.

Department/Agency: CISA				
	Engagement			
Standards Body	Subcommittees/working groups, etc.	What technology /technologies does the subcommittee/group set standards for?	Other relevant activities or information	
3rd Generation Partnership Project (3GPP)	3GPP	Cellular telecommunications technologies, including radio access, core network and service capabilities, and system description for mobile telecommunications.	CISA ECD participates to **influence** standards work in support of mission objectives for NS/EP Priority Services for Voice Video, and Data in 3GPP Systems (e.g., 4G and 5G mobile systems). Also, to ensure NS/EP Priority Services coexistence with other priority services (e.g., Emergency and Mission Critical Services for Group Type Communications).	,
	3GPP SA1	Services	CISA ECD participates to **influence** stage 1 (service description) specifications for Multimedia Priority Service (MPS and to ensure MPS support in evolving 3GPP systems (e.g., 5G) and emerging service features.	)
	3GPP SA2	Architecture	CISA ECD participates to **influence** stage 2 (architecture requirements) specifications in support of priority features for MPS.	
	3GPP SA3	Security	CISA ECD participates to **support** 4G and 5G security solutions benefiting MPS.	
	3GPP SA5	Management, orchestration, and charging	CISA ECD **actively monitors** work for MPS interests.	
	3GPP SA6	Mission critical applications	CISA ECD **actively monitors** work to ensure MPS coexistence with MCS.	
	3GPP CT1	User Equipment - Core Network Protocols	CISA ECD participates to **influence** protocol specifications	

			in support of priority features for MPS.
	3GPP CT3	Interworking with External Networks	CISA ECD participates to **influence** CT3 (e.g., policy, interconnection) specifications in support of priority features for MPS.
	3GPP CT4	Core Network Protocols	CISA ECD participates to **influence** CT4 (e.g., HTTP-based APIs) specifications in support of priority features for MPS.
	3GPP RAN1	Radio Layer 1	CISA ECD participates to **influence** RAN1 work in support of priority features for MPS.
	3GPP RAN2	Radio Layer 3 and Radio Layer 3	CISA ECD participates to **influence** RAN2 work in support of priority features for MPS.
	3GPP RAN3	UTRAN/E-UTRAN architecture and protocols for the Iu, Iur, Iub, S1 and X2 interfaces	CISA ECD participates to **influence** RAN3 work in support of priority features for MPS.
	3GPP RAN4	Performance and protocol aspects	CISA ECD **passively monitors** work for MPS interests.
Institute of Electrical and Electronic Engineers (IEEE)	IEEE 802 LAN/MAN Standards Committee (LMSC)	Local, metropolitan, and other area networks standards	CISA ECD participates to **influence** work to support NS/EP Priority Services in WLAN access networks (a.k.a WiFi networks).
	IEEE 802.11 WG	Wireless Local Area Network (WLAN) Standards	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for ethernet PHY/MAC protocol.
	IEEE 802.11be (TGbe)	Task group for WLAN enhancement	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for ethernet PHY/MAC protocol.
	IEEE 802.11TGm	Task Group for revising and updating the IEEE 802.11 Standards	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for supporting previous generation of WLAN PHY/MAC protocols.
	IEEE 802.11 UHR (Ultra High Reliability)	Study Group for next generation IEEE 802.11 Amendment	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for next generation WLAN PHY/MAC protocol.

International Telecommunication Union (ITU)	ITU Telecommunication Sector (ITU-T)	Telecommunication s Standards	CISA ECD **monitors** ITU-T activities for relevance to mission objectives related to NS/EP Priority Services support in global standards.
	ITU-T Study Group 11	Signaling requirements, protocols, test specifications and combating counterfeit products	CISA ECD **actively monitors** SG11 activities (signaling and protocol) for work on Emergency Telecommunications Service (ETS) (ITU-T term for NS/EP Priority Services).
	ITU-T Study Group 13	Future networks, with focus on IMT- 2020, cloud computing and trusted network infrastructures.	CISA ECD **passively monitors** SG13 activities for work on ETS.
	ITU-T Study Group 17	Telecommunication s and ICT Security	CISA ECD **passively monitors** SG17 activities for global standards on public network security benefiting NS/EP Priority Services security.
	ITU-T FG-AI4NDM	ITU-T Focus Group on AI for Natural Disaster Management	CISA ECD participates to **passively monitor** work for relevance to ECD mission objectives.
	US State Dept Coordination	US State Dept interagency coordination for ITU	CISA ECD participates in the US State Department interagency coordination process in support of ECD mission objectives.
Global Systems for Mobile Communication Alliance (GSMA)		Mobile network roaming and interoperability	CISA ECD monitors work for relevance to ECD mission objectives.
	GSMA Networks Group	Specifications for 5G Roaming and Interoperability	CISA ECD participates to **influence** work defining an MPS attribute in the GSMA Generic Slice Template specification.
Internet Engineering Task Force (IETF)		Internet Protocol (IP) Standards	CISA ECD participates to **influence** work relevant support of NS/EP Priority Services over IP transport networks.
	Secure Telephone Identity Revisited (stir)	Secure Telephone Identity (STI) Protocols	CISA ECD participates to **influence** work relevant to mission objectives for NS/EP Priority Services over IP transport networks.

	Automated Certificate Management Environment (acme)	ACME protocols and API	CISA ECD **actively monitors** work relevant to mission objective for NS/EP Priority Services over IP transport networks.	s
	Transport Area Working Group (tsvwg)	IP transport and routing protocols	CISA ECD **influence** work relevant to mission objectives for NS/EP Priority Services over IP transport networks.	
	Adaptive DNS Discovery (add)	DNS protocols	CISA ECD **actively monitors** work relevant to mission objective for NS/EP Priority Services over IP transport networks.	s
	Traffic Engineering (TE) Architecture and Signaling (teas)	Network Slicing	CISA ECD **actively monitors** work relevant to mission objective for NS/EP Priority Services over IP transport networks.	s
	Transport Layer Security (tls)	Transport Security	CISA ECD **actively monitors** work relevant to mission objective for NS/EP Priority Services security and Privacy	s
	Messaging Layer Security (mls)	Message security for Groups	CISA ECD **actively monitors** work relevant to mission objective for NS/EP Priority Services security and Privacy	s
	Remote Attestation Procedures (rats)	Remote Attestation	CISA ECD **actively monitors** work relevant to mission objective for NS/EP Priority Services security and Privacy	s
Alliance for Telecommunication s Industry Standards (ATIS)		National Telecommunication s Standards	CISA ECD participates to **influence** work to define national specific aspects for NS/EP Priority Services using global standards features (e.g., 3GPP, IETF).	
	Packet Technologies and Systems Committee	Services, architectures, and signaling,	CISA ECD participates to **influence** work to define national standards for NS/EP Priority Services for Voice, Video, and Data.	
	ATIS/SIP Forum IP-NNI Task Force	IP Network-to-Network Interconnections	CISA ECD participates to **influence** work to allow interconnection and interoperability of NS/EP Priority Services for Voice, Video, and Data.	

	Wireless Technologies and Systems Committee	Wireless/mobile telecommunications networks in the U.S.	CISA ECD participates to **influence** work relevant to support of NS/EP Priority Services for Voice, Video, and Data.
	5G North American Needs Focus Group	Coordinate North American Needs in 3GPP	CISA ECD participates to **influence** need for NS/EP Priority Services.
	5G Supply Chain Working Group	Development of ATIS standards on supply chain	CISA ECD participates to **passively monitor** work relevant to ECD mission objectives for NS/EP Priority Services.
	Next G Alliance	Development of the National Roadmap for 6G and Beyond.	CISA ECD participates to **passively monitor** work relevant to ECD mission objectives for NS/EP Priority Services.
WiFi Alliance		Development of requirements and test programs for Wi-Fi interoperability	CISA ECD participates to **influence** work to define a NSEP Priority Access features for WLAN PHY/MAC protocol interoperability.
	Wi-Fi 7 Marketing Task Group (MTG)	Development of use cases, requirements and features for Wi-Fi interoperability	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for WLAN PHY/MAC protocol interoperability.
	Wi-Fi 7 Technical Task Group (MTG)	Development of test-cases, Test and Validation for Wi-Fi interoperability	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for WLAN PHY/MAC protocol interoperability.
	Wi-Fi Optimized Connectivity Experience (OCE) Task Group (Marketing and Technical)	Development of requirements, features and use cases for Wi-Fi QoS interoperability	CISA ECD participates to **influence** WLAN QoS work relevant to ECD mission objective for NS/EP Priority Services.
O-RAN Alliance		Defining architecture and solution for intelligent, open, virtualized and fully interoperable Radio Access Networks	CISA ECD participates to actively monitor work relevant to mission objectives for NS/EP Priority Services

Wireless Broadband Alliance		Standards and guidelines for NextGen Wi-Fi, OpenRoaming, 5G and IoT.	CISA ECD **planned participation in 2023** to determine relevance to mission objectives for NS/EP Priority Services support in Wi-Fi access networks and OpenRoaming solution
OASIS Open	Automated Course of Action Operations (CACAO) for Cyber Security TC	Defining the standard for implementing course of action playbooks for cybersecurity operations.	CISA CSD participants to **influence** work relevant to CSD mission objectives.
	Common Security Advisory Framework (CSAF) TC	Standardizing automated disclosure of cybersecurity vulnerability issues	CISA CSD participants to **influence** work relevant to CSD mission objectives.
	Cyber Threat Intelligence (CTI) TC	Supporting automated information sharing for cybersecurity situational awareness, real-time network defense, and sophisticated threat analysis	CISA CSD participants to **influence** work relevant to CSD mission objectives as a co-chair of the Interoperability subcommittee.

- **FEMA**

FEMA provides subject-matter experts to participate on design standards committees and the update cycles of the I-Codes. These standards include: ICC 500, Standard for the Design and Construction of Storm Shelters; ICC 600, Standard for Residential Construction in High Wind Regions; ASCE 7, Minimum Design Loads and Associated Criteria for Buildings and Other Structures; ASCE/SEI/AMS Wind Speed Estimation Standard; ASCE 24, Flood Resistant Design and Construction; ASCE/SEI 41, Seismic Evaluation and Retrofit of Existing Buildings; ICC 605, Standard for Residential Construction in Regions with Seismic Hazard; ASTM E3075, Standard Test Method for Water Immersion and Drying for Evaluation of Flood Damage Resistance; ASTM Flood Damage Resistance Rating of Materials and Assemblies; ICC 1300, Standard for the Vulnerability-Based Seismic Assessment and Retrofit of One- and Two-Family Dwellings; and other applicable standards as needed. FEMA's building code-related resources can be found on FEMA.gov at Building Code Documents:

https://www.fema.gov/emergency-managers/risk-management/building-science/building- codes

- **FLETC**

The Federal Law Enforcement Training Centers (FLETC) has reviewed OMB Circular A-119 and DHS Directive 078-04 and has determined that it is currently not involved in, nor actively participating with standards development organizations, to develop voluntary consensus standards. FLETC will continue to examine its programs to ensure compliance with DHS Directive 078-04.

- **ICE/OFTP/AOU**

The OFTP Ballistics Laboratory (BALLAB) conducts research and testing of ammunition, firearms, and other law enforcement equipment. The work conducted by the BALLAB includes communication with users to collect general requirements, ongoing market research and product testing, solicitation testing to assist Office of Acquisition Management (OAQ) in the acquisition process, and quality surveillance testing during the contract period of performance. The BALLAB uses standards created and administered by the Sporting Arms and Ammunition Manufacturers' Institute (SAAMI) and International Organization for Standardization (ISO).

https://saami.org/ *https://www.iso.org/home.html*

- **MGMT/OCHCO**

MGMT/OCHCO did not have any activities under the use of voluntary consensus standards or the NTTAA during Fiscal Year 2022. MGMT/OCHCO works within the bounds of, and is guided by, the Mission Support Management Directorate Data Management Committee (MSMD DMC) to identify need, define/identify a standard, and track implementation.

Systems Engineering and Standards
DHS Directive 078-04 Standards Policy Governance
DHS Management Directive 10602 Homeland Security Standards Subject Area Working Groups

- **TSA**

TSA continues to support and fund the development of the Industry supported/sponsor data format standard "DICOS" (Digital Imaging and Communication in Security) through the governing body of NEMA (National Electrical Manufacturers Association). NEMA serves as both the facilitator for the development of the standard (with industry members participating in the development process) and publishing entity of the standard. This process and standard would be considered a "Voluntary Consensus" approach.

- **USCG**

The Coast Guard supports the provisions of OMB Circular A-119 and maintains one of the most robust standards programs in the Federal Government to meet our regulatory and research and development objectives. The Coast Guard remains committed to developing and adopting nationally and internationally recognized standards to improve maritime safety, security, and marine environmental protection, and to promote the competitiveness of U.S. businesses in the global marketplace. Incorporating voluntary consensus standards helps the Coast Guard fulfill its regulatory functions more efficiently, develop the Government/industry partnerships crucial to stewardship, and gain valuable public feedback necessary for effective policy development. The Coast Guard aggressively supports a broad range of standards development organizations through funding, active engagement, and membership on numerous committees. This vigorous participation helps us raise and resolve genuine issues related to public safety, national security,

and preservation of the marine environment with our industry partners.

The Coast Guard participates in the DHS Standards Council and the Interagency Council on Standards Policy. We also regularly collaborate with the National Institute for Standards and Technology Standards Directorate on training and conformity assessment issues. Visit our Director of Commercial Regulations & Standards website at for further information.

http://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention- Policy-CG- 5P/Commercial-Regulations-standards-CG-5PS

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

No GUS are being used in lieu of existing voluntary consensus standards. Responses: No Inputs
The following Components responded with no inputs for the FY2022 reporting timeframe:

- OCIO
- PARM
- OGC
- OCFO
- CPO
- OCSO
- S&T Chief Scientist
- S&T OSE (TCD, ORA, TED & TST)

Department of Housing and Urban Development (HUD) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

Standards are used to guide the work of the grantees and other HUD supported agencies in providing quality housing and improvements in America's communities. Standards support the achievement of the HUD mission by our state and local partners. In most cases, HUD and our partners use standards developed by or in conjunction with other related users, such as model building codes developed for and adopted by communities nationwide. Because there are virtually no differences between HUD- assisted and market-based construction and development, use of standards such as building codes that are developed through a public process for the entire design and construction industry are relevant and appropriate. Because of the way HUD supports local housing efforts, the communities use the building codes that have been adopted at the state or local level for both the HUD-assisted projects as well as the broader construction market. In rare cases, HUD is responsible for the standards, as it is the case with the Government Standard: 24 CFR 3280 – Manufactured Home Construction and Safety Standards. As mandated in legislation, HUD publishes and enforces the construction standard for manufactured housing, which is being converted to a consensus standard.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 1

(1) Government Unique Standard

24 CFR 3280 – Manufactured Home Construction and Safety Standards [Incorporated: 2000]

Voluntary Standard

ANSI A119.1 – Recreation Vehicles and NFPA 501C – Standard on Recreational Vehicles

Rationale

HUD-Unique Manufactured Home Construction and Safety Standards. HUD was required by legislation to "establish Federal construction and safety standards for manufactured homes and to authorize manufactured home safety research and development".

Updated FY2022: In 2022, HUD published a proposed rule updating the Manufactured Home Construction and Safety Standards on July 19, 2022. HUD continues working with the Home Innovation Research Labs to support the Manufactured Housing Consensus Committee in its work for providing recommendations to HUD for future updates to the standards.

Department of the Interior (DOI) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The Bureau of Indian Affairs (BIA) and The Bureau of Indian Education (BIE), pursuant to the Indian Affairs Manual, Part 20, Chapter 5 https://www.bia.gov/sites/bia.gov/files/assets/public/raca/manual/pdf/idc-021344.pdf, the IA-PMS is the system of record for reporting and analyzing data collected on Indian Affairs (IA) programs. The system consists of performance measures as defined by the 1993 Government Performance and Results Act (GPRA); measure definition templates to facilitate consistent reporting; and performance targets for monitoring overall program success. IA uses the IA-PMS to record quarterly and annual data on bureau-specific and strategic plan (SP) performance measures. Central Office programs, regions, and agencies are required to report on performance measures in a timely and accurate manner and are responsible for the validation and verification (V&V) of all data reported in the IA-PMS. The collection of GPRA performance information is a collaborative effort. The collection of timely, accurate, and appropriate performance information is essential to successful performance management of federal Indian and Alaska Native programs. Tribal governments or tribal organizations operating IA programs under grants, contracts or compacts authorized by the Indian Self-Determination and Education Assistance Act, as amended (25 U.S.C. §450 et seq.) are required to comply with policies and procedures if required by statute or regulation.

The Bureau of Trust Funds Administration (BTFA) formerly known as the Office of the Special Trustee for American Indians, manages the financial assets of American Indians held in trust by the Department of the Interior. The BTFA disburses more than $1 billion annually and has more than $8 billion under active day-to-day management and investment on behalf of Tribes and individuals. The BTFA manages the financial assets in accordance with applicable financial laws and regulations. BTFA also follows financial accounting standards such as those issued by the Financial Accounting Standards Board (https://www.fasb.org/home) and auditing of financial statements occur in accordance with the *Generally Accepted Government Auditing Standards* issued by the U.S. Government Accountability Office (https://www.gao.gov/yellowbook).

The Bureau of Land Management (BLM) Maintains metadata for spatial and geographic information according to the standards established by the FGDC. Bridge Assessments are inspected and reported according to the US Department of Transportation Federal Highway Administration National Bridge Institutehttps://www.fhwa.dot.gov/bridge/mtguide.pdf. Heritage resource surveys and reports submitted according to the State Historical Preservation Office data standards (State of Idaho example).

Sensitive species (plants and wildlife) observations are collected, maintained and reported according to the State Fish/Game/Wildlife data standard (See Idaho example). Water quality sampling data are collected, reported and maintained according to EPA standards. Timekeeping, financial, business, collections and

billing (FBMS and CBS) data entry and management follows OPM data standards. 33 BLM specific data standards can be found here.

The Bureau of Reclamation (BOR) leads and participates in standards activities across the enterprise. The following highlight standards involvement in various programs and geographic locations.

Our Technical Service Center (TSC) showcases its National Codes & Design Standards page (https://www.usbr.gov/tsc/techreferences/industrystandards-non_rec/nationalcodes-ds_non-rec.html

), illustrating how our design activities must be performed in accordance with established Reclamation design criteria and standards, and approved national design standards. National codes and design standards provide a consistency of standard practice across a wide variety of engineering disciplines. The adoption of national codes and standards reduces the effort to develop and maintain Reclamation standards. Reclamation designers use the most current edition of national codes and design standards consistent with Reclamation design standards. This list identifies primary national codes and design standards used by Reclamation designers but does not include all codes, standards, and guidelines that may be referenced by these documents. Reclamation design standards may include exceptions to requirements of national codes and design standards.

The North American Electric Reliability Corporation (NERC) and Western Electricity Coordinating Council (WECC) enforce standards necessary to maintain the reliability of the interconnected electric power grid which includes BOR facilities. BOR participates in the NERC and WECC committees and standard drafting teams to provide subject matter expertise and guide the development of the technical aspects of the NERC or WECC standards. BOR is required to maintain compliance with the standards; however, there are times when compliance with the standards is not congruent with the mandates placed on BOR. Participation in the development of the standards allows BOR to provide direct influence at the crucial times in the development of the standards to align the drafted requirements with the mandates thereby ensuring BOR's ability to maintain compliance and the reliability of BOR facilities. Our Hydropower standards program is described here: https://www.usbr.gov/power/data/fist_pub.html.

Finally, Reclamation's Information Resources Office (IRO) programmatically adopts and uses voluntary consensus standards through its affiliation with various standards bodies. The energy standard for data centers (American National Standard 90.4) was initiated to promote energy efficient design of data centers, a rapidly expanding and energy-intensive category among buildings in the United States and worldwide. The IRO utilizes the Information Technology Infrastructure Library (ITIL) framework, which is a set of industry best practices and standards for IT service management and delivering IT services. In addition, IRO focuses on integration of several ISO standards through the Control Objectives for Information and Related Technologies (COBIT) framework for the management, organization, development, and implementation strategies for IT governance and includes ISO 9000 (Quality Management); ISO 15504 (Process assessment); ISO 20000 (Information Technology); ISO 27000 (Information Security); ISO 31000 (Risk Management); ISO 38500 (IT Governance).

The Bureau of Safety and Environmental Enforcement (BSEE) has a long history of using industry standards to supplement and enhance its regulatory program. As of December 2020, BSEE has incorporated by reference 125 industry standards in its regulations (see 30 CFR § 250.198). BSEE's Standards Development Section (SDS) is responsible for tracking, engaging in, and advising on, industry standards relevant to BSEE's mission. The SDS coordinates SMEs from the offshore industry and BSEE to work together through the SDOs to develop standards as required by the NTTAA. The SDS is currently monitoring 10 different SDOs in the development of 125 standards presently Included by reference (IBR). There are different SDOs that develop industry standards such as the American Society of

Mechanical Engineers (ASME) or the American Petroleum Institute (API). The SDS also engages in the development of other standards in addition to the 125 incorporated standards if it is deemed a priority by BSEE. The 10 SDOs whose standards are IBR are API, ASME, NACE, ASTM, AWS, AGA, IEC ISO, and the Center for Offshore Safety.

Standards that significantly advance safety and environmental stewardship are a priority. The work of the SDS has significantly advanced the BSEE mission. Examples of advancing the BSEE mission include an addendum on quality control for supply chains written for API Specification Q1, a new performance-based approach to developing SEMS using API RP 75, a high-pressure high-temperature equipment design document, API 17TR8, and a bolting material guidance document, API 21TR1, to mitigate future bolting failures identified in the BSEE QC FIT report.

The federal regulations governing the development of offshore wind facilities, 30 Code of Federal Regulations (CFR) § 585, were published in 2009. These regulations outline the development process for an offshore wind project in U.S. waters. However, because the U.S. offshore wind industry was less mature in 2009, adequate U.S. standards did not exist. For this reason, no specific standards were incorporated by reference into 30 CFR § 585. Rather, the regulations prescribe that "best practices" be used, with the expectation that these practices would evolve as the U.S. offshore wind industry gained experience. Such best practices are the foundation upon which offshore wind standards will be based.

In addition to the above approach to standards, BSEE refers to the Public Petroleum Data Model (PPDM) for standard design patterns in designing custom databases for regulatory functions related to offshore oil and gas and BSEE also follows FGDC standards where applicable for GIS functions and geospatial data applications.

The above information is from the Standards Development section of BSEE's website (Standards Development Section | Bureau of Safety and Environmental Enforcement (bsee.gov))as it directly addresses this data call.

The Office of Natural Resources Revenue (ONRR) collects, accounts for, and verifies natural resource and energy revenues due to States, American Indians, and the U.S. Treasury. ONRR manages financial assets in accordance w/ laws, regulations, and financial and accounting standards issued by The Federal Accounting Standards Advisory Board fasab.gov. ONRR conducts audits following Government Auditing Standards Yellow Book | U.S. GAO to determine company compliance with lease terms, laws, and regulations.

ONRR's public websites are managed according to the 21st IDEA Act and the U.S Website Design Standards. (USWDS)

ONRR uses the Professional Petroleum Data Management Association Well Identification (ppdm.org) for US Well Number Standards and the Federal Information Processing Series (FIPS) for U.S. state and county codes:

https://standards.incits.org/apps/group_public/project/details.php?project_id=2399

https://standards.incits.org/apps/group_public/project/details.php?project_id=2398

The U.S. Fish and Wildlife Service (FWS) utilizes a variety of Voluntary Consensus Standards (VCS) in managing a wide array of management and resource data and information in support of its mission. The standards are embedded in multiple software, hardware, services, and systems. The FWS's policy on data standards is described in the FWS Manual Chapter 274 FW 2: Establishing Service Data Standards (http://www.fws.gov/policy/274fw2.html). It follows the Department of Interior Information Resource Management policy (Series: 17-INFORMATION RESOURCES MANAGEMENT (Parts 375-387) on https://www.doi.gov/elips/browse), the OMB Circular A-130: Management of Federal Information Resources (https://www.federalregister.gov/documents/2016/07/28/2016-17872/revision-of-omb-circular-no-a-130-managinginformation-as-a-strategic-resource), and OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities.

The FWS data standards are found here: https://www.fws.gov/data-standards. Of particular note, is the VCS for the Classification of Wetlands and Deep-water Habitats of the United States. The Service's definition and classification system provides standardization of concepts and terms used to describe the biological limit of wetland types found in the United States, and is used nationwide by many Federal, State, and local agencies as part of the management of their wetland resources.

The Data Science Committee has created a working group tasked with reviewing FWS data standards to bring them into compliance with Service policy 274 FW 2 listed above. All FWS standards will be assigned a data standard steward, assessed for relevancy, determine the frequency and process to keep theses updated to industry standards.

The National Park Service (NPS) preserves unimpaired the natural and cultural resources and values of the National Park System for the enjoyment, education, and inspiration of this and future

generations. The NPS uses a variety of standards to support bureau operations including many government unique standards (GUS) that do not have a similar voluntary consensus standards (VCS), see NPS Spatial Data Standards, Federal Camping Data Standard, Integrated Taxonomic Information System, EPA Pesticide Product Information System (PPIS), and EPA Water Quality Exchange (WQX). Data is also shared via Application Programming Interface (APIs) that follow the industry led OpenAPI specification. The NPS also maintains metadata for spatial and geographic information according to the standards established by the FGDC as well as metadata that meets project open data requirements.

The U.S. Geological Survey (USGS) employs a variety of Voluntary Consensus Standards (VCS) in managing a plethora of scientific data and information that support the mission of the Bureau. The USGS Survey Manual Chapter 502.2 - Fundamental Science Practices: Planning and Conducting Data Collection and Research addresses data and metadata standards states: "The data collected, and the techniques used by USGS scientists conform to or reference national and international standards and protocols if they exist and when they are relevant and appropriate. For datasets of a given type, and if national or international metadata standards exist, the data are indexed with metadata that facilitate access and integration." Examples can be found on the USGS Data Management Website (https://www.usgs.gov/data-management/data-standards) and include use of standards such as the International Organization for Standardization (ISO), Darwin Core, Climate, and Forecast CF- Conventions, US Topo Maps, USGS National Geospatial Program Standards and Specifications, Federal Geographic Data Committee (FGDC) National Data Standards Publications, Open Geospatial Consortium, Vegetation Classification: United States National Vegetation Classification (USNVC), Biological Taxonomy: Integrated Taxonomic Information System (ITIS), geographic locations descriptors, geologic time data standards such as Divisions of Geologic Time – Major Chronostratigraphic and Geochronologic Units, and Date/Time standards.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 0

Department of Justice (DOJ) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

Led by the Attorney General, the Department of Justice (DOJ) comprises more than 40 separate component organizations and has approximately 116,000 employees who carry out the missions of its components. While the DOJ's headquarters are in Washington, D.C., it conducts most of its work in field locations throughout the country and overseas. The DOJ mission is to enforce the law and defend the interests of the United States according to the law; to ensure public safety against threats foreign and domestic; to provide federal leadership in preventing and controlling crime; to seek just punishment for those guilty of unlawful behavior; and to ensure fair and impartial administration of justice for all Americans. DOJ is meeting these mission challenges through three strategic goals focused on advancing the Department's priorities and reflecting the outcomes the American people deserve. These goals are:

- Goal 1—Prevent Terrorism and Promote the Nation's Security Consistent with the Rule of Law;
- Goal 2—Prevent Crime, Protect the Rights of the American People, and Enforce Federal Law; and
- Goal 3—Ensure and Support the Fair, Impartial, Efficient, and Transparent Administration of Justice at the Federal, State, Local, Tribal, and International Levels.

DOJ uses standards wherever reasonable, recognizing the importance of Voluntary Consensus Standards (VCS) in achieving its mission goals. Implementation of VCS in both Departmental systems and those funded by Departmental grants:

- Improves collaboration and cooperation with criminal justice partners and the private sector;
- Makes services, products, and systems development more efficient (including cost and/or implementation time savings);
- Ensures equipment and systems are of the highest quality, safe, and effective as well as compatible and interoperable;
- Supports innovation, free and fair competition, commerce or trade while avoiding duplication of private sector activities;
- Ensures the results of analysis are unbiased and scientifically valid;
- Provides validation that facilities are operating safely, effectively, and are managed in accordance with sound principles;
- Enables reuse of technical tools to support multiple projects, reduce dependency on custom solutions; minimize project risk, and reduce dependency on a too specialized workforce;
- Provides an opportunity to pull communities-of-interest together;

- Allows commercial industry to reduce product development costs and pass those cost savings on to the Department;
- Improves procurements, contracting, and grant making functions.

The following summarizes some of DOJ's standards and conformity assessment activities in 2022, demonstrating the Department's active participation in improving and applying standards to deliver the mission.

The Federal Bureau of Investigation (FBI) remains compliant in carrying out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The FBI has not currently identified the need for any government unique standards in lieu of consensus-based standards.

The FBI's Science & Technology Branch (STB) ensures the FBI is represented in appropriate Standards Development Organizations (SDOs) and bodies to position the FBI to develop and exploit technology in ways that recognize and protect civil liberties, allows for auditing of use, and enables the FBI mission. The FBI's centralized SDO authority resides with the Internet Governance (IG) and 5G Program Office led by an FBI Senior Leader. STB and its corresponding divisions, including Criminal Justice Information Services Division (CJIS), Operational Technology Division (OTD) and the Laboratory Division (LD) follow the policies of OMB Circular A-119 by regularly participating with commercial and private-sector on standard development of voluntary consensus standards via committees, working groups, meetings, conferences and other engagements.

<u>FBI-Science & Technology Branch (STB) regularly participates in the following SDOs and bodies:</u>

- **Internet Corporation for Assigned Names and Numbers (ICANN**). International nonprofit responsible for the management of the Domain Name System (DNS). The FBI is an active, engaging participant in ICANN recurring meetings.
    - **Governmental Advisory Committee (GAC)**. An advisory committee to ICANN established via ICANN Bylaws and provides advice to ICANN on public policy aspects of ICANN's Domain Name System responsibilities. FBI participation provides direct access to the ICANN Board on public policy/LE-related issues. Enables early access to weigh in on development processes and ensure consistency with laws and national security interests. Provides access to experts across the national and international spectrum to engage on implications and mitigation strategies (if needed).
    - **Public Safety Working Group (PSWG)**. ICANN Governmental Advisory Committee (GAC) Working Group devoted to evaluating policies and procedures that implicate the safety of the public. Current strategies include developing DNS abuse and cybercrime mitigation capabilities of the ICANN and LE communities, preserving and improving domain registration directory services effectiveness, and leveraging stakeholders to influence balanced ICANN-level governance. The FBI directly contributed to development of a voluntary standard "framework"** for law enforcement referrals to domain registry operators of bulk lists of domain names linked to command and control of criminally operated botnets. Additionally, the FBI continues to provide public safety input to ongoing policy development for a replacement to the worldwide web's "WHOIS" system.

        - **Framework on Domain Generating Algorithms (DGAs) Associated with Malware and Botnets, link

- **International Telecommunications Union (ITU).** The FBI regularly attends meetings in ITU which allocates global radio spectrum and satellite orbits, develops the technical standards that ensure networks and technologies seamlessly interconnect, and strive to improve access to ICTs to underserved communities worldwide.

- **Internet Governance Forum (IGF).** The FBI continues to be an active participant in this global forum hosted by the United Nations Department of Economic and Social Affairs (UNDESA) and administered by the Multi-stakeholder Advisory Group (MAG).
    - **Internet Governance Forum USA (IGF-USA)**. The FBI continues to be an active participant in the IGF-USA recurring general meetings as well as working group meetings to illuminate issues and cultivate constructive discussions about the future of the internet.
- **The 3rd Generation Partnership Project (3GPP).** The FBI continues to participate in development of service-based interception capabilities for 5G-based communication services in 3GPP. This participation is meant to satisfy the industry consultation requirements of the Communications Assistance for Law Enforcement Act (CALEA) for the development of industry standards for covered services.
- **International Organization for Standardization (ISO)**. FBI is represented in the Committees/Working Groups of the ISO. ISO is an independent, non-governmental international organization with a membership of 167 national standards bodies. The ISO brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.
- **International Committee for Information Technology Standards (INCITS).** FBI is represented in the Working Groups of the INCITS. INCITS is the central U.S. forum dedicated to creating technology standards for the next generation of innovation.
- **Iris Experts Group (IEG)** within the newly formed **Organization of Scientific Area Committees** - part of the **Facial Identification Subcommittee**. The IEG is a forum for the discussion of technical questions of interest to US government (USG) agencies and their staff that are employing or may employ iris recognition to carry out their mission. FBI continues to be represented. The **Facial Identification Subcommittee** focuses on standards and guidelines related to the image-based comparisons of human facial features.
- **ASTM E30 Committee on Forensic Sciences**. FBI-OTD SME chairs semi-annual meetings of E30 as well as meetings of the Executive Committee. The Committee has jurisdiction over 60 standards, published in the Annual Book of ASTM Standards, Volume 14.02. E30 has 5 technical subcommittees that manage these standards.
- **Organization of Scientific Area Committees for Forensic Science (OSAC).** FBI-OTD SME participated in (2) meetings of the OSAC FSSB Outreach task group, which is currently focused on engaging with forensic science stakeholders to adopt OSAC standards. The OSAC addresses a lack of discipline-specific forensic science standards. OSAC fills this gap by drafting proposed standards and sending them to SDOs which further develop and publish them.
    - **Digital Multimedia Scientific Area Committee (DMSAC)**. FBI serves as a member of DMSAC. The Committee sets development standards for forensic analysis of multimedia and digital evidence, to include image, video, audio/voice, and computer/digital data.
        - **Speaker Recognition Subcommittee (SR).** Works in the development of standards specific to forensic analysis of human voice data. The SR subcommittee reports to the DMSAC committee. FBI-OTD SME has served as the chair of SR for the past three years and conducts monthly meetings for the advancement of documents supporting the establishment of standards in forensic speaker recognition.

- **National Information Exchange Model (NIEM).** FBI-OTD SME participates in bi-weekly meetings to advise the NIEM for the exchange of audio and voice information. The NIEM defines standard terminology, models, and relationships for the exchange of data across public and private organizations.
- **Telecommunications Industry Association (TIA) Engineering Committee (TR8).** FBI SMEs are represented and engage in TIA's work to formulate and maintain standards for private radio communications systems and equipment for both voice and data applications. TR-8 addresses all technical matters for systems and services, including definitions, interoperability, compatibility and compliance requirements.
- **APCO Project 25 Interface Committees (APIC).** FBI SMEs are represented. APIC is an ad hoc committee of the Private Radio Section (PRS) in the Wireless Communication Division (WCD) of the TIA. The APIC task groups are not standard formulating groups. The APIC task groups do develop documents that are reviewed by users and industry representatives, decisions based on consensus.
- **Federal Partnership for Interoperable Communications (FPIC).** Serves as a coordination and advisory body to address technical and operational wireless issues relative to interoperability within the public safety emergency communications community, interfacing with voluntary representatives from federal, state, local, territorial, and tribal organizations to include the FBI
    - **Federal Partnership for Interoperable Communications (FPIC) Security Subcommittee**. FBI SMEs are being represented. In coordination with the National Law Enforcement Communications Center (NLECC) and other public safety agencies, developed a standardized SLN assignment list for National Encrypted Interoperability.
- **Alliance for Telecommunications Industry Solutions (ATIS).** FBI participated in regard to Packet Technology and Systems Committee (PTSC) and lawfully Authorized Electronic Surveillance (PTSC LAES). ATIS is a standards organization that develops technical and operational standards and solutions for the ICT industry.

- **Internet Engineering Task Force (IETF)**. Engineering group that develops technical standards of the internet's architecture including encryption, cybersecurity, network security, routing and other key protocols. The FBI has engaged over many years to build alliances. Primary attenders are industry along with academia and organizations such as NIST, NTIA, NSA, FBI and UK/NCSC.
- **SAFECOM**. FBI SMEs are represented. Through collaboration with emergency responders and elected officials across all levels of government, SAFECOM works to improve emergency response providers' inter-jurisdictional and interdisciplinary emergency communications interoperability across local, regional, tribal, state, territorial, international borders, and with federal government entities. SAFECOM works with existing federal communications programs and key emergency response stakeholders (to include the FBI) to address the need to develop better technologies and processes for the coordination of existing communications systems and future networks.
    - **National Council of Statewide Interoperability Coordinators (NCSWIC).** Established by the Department of Homeland Security's (DHS) Cybersecurity and

Infrastructure Security Agency (CISA), the NCSWIC supports Statewide Interoperability Coordinators (SWIC) from the 56 states and territories, by developing products and services to assist them with leveraging their relationships, professional knowledge, and experience with public safety partners involved in interoperable communications at all levels of government to include the FBI.

- **3D Toolmark Technologies Technical Working Group (TWG).** FBI SMEs are represented. The TWG provides guidance and recommendations to the Firearms/Toolmarks community in instrument assessment and Virtual Comparison Microscopy (VCM). Creating standards for the F/T community to establish acceptable measuring practices, methodology/Standard Operating Procedures (SOPs), and quality assurance protocols that can be utilized to access a laboratory's compliance during accreditation.

- **American Academy of Forensic Sciences-Academy Standards Board.** FBI SMEs are represented. SDO with the purpose of providing accessible, high-quality science-based consensus forensic standards.

- **American Society for Testing and Materials (ASTM) International.** FBI-LD SMEs are represented. International SDO that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services.

- **International Society for Forensic Genetics.** FBI SMEs are represented. The society aims to promote scientific knowledge in the field of genetic markers as applied to forensic science. This is mainly being achieved through regular meetings regionally or internationally and their journal Forensic Science International: Genetics and the work of our expert DNA commissions.

- **National Fire Protection Association.** FBI SMEs are represented. International nonprofit organization in standards development devoted to eliminating death, injury, property and economic loss due to fire, electrical and related hazards.

- **Scientific Working Group-DNA Analysis Methods (SWGDAM).** FBI SMEs are represented. Serves as a forum to discuss, share, and evaluate forensic biology methods, protocols, training, and research to enhance forensic biology services as well as provide recommendations to the FBI Director on quality assurance standards for forensic DNA analysis.

- **Scientific Working Group-Seized Drugs (SWGDRUG).** FBI SMEs are represented. Maintains a database of reference mass spectra, or "molecular fingerprints" of controlled substances. This database is a cornerstone in the fight against illicit drugs, including newly emerging fentanyl analogues and other synthetic opioids. NIST scientists perform rigorous quality assurance on all new mass spectra added to the database, giving confidence to forensic chemists that the results they obtain using this database are accurate and reliable.

- **United States Technical Advisory Group-Technical Committee 272.** FBI SMEs are represented. The Committee is at the forefront of standardization and guidance in the field of Forensic Science. This includes the development of standards that pertain to laboratory and field based forensic science techniques and methodology in broad general areas such as the detection and collection of physical evidence, the subsequent analysis and interpretation of the evidence, and the reporting of results and findings.

The National Institute of Justice (NIJ) continues to operate its NIJ Compliance Testing Program. In calendar year (CY) 2022, over 90 models of ballistic-resistant body armor were submitted for testing. In

addition to initial testing, follow-up inspection and testing was conducted on approximately 340 models complying with NIJ Standard 0101.06, Ballistic Resistance of Body Armor. NIJ continues to participate in ASTM International and National Fire Protection Association (NFPA) committees to develop standardized methods and practices to test ballistic-resistant and other life safety equipment as well as standards for testing law enforcement public order personal protective equipment. Through ANSI, NIJ also supports ISO/IEC JTC 1/SC 37 Biometrics, which focuses on the standardization of generic biometric technologies pertaining to human beings to support interoperability and data interchange among applications and systems. More about NIJ's standards and conformity assessment activities can be found at: https://nij.ojp.gov/equipment-standards-and-conformity-assessment.

The Department's Office of the Chief Information Officer actively applies the ISO 20000 and 27001 standards for the delivery of IT and information security services and has undergone formal audits to obtain ISO certification for compliance with these standards. The Department recertified its IT service management certification originally obtained in 2017 to the updated ISO/IEC 20000-1:2018 standard and achieved initial certification under the ISO 27001:2013 information security management standard. Application of these standards has significantly improved delivery of OCIO enterprise IT and cybersecurity services, ensuring the continuous evaluation of service performance and use of standard practices as defined by criteria well-recognized across industry and government.

2. Please keep track changes on to record or rescind any new government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2022. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2022. If no changes, record the number of GUS in FY2022, save the file, and send to nrioux@nist.gov.

To add a new GUS, please go to Table 2: Government Unique Standards Added in FY2022 and use the template provided to add the GUS, VCS, and rationale. If more than one GUS is being added, please follow the template in listing any new GUS.

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please cut the rescinded standard and paste in Table 3: Government Unique Standards Rescinded in FY2022. Please add a 'Rationale for Rescinding' explaining why the standard was rescinded.

Please record below the total number of GUS currently in use (previous years and new as of this FY). This number should include the previous total plus any new GUS added, and minus any GUS rescinded:

Number of GUS in FY2022: 0 + (new) - (rescinded) = 0

Table 1: Current Government Unique Standards FY2022

Department of Labor (DOL) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The United States Department of Labor (DOL) promulgates safety and health standards, which provide minimum requirements for the protection of employees from workplace hazards. DOL consults and routinely relies on Voluntary Consensus Standards (VCS) whenever a Federal standard is written or updated. There are approximately 200 consensus standards referenced throughout DOL standards. The references appear in hundreds of requirements and range from informational to mandatory requirements. Since the VCS are on a shorter update cycle than Federal standards, the VCS provide a more current view of industry standards and practices than DOL can effectively or economically achieve. DOL updated some of its existing standards to incorporate the new editions of cited voluntary consensus standards.

Additionally, DOL uses VCS for enforcement support in the absence of a Federal safety or health standard. DOL may also use a VCS where a federal standard exists, but compliance with the VCS in lieu of the Federal standard does not adversely affect worker safety and health. These uses improve public health and safety and allow industry to use newer technology and more flexible and innovative methods to protect workers.

Nearly 60 DOL employees participated on more than 160 committees, representing 23 VCS bodies. DOL benefits from participation in the VCS process and from the expertise of other VCS committee members as DOL seeks to update its existing Federal standards and develop new ones. DOL is kept abreast of current trends and is at the forefront of emerging technologies.

DOL's Federal standards are comprehensive but they do not address every hazard in every workplace. Compliance Safety and Health Officers reference VCS during inspections and investigations when no Federal standards apply to specific circumstances. VCS are also used for compliance assistance as reference to industry best practices.

The Department of Labor maintains electronic access to its standards at:

https://www.osha.gov/law-regs.html

https://www.msha.gov/regulations/standards-regulations

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 17

(1) Government Unique Standard
29 CFR 1910 Subpart S - Electrical Standard (Incorporated: 2007) [Incorporated: 2007]

Voluntary Standard
NFPA 70 - National Electric Code
NFPA 70E - Electrical Safety Requirement for Employee Workplaces
ANSI/IEEE C2 - National Electrical Safety Code
ANSI/ASME B30.4 - Portal, Tower, and Pedestal Cranes
NFPA 33 - Spray Application Using Flammable or Combustible Materials
ANSI Z133.1 Arboricultural Operations for Pruning, Repairing, Maintaining, and Removing Trees, and Cutting Brush

Rationale
Several voluntary consensus standards were relied upon for the various provisions in the final rule, however, no single VCS is available to cover all the workplace applications that are addressed by OSHA. The Agency believes that it would be less burdensome for the regulated community to use one OSHA standard rather than purchase and use the 6 individual consensus standards it used to write the rule.

(2) Government Unique Standard
29 CFR 1910.1200 - Hazard Communication Standard (Incorporated: May 2012) [Incorporated: 2012]

Voluntary Standard
ASTM D 56-05, Standard Test Method for Flash Point by Tag Closed Cup Tester, Approved May 1, 2005, IBR approved for Appendix B to Sec. 1910.1200
ASTM D 86-07a, Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure, Approved April 1, 2007, IBR approved for Appendix B to Sec. 1910.1200
ASTM D 93-08, Standard Test Methods for Flash Point by Pensky-Martens

Rationale
Voluntary consensus standards (VCS) were relied upon for the various provisions in the final rule. This revision was undertaken to align the U.S. with other countries utilizing the United Nations Globally Harmonized System of Classification and Labeling. It was based on various standards and guidance materials used in international negotiations under the United Nations. No single VCS is available to cover all the hazard communication issues that are addressed by OSHA in this final rule. The Agency believes that it is less burdensome for the regulated community to use the one OSHA standard rather than require the purchase and use of numerous individual consensus standards it used to write the rule.

(3) Government Unique Standard
29 CFR 1915 Subpart F – General Working Conditions in Shipyard Employment (Incorporated: 2011) [Incorporated: 2011]

Voluntary Standard
ANSI/IESNA RP–7–01, Recommended Practice for Lighting Industrial Facilities
ANSI/ISEA Z308.1–2009, Minimum Requirements for Workplace First Aid Kits and Supplies
ANSI Z358.1–2009, Emergency Eyewash and Shower Equipment
ANSI Z4.1–1995 and Z4.3–1995, Sanitation
ANSI/ASME B56.1–1992, Recognition of the hazard of powered industrial truck tipover and the need for the use of an operator

Rationale
Several voluntary consensus standards (VCS) were relied upon for the various provisions in the final rule, however, no single VCS is available to cover all the workplace hazards that are addressed by OSHA in this final rule. The Agency believes that it is less burdensome for the regulated community to use the one OSHA standard rather than require the purchase and use of numerous individual consensus standards it used to write the rule.

(4) Government Unique Standard
29 CFR 1926 Subpart CC Cranes and Derricks in Construction (Incorporated: 2010) [Incorporated: 2010]

Voluntary
Standard ASME
B30.2-2005 ASME
B30.5-2004 ASME
B30.7-2001 ASME
B30.14-2004
AWS D1.1/D1.1M:2002 ANSI/AWS D14.3-94
BS EN 13000:2004
BS EN 14439:2006
ISO 11660-
1:2008(E) ISO
11660-2:1994(E)
ISO 11660-
3:2008(E) PCSA
Std. No.2
SAE J185
SAE J987
SAE
J1063
ANSI B30.5-1968

Rationale
Sixteen voluntary consensus standards (VCS) were relied upon for the various provisions in the final rule, however, no single VCS is available to cover all varieties of cranes and derricks and their applications.

(5) Government Unique Standard
29 CFR 1926.1002 Roll-Over Protective Structures (Incorporated: 2006) [Incorporated: 2006]

Voluntary Standard
SAE J1194-1999

Rationale
Many consensus standards were relied upon for various provisions in the final rule. The primary VCS that applies directly to ROPS is SAE J1194-1999 which incorporates by reference several other VCSs. If SAE J1194-1999 was adopted into the OSHA provisions, the regulated community would have to consult not only the primary VCS but all of the VCSs that are incorporated into it as well. OSHA believes it is less burdensome for the regulated community to use one OSHA standard rather than require the purchase and use of several VCSs.

(6) Government Unique Standard
30 CFR Part 75 - Safety Standards for Underground Coal Mines (Section 75.403 - Maintenance of Incombustible Rock Dust) - Incorporated: 2011 [Incorporated: 2011]

Voluntary Standard
ASTM C110-09 - Standard Test Methods for Physical Testing of Quicklime, Hydrated Lime, and Limestone
ASTM C737-08 - Standard Specification for Limestone Dusting of Coal Mines

Rationale
MSHA issued a final rule in June 2011 that finalized an Emergency Temporary Standard (ETS) on Maintenance of Incombustible Content of Rock Dust in Underground Bituminous Coal Mines. The basis of the ETS and final rule was a recommendation of the National Institute for Occupational Safety and Health contained in their Report of Investigations 9679 published in 2010. The ASTM consensus standards do not include the NIOSH recommendations or address the specific hazard covered in the MSHA ETS and final rule.

(7) Government Unique Standard
30 CFR Part 75 - Sealing of Abandoned Areas - Emergency Temporary Standard. [Incorporated: 2007]

Voluntary Standard
ACI 318-05 - Building Code Requirements for Structural Concrete and Commentary
ACI 440.2R-02 - Design and Construction of Externally Bonded FRP Systems for Strengthening Concrete Structures
ASTM E119-07 - Standard Test Methods for Fire Tests of Building Construction and Materials
ASTM E162-06 - Standard Test Method for Surface Flammability of Materials Using a Radiant Heat Energy Source

Rationale
Four consensus standards were relied upon for various provisions in the emergency temporary standard, but no one consensus standard is available that covered all of the topics covered by MSHA's Emergency Temporary Standard.

(8) Government Unique Standard
Electric Motor-Drive Equipment Rule [Incorporated: 2001]

Voluntary Standard
IEEE Standard 242-1986 Recommended Practice for Protection and Coordination of Industrial and Commercial Power Systems (IEEE Buff Book) and NFPA 70 - national Electric Code

Rationale
The MSHA rule is a design-specific standards. The NFPA and IEEE standards were used as a source for the rule; however, the exact requirements of the rule were tailored to apply specifically to electric circuits and equipment used in the coal mining industry.

(9) Government Unique Standard
Exit Routes, Emergency Action Plans, and Fire Prevention Plans, 29 CFR 1910, Subpart E [Incorporated: 2003]

Voluntary Standard
Life Safety Code, NFPA 101-2000

Rationale
The OSHA standard addresses only workplace conditions whereas the NFPA Life Safety Code goes beyond workplaces. However, in the final rule OSHA stated that it had evaluated the NFPA Standard 101, Life Safety Code, (NFPA 101-2000) and concluded that it provided comparable safety to the Exit Route Standards. Therefore, the Agency stated that any employer who complied with the NFPA 101-2000 instead of the OSHA Standard for Exit Routes would be in compliance.

(10) Government Unique Standard
Fire Protection for Shipyards, 29 CFR Part 1915, Subpart P [Incorporated: 2004]

Voluntary Standard
NFPA 312-2000 Standard for Protection of Vessels During Construction, Repair, and Lay-Up
NFPA 33-2003 Standard for Spray Application Using Flammable or Combustible Materials

Rationale
Many consensus standards were relied on for various provisions in OSHA's final rule, including 15 consensus standards that are incorporated by reference. However, OSHA and its negotiated rulemaking committee determined that there was no, one consensus standard available that covered all the topics in the rule.

(11) Government Unique Standard
Longshoring and Marine Terminals; Vertical Tandem Lifts [Incorporated: 2009]

Voluntary Standard
ISO 668:1995 - Series 1 freight containers--Classification, dimensions and ratings
ISO 1161:1984 - Series 1 freight containers--Corner fittings--Specification
ISO 1161:1984/Cor. 1:1990 - Technical corrigendum 1:1990 to ISO 1161:1984
ISO 1496-1:1990 - Series 1 freight containers--Specifications and testing--Part 1: General cargo containers for general purposes
ISO 1496-1:1990/Amd. 1:1993

Rationale
Several voluntary consensus standards were relied upon for the various provisions in the final rule, however, no single VCS is available to cover all the workplace applications that are addressed by OSHA. The Agency believes that it would be less burdensome for the regulated community to use one OSHA standard rather than purchase and use the nine individual consensus standards used in this rule.

(12) Government Unique Standard
OSHA's Respirable Crystalline Silica Standard for Construction [Incorporated: 2016]

Voluntary Standard
ASTM's E 2625 – 09, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica for Construction and Demolition Activities

Rationale
Rationale for not using: OSHA's standard includes a number of requirements that differ from the specifications in the ASTM standard because the requirements in the OSHA standard better effectuate the purposes of the OSH Act and protect employees from the significant risks posed by exposures to respirable crystalline silica (silica). The major differences include:

Both standards contain tables that specify control measures and respiratory protection for several common construction tools and tasks. OSHA's table (Table 1) differs from the ASTM tables in several respects; the OSHA standard divides respirator requirements according to duration of tasks and includes short duration tasks. Gives employers required to do exposure assessment a choice between complying with a scheduled monitoring approach or a performance-oriented approach. Requires a written plan to be reviewed annually; made available to employees, their representatives, OSHA and NIOSH upon request; address restricting access and requires a competent person to implement the plan.

Differences between the medical surveillance programs include, the ASTM standard triggers medical surveillance for employees exposed above the PEL or other occupational exposure limit for 120 or more days a year, while the OSHA standard triggers medical surveillance for employees who are required to use a respirator under the silica standard for 30 or more days a year. Medical examinations to be conducted within 30 days, spirometry testing is mandatory, an X-ray classification of 1/0 triggers

referral to a specialist, tuberculosis testing for the initial examination of all employees who qualify for medical surveillance, allows employees to make their own placement decisions and the OSHA standard withholds medical information from the employer because of privacy concerns.

Hazard communication and training specifications differ from requirements in the OSHA standard in the following ways, requires training of all employees covered by the standard. The OSHA standard is more performance-based in order to allow flexibility for employers to provide training. Some training topics differ.

Recordkeeping specifications in the standard differ in that the ASTM standard specifies that medical and exposure records be retained for 40 years or for duration of employment plus 20 years.

(13) Government Unique Standard
OSHA's Respirable Crystalline Silica Standard for General Industry and Maritime [Incorporated: 2016]

Voluntary Standard
ASTM's E 1132 – 06, Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica

Rationale
Rationale for not using: OSHA's standard includes a number of requirements that differ from the specifications in the ASTM standard because the requirements in the OSHA standard better effectuate the purposes of the OSH Act and protect employees from the significant risks posed by exposures to respirable crystalline silica (silica). The major differences include:

The OSHA standard gives employers required to do exposure assessment a choice between complying with a scheduled monitoring approach or a performance-oriented approach, requires employers to establish regulated areas, requires a written plan to be reviewed annually and made available to employees, their representatives, and OSHA and NIOSH upon request.

Differences between the medical surveillance program include, that the ASTM standard triggers medical surveillance for employees exposed above the PEL or other occupational exposure limit (OEL) for 120 or more days a year, while the OSHA standard triggers medical surveillance for employees exposed at or above the action level (half the PEL) for 30 or more days a year. That the medical examinations to be conducted within 30 days, spirometry testing is not optional, X-ray classification of 1/0 triggers referral to a specialist, requires tuberculosis testing for the initial examination of all employees who qualify for medical surveillance, allows employees to make their own placement decisions and the OSHA standard withholds medical information from the employer because of privacy concerns.

(14) Government Unique Standard
Personal Fall Protections Systems (29 CFR 1910.140) [Incorporated: 2017]

Voluntary Standard
ANSI/ALI A14.3-2008
ANSI/ASSE A10.32-
2012 ANSI/ASSE
Z359.0-2012
ANSI/ASSE Z359.1-
2007 ANSI/ASSE
Z359.3-2007
ANSI/ASSE Z359.4-
2013 ANSI/ASSE
Z359.12-2009
ANSI/IWCA I-14.1-2001

Rationale
The Agency believes that it is less burdensome for the regulated community to use the one OSHA standard rather than require the use of numerous individual consensus standards.

(15) Government Unique Standard
Sanitary Toilets in Coal Mines, 30 CFR 71, Subpart E [Incorporated: 2003]

Voluntary Standard
Non-Sewered Waste Disposal Systems--Minimum Requirements, ANSI Z4.3-1987

Rationale
The ANSI standard was not incorporated by reference because certain design criteria allowed in the ANSI standard, if implemented in an underground coal mine, could present health or safety hazards. For instance, combustion or incinerating toilets could introduce an ignition source which would create a fire hazard. For certain other design criteria found in the ANSI standard, sewage could seep into the groundwater, or overflow caused by rain or run-off could contaminate portions of the mine.

(16) Government Unique Standard
Steel Erection Standards [Incorporated: 2002]

Voluntary Standard
ANSI A10.13 - Steel Erection
ASME/ANSI B30 Series Cranes Standards

Rationale
Many consensus standards were relied upon for various provisions in the final rule, but there was no one consensus standard available that covered all of the topics covered by OSHA's final rule.

(17) Government Unique Standard
Walking-Working Surfaces (29 CFR 1910 Subpart D) [Incorporated: 2017]

Voluntary Standard
ANSI/ASSE Z359.0-
2012 ANSI A14.1-2007

ANSI A14.2-2007
ANSI A14.3-2008
ANSI A14.5-2007
ANSI A14.7-2011
ANSI/TIA 222-G-1996
ANSI/TIA 222-G-2005
ASTM C 478-13

ASTM A 394-08
ANSI/ASSE A1264.1-2007
NFPA 101-2012

ICC IBC-2012
ANSI/ITSDF B56.1-2012

ASME/ANSI MH14.1-1987
ANSI MH30.1-2007

ANSI MH30.2-2005
ANSI/ASSE Z359.4-2012
ANSI/IWCA I-14.1-2001
ANSI/ASSE A10.18-2012

Rationale
The Agency believes that it is less burdensome for the regulated community to use the one OSHA standard rather than require the use of numerous individual consensus standards.

Department of State (DOS) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The U.S. Department of State leads America's foreign policy through diplomacy, advocacy, and assistance by advancing the interests of the American people, their safety and economic prosperity.

The Department recognizes that standards play an important part in achieving these objectives. Our standards policy, engagement with standards development organizations, and our use of standards within the agency supports the U.S. government's standards policy, which recognizes the importance of voluntary consensus standards and gives weight to a flexible "bottom-up approach," in which the needs of private industry and government agencies drive the choice in standards, rather than a "top-down" approach that may be unnecessarily restrictive.

The Bureau of Economic and Business Affairs

The Bureau of Economic and Business Affairs (EB) is the Department's lead for international economic agreements, which shape the global rules of trade and investment and enable the United States to maintain a high rate of growth while fostering global prosperity, security, and opportunity. EB is the Department's principal interface with all other economic agencies and provides the Secretary of State with a global perspective on economic and business issues; it leads on economic engagement with key strategic bilateral and multilateral partners; advises the Secretary on Millennium Challenge Corporation (MCC) grants and International Financial Institution (IFI) loans; leads the Department on international trade, transportation, and telecommunications policy; is responsible for the Organization for Economic Cooperation and Development (OECD), G-7, and G-20 engagements; and is one key agency for designing and implementing economic sanctions.

Every day, EB creates jobs at home, boosts economic opportunities overseas, and makes America more secure. EB promotes a strong American economy by leveling the playing field for American companies doing business in global markets, attracting foreign investors to create jobs in America, and deploying economic tools to deny financing to terrorists, human rights abusers, and corrupt officials. Economics has become the indispensable foreign policy tool of our time. Everything we do is to ensure that the United States remains the world's strongest and most dynamic economy.

EB houses the Department's Standards Executive. The Standards Executive coordinates standards policy within the Department, represents the Department on the Interagency Committee on Standards Policy (ICSP), and works with the interagency to evaluate and address domestic and international standards and technical regulations that may impact U.S. commitments in international bodies and trade agreements, or harm U.S. commercial interests. Web site: Bureau of Economic and Business Affairs

The Bureau of Cyberspace and Digital Policy
The Bureau of Cyberspace and Digital Policy (CDP) leads and coordinates the Department's work on

cyberspace and digital diplomacy to encourage responsible state behavior in cyberspace and advance policies that protect the integrity and security of the infrastructure of the Internet, serve U.S. interests, promote competitiveness, and uphold democratic values. CDP addresses the national security challenges, economic opportunities, and values considerations presented by cyberspace, digital technologies, and digital policy and promotes technology standards and norms that are fair, transparent, and support our values.

CDP's International Information and Communications Policy, Office of Multilateral Affairs (CDP/ICP/MA) leads delegations to International Telecommunication Union (ITU) international standards development meetings. The U.S. delegation is selected from the public and private sector and looks to facilitate the use and implementation of Voluntary Consensus Standards where reasonable and appropriate. The ITU, a specialized agency of the United Nations, is an intergovernmental organization in which 193 governments and over 900 non-governmental organizations and entities from the private sector cooperate.

The ITU is made up of three sectors: the Telecommunication Development (ITU-D) sector, the Telecommunication Standardization (ITU-T) sector, and the Radiocommunication (ITU-R) sector. Telecommunication standards are developed in the ITU-T sector. The resulting standards form the basis for much of the technical and policy aspects of international telecommunications and provide important input to the development of national regulatory policy.

As part of its engagement with the ITU, CDP/ICP/MA ensures new areas of standardization proposed by the ITU-T reflect the needs and interests of the U.S. public and private sector and are within the mandate of the ITU-T. CDP/ICP/MA coordinates development of the government's technical, policy, and regulatory positions based on advice provided by government agencies and U.S. industries. CDP/ICP/MA also encourages the participation of
U.S. companies in these activities.

Web site: Bureau of Cyberspace and Digital Policy

The Bureau of Overseas Building Operations

The Bureau of Overseas Buildings Operations (OBO) directs the Department's worldwide overseas building program. Working with other offices and bureaus, foreign affairs agencies, and Congress, OBO's challenge is to set worldwide priorities for the design, construction, acquisition, maintenance, and use of secure and high-performing embassies and consulates.
OBO prefers to use industry standard references whenever possible and amend those standards as required to suit OBO's unique mission. Using industry standards saves time for our private sector partners (e.g., architects, engineers, and contractors), because they are consistent with industry norms. At overseas locations, OBO strives to meet a variety of standards and searches for local equivalents that provide a high degree of safety and reliability.
OBO uses the International Code Council (ICC) Codes, with amendments, as its base codeand the National Fire Protection Association (NFPA) 70 National Electrical Code serves as the base code for electrical code provisions. OBO also utilizes AIA MasterSpec specifications, where possible, as the baseline for developing a number of OBO Standard Specification sections.
These referenced codes and the OBO Standard Specification sections, in turn, identify a much greater number of industry standards (including some cited below).

These codes and specifications are updated periodically. The Foreign Affairs Manual in provision 15 FAM 900 incorporates consensus standards into the overseas safety, health, and environmental management program. OBO also applies the Secure Embassy Construction and Counterterrorism Act of 1999 (SECCA) statutory requirements and participates on the Overseas Security Policy Board (OSPB)

as all agencies under Chief of Mission authority must comply with OSPB standards set forth in the classified section of the Foreign Affairs Handbook, 12 FAH-6.

Web site: Bureau of Overseas Buildings Operations

Examples of OBO's use of standards include:

- ACGIH TLVs and RELs for occupational exposure limits
- ANSI/ASHRAE 62 – Ventilation for Acceptable Indoor Air Quality and ANSI/ASHRAE 55 – Thermal Environmental Conditions for Human Occupancy for ventilation design and human comfort
- The American Conference of Governmental Industrial Hygienists (ACGIH) standards for ventilation for hazard control
- ANSI/IWCA I-14.1 for Window Cleaning Safety.
- ANSI/ASSE Z359.1 Personal Fall Arrest Systems
- NFPA 70E – Standards for Electrical Safety in the Workplace and TUV, CSA, and UL standards for electrical appliances
- NFPA 1 – Fire Code
- NFPA 101 – Life Safety Code
- NFPA 72 – National Fire Alarm and Signaling Code
- NFPA 13 – Standard for the Installation of Sprinkler Systems
- NFPA 24 - Standard for the Installation of Private Fire Service Mains
- NFPA 25 - Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems
- NFPA 96 - Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations
- NFPA 70 – National Electrical Code
- International Building Code and many other International Code Council (ICC) codes.
- For Building Information Modeling (BIM): Conformity is assessed by BIM managers during design reviews
- National BIM Standard, NBIMS-US™
- National CAD Standard
- ISO 15686-4: Building Construction — Service Life Planning — Part 4: Service Life Planning using Building Information Modelling
- ISO 16739-1: Industry Foundation Classes (IFC) for data sharing in the construction and facility management industries — Part 1: Data schema

- ISO 12006-2: Building construction — Organization of information about construction works — Part 2: Framework for classification.
- Association of Home Appliance Manufacturers (AHAM) verified as a standard for room air purifiers/cleaners
- National Sanitation Foundation (NSF) standards for bottled drinking water, water treatment chemicals, treatment system components, and coatings, when possible.
- ISO 17025 for water testing laboratories
- For point-of-use water treatment devices, the Department NSF, WQA, CSA and WHO
- As hallmarks of quality-bottled drinking water, the Department also uses NSF, IBWA, UL, along with approval for U.S. Military purchase
- ASTM E-1526 – Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process
- ANSI/TIA standards (various)
- ANSI/JTC Joint Standard 607 – Generic Telecommunications Bonding and Grounding for Customer Premises
- ANSI/BICSI N1 – Installation Practices for Telecommunications and ICT Cabling and Related Cabling Infrastructure
- BICSI Telecommunications Distribution Methods Manual
- IEEE C2 – National Electrical Safety Code
- ISO/IEC-1 1180 – Information Technology – Generic Cabling for Customer Premises
- SECCA – collocation and setback requirements for U.S. diplomatic facilities abroad
- OSPB –uniform policies and security standards for U.S. diplomatic facilities abroad

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 1
(1) Government Unique Standard
General 2022 OBO Design Standards (annual update)

Rationale

The OBO Design Standards incorporates the ICC model building codes by reference to leverage industry codes and standards to the degree they support OBO's mission of delivering safe, secure, functional, and resilient facilities. In some cases, it is necessary to amend, modify, or focus industry codes and standards to address unique considerations such as for coordination with Department security requirements and SECCA laws. This strategy of using "code supplements" to modify generic model building codes is consistent with the practice of domestic state and local jurisdictions. It is also practical for the Department of State to further transform and standardize some U.S. industry provisions into contractual requirements, which at the national level in the United States are addressed only as guidance for local jurisdictions; this is the case for some considerations related to zoning and utilities.

Department of Transportation (DOT) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advancement Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The U.S. Department of Transportation (DOT) and its Operating Administrations rely upon a transparent and collaborative regulatory and guidance program to support the Department's strategic goals: safety, economic strength and global competitiveness, equity, climate and sustainability, and transformation. We employ our infrastructure and safety grants, training programs, and enforcement authorities for automobiles, aviation, highways, railroads, trucks, motorcoaches, maritime operators, public transit, pipelines, and hazardous materials as effectively as possible to reduce transportation-related fatalities and serious injuries across the transportation system. DOT uses voluntary consensus standards activities as a potent tool in our regulatory, guidance, safety advisory, and international harmonization activities. In addition, DOT relies upon targeted standards development processes with domestic and international standards developing organizations (SDOs) to advance innovative transportation technologies -- such as automated driving systems (ADS) and unmanned aircraft systems (UAS) -- and to advance the state of practice across all modes of transportation.

Over the past year, among other standards-related activities, DOT has taken the following actions:

- The National Highway Traffic Safety Administration (NHTSA) significantly improved bus safety by issuing a final rule to establish Federal Motor Vehicle Safety Standard (FMVSS) No. 227, ''Bus rollover structural integrity,'' to enhance the rollover structural integrity of over-the-road buses (motorcoaches), and other buses with a gross vehicle weight rating (GVWR) greater than 11,793 kilograms (kg) (26,000 pounds (lb)); for example, school buses. In addition, to reduce the likelihood of ejection, this final rule prohibits emergency exits from opening in the rollover test. NHTSA decided to base FMVSS No. 227 on a European standard, ECE R.66, finding the ECE R.66 test to be the most suitable test available for ensuring a minimum reasonable level of protection for passengers traveling in buses that are associated with the highest crash risk. This also reduced unnecessary differences in regulatory requirements between the U.S. and its trading partners.

- The Pipeline and Hazardous Materials Safety Administration issued a significant final rule improving pipeline safety, by extending existing design, operational and maintenance, and reporting requirements under the Federal Pipeline Safety Regulations to onshore natural gas gathering pipelines (''gathering lines'') in rural areas. PHMSA currently incorporates by reference all or parts of more than 80 standards and specifications developed and published by standard development organizations (SDO).

- In response to petition, National Highway Traffic Safety Administration (NHTSA) issued a final rule permitting the certification of adaptive driving beam (ADB) headlamps. ADB headlamps utilize technology that actively modifies a vehicle's headlamp beams to provide more illumination while not glaring other vehicles. The NHTSA rule follows SAE J3069 where warranted, but deviates from that standard where necessary.

• The Federal Highway Administration (FHWA) issued a final rule updating the National Bridge Inspection Standards (NBIS) for highway bridges. FHWA updated the NBIS to address legislative requirements, and incorporate technological advancements including the use of unmanned aircraft systems for bridge inspection. These revisions draw upon four sections of the American Association for Highway and Transportation Officials (AASHTO) Bridge Element Inspection Standards.

• The National Highway Traffic Safety Administration (NHTSA) amended the test procedure for FMVSS No. 141, "Minimum Sound Requirements for Hybrid and Electric Vehicles (HAV)". To protect pedestrians and other road users, FMVSS No. 141 requires HEVs to emit a pedestrian alert sound while operating in certain conditions. NHTSA utilized SAE J2889 as a basis for the test procedures, which include a specific deviation from the J2889 procedures in response to public comments.

• The Federal Aviation Administration (FAA) updated consensus standards for light-sport aircraft. ASTM International (ASTM) Committee F37 on Light-Sport Aircraft developed the new and revised standards with FAA participation. The FAA found the new and revised standards acceptable for certification under the provisions of the Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft.

• The Federal Motor Carrier Safety Administration (FMCSA) enhanced safety enforcement by issuing a final rule to amend its Hazardous Materials Safety Permits regulations to incorporate by reference the updated Commercial Vehicle Safety Alliance (CVSA) handbook containing inspection procedures and Out-of-Service Criteria (OOSC) for inspections of shipments of transuranic waste and highway route controlled quantities of radioactive material.

• The National Highway Traffic Safety Administration (NHTSA) issued a final rule amending several federal motor vehicle safety standards and consumer information regulations to update the standard reference test tire (SRTT) used therein. The SRTT is used in those standards and regulations as a baseline tire to rate tire treadwear, define snow tires based on traction performance, and evaluate pavement surface friction. This rulemaking addresses the standard reference test tire (SRTT) manufactured according to specifications set forth in an ASTM International (ASTM) standard, E1136, ''Standard Specification for P195/75R14 Radial Standard Reference Test Tire'' (14-inch SRTT).

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2021. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY): 11

(1) Government Unique Standard

49 CFR 571.102, Transmission shift position sequence, starter interlock, and transmission braking effect (2005) [Incorporated: 2016]

Voluntary Standard
SAE J915

Rationale
This regulation was issued on July 1, 2005. SAE J915, "Automatic Transmissions- Manual Control Sequence," published on July 1, 1965, and updated on March 9, 2017. NHTSA has not incorporated this

standard because its content currently relies on 49 CFR 571.102 and 571.114, and the SAE J915 abstract also states that some portions of the standard are unique and may not represent current common practices within the user community. NHTSA is evaluating industry standards to inform the next steps of any revisions to its regulations.

(2) Government Unique Standard

49 CFR 571.114, Theft protection and rollaway prevention (2006) [Incorporated: 2016]

Voluntary Standard
SAE J2948

Rationale
NHTSA published this regulation on April 7, 2006. SAE Recommended Practice, SAE J2948 "Keyless Ignition Control Design" was published on January 13, 2011. NHTSA reviewed and referenced SAE J2948 in an NPRM it issued on December 12, 2011 and is considering whether to finalize this regulatory action.

(3) Government Unique Standard

49 CFR 571.123, Motorcycle controls and displays [Incorporated: 2016]

Voluntary Standard
ISO 2575

Rationale
NHTSA first published this regulation on April 12, 1977. ISO 2575, “Road vehicles -- Symbols for controls, indicators and tell-tales,” was published in 2004, and specifies symbols for use on vehicle controls and indicators. On November 26, 2014, NHTSA issued an NPRM proposing to allow the use of an ISO 2575 warning label for ABS failure indication. NHTSA is considering whether to finalize this regulatory action.

(4) Government Unique Standard

49 CFR 571.129 New non-pneumatic tires for passenger cars (1990) [Incorporated: 2016]

Voluntary Standard
SAE J918c

Rationale
This regulation was published on July 20, 1990. Although not incorporated by reference, the performance and test requirements are based upon SAE recommended practice, “Passenger Car Tire Performance,” J918c, last updated on May 1, 1970. NHTSA is evaluating industry standards to inform the next steps of any revisions to its regulations.

(5) Government Unique Standard

49 CFR 571.138, Tire pressure monitoring systems (2005) [Incorporated: 2016]

Voluntary Standard
SAE J2657

Rationale
NHTSA published this regulation on April 8, 2005. SAE J2657, Tire Pressure Monitoring Systems for Light Duty Highway Vehicles, was published on December 16, 2004. While SAE J2657 was not incorporated in the final rule, the regulation has many commonalities. However, SAE J2657 does not

contain

requirements or test procedures for a malfunction indicator and requires different levels of rigorousness. NHTSA is evaluating industry standards to inform the next steps of any revisions to its regulations.

(6) Government Unique Standard

49 CFR 571.207, Seating Systems [Incorporated: 2016]

Voluntary Standard
SAE J879
SAE J879B

Rationale
This regulation was published on April 8, 2005. Although not incorporated by reference, the test procedures and performance requirements are based on SAE J879, "Passenger Car Front Seat and Seat Adjuster," published on November 1, 1963, and SAE J879B, "Motor Vehicle Seating Systems," published on July 1, 1968. NHTSA is evaluating industry standards to inform the next steps of any revisions to its regulations.

(7) Government Unique Standard

49 CFR 571.226, Ejection Mitigation [Incorporated: 2010]

Voluntary Standard
SAE J2568—Intrusion Resistance of Safety Glazing Systems for Road Vehicles
BSI AU 209—Vehicle Security

Rationale
This regulation was published on January 19, 2011. SAE J2568 - Intrusion Resistance of Safety Glazing Systems for Road Vehicles was published on April 24, 2001 and BSI AU 209 - Vehicle Security was published in August 1995. NHTSA studied the test procedures and performance requirements in these standards but did not adopt them because they did not meet NHTSA's safety objectives and in some cases, were costlier. NHTSA is evaluating industry standards to inform the next steps of any revisions to this regulation.

(8) Government Unique Standard

49 CFR 571.302 Flammability of Interior Materials (1971) [Incorporated: 2016]

Voluntary Standard
ASTM D5132
SAE J369

Rationale
This regulation was published on December 2, 1971. Although not incorporated by reference, these standards are technically equivalent to the regulation: ASTM D5132, "Standard Test Method for Horizontal Burning Rate of Polymeric Materials Used in Occupant Compartments of Motor Vehicles," published in 1994 and SAE J 369, "Flammability of Polymeric Interior Materials - Horizontal Test Method," published on March 1, 1969. NHTSA initiated a research program in 2016 to evaluate the test procedures of the industry standards to inform the next steps of any revision to this regulation.

(9) Government Unique Standard

49 CFR 571.305, Electric-powered vehicles: electrolyte spillage and electrical shock protection (2000) [Incorporated: 2016]

Voluntary Standard
SAE J1766

Rationale
The standard was issued on September 27, 2000, and was based on SAE J1766, "Recommended practice for electric and hybrid electric vehicle battery systems crash integrity testing," published on February 1, 1996. NHTSA reviewed the 2016 revision of SAE J1766 and other industry standards for electric vehicles in an NPRM it issued on March 10, 2016 and is considering whether to finalize this regulatory action.

(10) Government Unique Standard

49 CFR Part 563, Event Data Recorders (2006) [Incorporated: 2016]

Voluntary Standard
SAE J1698–1
IEEE P1616

Rationale
This regulation was issued on August 28, 2006. NHTSA did not incorporate either the SAE Vehicle Event Data Interface (J1698–1) Committee or the IEEE Motor Vehicle Event Data Recorder (MVDER) working group (P1616) because both standards were developed and issued during the rulemaking process.
NHTSA is evaluating industry standards to inform the next steps of any revisions to its regulations.

(11) Government Unique Standard

Brake Performance, 49 CFR 393.52 - FMCSA's Performance-Based Brake Testers (PBBTs) Requirement [Incorporated: 2002]

Voluntary Standard
SAE J667 - Brake Test Code Inertia Dynamometer (cancelled February 2002)
SAE J1854 - Brake Force Distribution Performance Guide - Trucks and Buses

Rationale
FMCSA used government-unique standards in lieu of voluntary consensus standards when it implemented its final rule to allow inspectors to use performance-based brake testers (PBBTs) to check the brakes on large trucks and buses for compliance with federal safety standards and to issue citations when these vehicles fail (67 FR 51770, August 9, 2002). The FMCSA evaluated several PBBTs during a round robin test series to assess their functional performance and potential use in law enforcement. The standard, a specific configuration of brake forces and wheel loads on a heavy-duty vehicle, was used to evaluate the candidate PBBTs and their operating protocols. The agency's rationale for use of the government-unique standards was to verify that these measurements and new technology could be used by law enforcement as an alternative to stopping distance tests or on-road deceleration tests.
PBBTs are expected to save time and their use could increase the number of commercial motor vehicles that can be inspected in a given time. Only PBBTs that meet specifications developed by the FMCSA can be used to determine compliance with the Federal Motor Carrier Safety Regulations. The final rule represents a culmination of agency research that began in the early 1990s.

Environmental Protection Agency (EPA) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

Please refer to EPA's standards-specific website: www.epa.gov/vcs

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY) 0

Current total GUS: 39

(1) Government Unique Standard
EPA Method 1 – Traverse Points, Stationary Sources [Incorporated: 2001]

Voluntary Standard
ASTM D3154-00, Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale
1. The standard appears to lack in quality control and quality assurance requirements. It does not include the following: (1) Proof that openings of standard pitot tube have not plugged during the test; (2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, their calibration must be checked after each test series; and (3) the frequency and validity range for calibration of the temperature sensors. 2. They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

Voluntary Standard
ASTM D3154-91 (1995), Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale
Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

(2) Government Unique Standard
EPA Method 10 [Incorporated: 2015]

Voluntary Standard
ANSI/ASME PTC 19-10-1981-Part 10 ISO
10396:1993 (2007)
ISO 12039:2001
ASTM D5835-95 (2007)
ASTM D6522-00 (2005)
CAN/CSA Z223.2-M86 (1999)
CAN/CSA Z223.21-M1978
ASTM D3162-94 (2005)

Rationale
The use of these voluntary consensus standards would not be practical with applicable law due to a lack of equivalency, documentation, validation data and other important technical and policy considerations.

(3) Government Unique Standard
EPA Method 101 - Mercury Emissions, Chlor-Alkali Plants (Air) [Incorporated: 2001]

Voluntary Standard
ASTM D6216-98 - Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications.

Rationale
The EPA is incorporating ASTM D6216 (manufacturers certification) by reference into EPA Performance Specification 1, Sect. 5 & 6 in another rulemaking. ASTM D6216 does not address all the requirements specified in PS-1.

(4) Government Unique Standard
EPA Method 101a - Mercury Emissions Sewer/Sludge Incinerator [Incorporated: 2001]

Voluntary Standard
ASTM D6216-98 - Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications.

Rationale
The EPA is incorporating ASTM D6216 (manufacturers certification) by reference into EPA Performance Specification 1, Sect. 5 & 6 in another rulemaking. ASTM D6216 does not address all the requirements specified in PS-1.

(5) Government Unique Standard
EPA Method 10A – Carbon Monoxide for Certifying CEMS [Incorporated: 2001]

Voluntary Standard
CAN/CSA Z223.21-M1978, Method for the Measurement of Carbon Monoxide: 3—Method of Analysis by Non-Dispersive Infrared Spectrometry.

Rationale
1. It is lacking in the following areas: (1) Sampling procedures; (2) procedures to correct for the carbon dioxide concentration; (3) instructions to correct the gas volume if CO2 traps are used;
(4) specifications to certify the calibration gases are within 2 percent of the target concentration; (5) mandatory instrument performance characteristics (e.g., rise time, fall time, zero drift, span drift, precision); (6) quantitative specification of the span value maximum as compared to the measured value: The standard specifies that the instruments should be compatible with the concentration of gases to be measured, whereas EPA Method 10 specifies that the instrument span value should be no more than 1.5 times the source performance standard. 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

(6) Government Unique Standard
EPA Method 12 – Inorganic Lead, Stationary Sources [Incorporated: 2000]

Voluntary Standard
ASTM D4358-94 (1999), Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy

Rationale
These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.

Voluntary Standard
ASTM E1741-95 (1995), Standard Practice for Preparation of Airborne Particulate Lead Samples Collected During Abatement and Construction Activities for Subsequent Analysis by Atomic Spectrometry

Rationale
These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.

(8) Government Unique Standard
EPA Method 17 - Particle Matter (PM) In Stack Filtration [Incorporated: 2001]

Voluntary Standard
ASME C00049

Rationale
EPA looked at this standard for both Pulp and Paper Hazardous Air Pollutant rules and for the Small Municipal Waste Combustion rule. Contains sampling options beyond which would be considered

acceptable for Method 5.

Voluntary Standard
ASTM D3685/3685M-95 - Standard Test method for Sampling and Determination of Particle Matter in Stack Gases
Rationale
EPA looked at this standard for both Pulp and Paper Hazardous Air Pollutant rules and for the Small Municipal Waste Combustion rule. Contains sampling options beyond which would be considered acceptable for Method 5.

(9) Government Unique Standard
EPA Method 18 [Incorporated: 2016]

Voluntary Standard
ASTM D6420-99 (2010)
ASTM D6060-17

Rationale
ASTM D6420-99 (2010) "Test method for Determination of Gaseous Organic Compounds by Direct Interface Gas Chromatography/Mass Spectrometry"
The use of this voluntary consensus standard would not be practical due to a lack of equivalency, documentation, validation data and other important technical and policy considerations. The EPA did not receive comments during the notice and comment period that caused us to alter the standards and methods in the final permits.
ASTM D6060-17 - Practice for Sampling of Process Vents with a Portable Gas Chromatography This ASTM standard lacks key quality control and assurance requirements included in EPA Method 18. For example, ASTM D6060: 1) lacks the requirement of three reference standards in triplicate; 2) lacks the calibration acceptance criteria that the triplicate calibration standards agree within 5 percent of their average; 3) lacks a post-sampling volume flow rate check and requirement to repeat the test if the pre- and post-test flowrates differ by more than 20 percent; 4) lacks triplicate samples for recovery tests and allows a 15 percent difference between the pre-test and recovery test data vs. 10 percent for Method 18; 4) lacks the accuracy performance criteria of 10 percent of the preparation value for audit samples; 5) lacks reporting/documentation requirements. Also, ASTM D6060 does not include procedures for sample collection using other media, such as bags and solid sorbents.

(10) Government Unique Standard
EPA Method 2 – Velocity and S-type Pitot [Incorporated: 1999]

Voluntary Standard
ASTM D3464-96 (2001)
ASTM D3154 – 00 (2014)
ASTM D3463-96 (2014)
ASTM D3796-90 (2016)
ASME B133.9-1994 (2001)

Rationale
ASTM D3464-96 (2001), Standard Test Method Average Velocity in a Duct Using a Thermal Anemometer: Applicability specifications are not clearly defined, e.g., range of gas composition, temperature limits. Also, the lack of supporting quality assurance data for the calibration procedures and specifications, and certain variability issues that are not adequately addressed by the standard limit EPA's ability to make a definitive comparison of the method in these areas.
ASTM D3154 – 00 (2014), Standard Method for Average Velocity in a Duct (Pitot Tube Method): (added to Annual Report in FY2018) This standard appears to cover EPA's Part 60 Methods 1, 2, 2C, 3, 3B, 4, but lacks in quality control and quality assurance requirements. Specifically, ASTM D3154 00 does not include the following: 1) proof that openings of standard pitot tube have not plugged during the test; 2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, heir calibration must be checked after each test series; and 3) the frequency and validity range for calibration of the temperature sensors. (not for EPA Methods 1, 2, 2C, 3, 3B, 4).
ASTM D3463-96 (2014), Standard Test Method Average Velocity in a Duct Using a Thermal Anemometer: (added to Annual Report in FY2018) The applicability specifications in this ASTM standard are not clearly defined, e.g., range of gas composition, temperature limits. Also, the lack of supporting quality assurance data for the calibration procedures and specifications, and certain variability issues that are not adequately addressed by the standard limit EPA's ability to make a definitive comparison of the method in these areas.
ASTM D3796-90 (2016), Standard Practice for Calibration of Type S Pitot Tubes: (added to Annual Report in FY2018) This ASTM standard is intended to be a calibration procedure for the S-type pitot tube and not a method by which stack gas velocity and/or volumetric flowrates can be measured as in EPA Method 2. In addition, the calibration procedure does not require an inclined manometer and does not specify any additional accuracy verifications for the use of other types of differential pressure gauges.
ASME B133.9-1994 (2001) - Measurement of Exhaust Emissions from Stationary Gas Turbine Engines (this is the latest version, method has been withdrawn with no future updates): (added to Annual Report in FY2018) Not a quantitative method, per se, although a good primer for this source category that includes technical descriptions of manual and instrumental sampling procedures, as well as performance specifications for instrumental methods. This standard has many good references, including the EPA Methods and Performance Specifications. Only use for engines and turbines. Not a method. (not for EPA Methods 2, 3A, 4, 5).

Voluntary Standard
ISO 10780:1994, Stationary Source Emissions-- Measurement of Velocity and Volume Flowrate of Gas Streams in Ducts
Rationale
The standard recommends the use of an L-shaped pitot, which historically has not been recommended by EPA. The EPA specifies the S-type design, which has large openings that are less likely to plug up with dust.

Voluntary Standard

ISO 10780:1994, Stationary Source Emissions-- Measurement of Velocity and Volume Flowrate of Gas Streams in Ducts
Rationale
The standard recommends the use of an L-shaped pitot, which historically has not been recommended by EPA. The EPA specifies the S-type design, which has large openings that are less likely to plug up with dust.

(11) Government Unique Standard
EPA Method 21 - Volatile Organic Compound (VOC) Leaks [Incorporated: 2003]
Voluntary Standard
ASTM E1211-97 - Standard Practice for Leak Detection and Location Using Surface-Mounted Acoustic Emission Sensors
Rationale
This standard will detect leaks but not classify the leak as VOC, as in EPA Method 21. In addition, in order to detect the VOC concentration of a known VOC leak, the acoustic signal would need to be calibrated against a primary instrument. Background noise interference in some source situations could also make this standard difficult to use effectively.
(12) Government Unique Standard
EPA Method 24 – Determination of Volatile Matter Content, Water Content, Density, Volume Solids, and Weight Solids of Surface Coating [Incorporated: 2018]
Voluntary Standard
ASTM D3960-05, ASTM D6053-14, ISO 11890-1 (2000), ISO 11890-2 (2000) Part 2, ISO 3233:1998
Rationale
ASTM D3960-05 - Standard Practice for Determining Volatile Organic Compound (VOC) Content of Paints and Related Coating: This standard measures the VOC content whereas EPA Method 24 determines volatile matter content (and water content, density, volume solids, and weight solids). If the regulation allows for the use of VOC content as a surrogate for HAP, then this method is an acceptable alternative to Method 24. If the regulation requires the measurement of volatile matter content, as in Method 24, then this standard is not acceptable;
ASTM D6053-14 - Standard Test Method for Determination of Volatile Organic Compound (VOC) Content of Electrical Insulating Varnishes: Under a separate action, the EPA is incorporating ASTM D6053-96 by reference into EPA Method 24. This standard will only be applicable for a specific type of coating (electrical insulating varnishes). Specimen size for magnet wire coating must be 2.0 grams +/- 0.1 grams;
ISO 11890-1 (2000) Part 1: Paints and Varnishes Determination of Volatile Organic Compound (VOC) Content Difference Method: This standard has different test conditions than EPA Method 24 and therefore is unacceptable as an alternative to Method 24 because measured nonvolatile matter content can vary with experimental factors such as temperature, length of heating period, size of weighing dish, and size of sample. ISO 11890-1 allows for different dish weights and sample sizes than the one size (58 mm in diameter and sample size of 0.5 g) of EPA Method 24. ISO 11890-1 also allows for different oven temperatures and heating times depending on the type of coating, whereas EPA Method 24 requires 60 minutes heating at
110oC at all times. Nonvolatile matter content is not an absolute quantity but is dependent on temperature and heating period. The size of the weighing dish and the size of the sample may also affect the nonvolatile matter measured. Because the EPA Method 24 test conditions and procedures define volatile matter, ISO 11890 1 is unacceptable as an alternative;
ISO 11890-2 (2000) Part 2: Paints and Varnishes-Determination of Volatile Organic Compound (VOC)

Content Gas Chromatographic Method: This standard only measures the VOC added to the coating and would not measure any VOC generated from the curing of the coating. The EPA Method 24 does measure cure VOC, which can be significant in some cases, and, therefore, ISO 11890-2 is not an acceptable alternative to EPA Method 24.
ISO 3233:1998 - Paints and Varnishes-Determination of Percentage Volume of Nonvolatile Matter by Measuring the Density of a Dried Coating: This ISO standard is more applicable as a manufacturing tool than an emissions standard, since it measures the amount of coverage of a coating using a dipping plate.

(13) Government Unique Standard
EPA Method 28 (Section 10.1) – Wood Heaters, Certificate and Auditing [Incorporated: 2003]
Voluntary Standard
ASME Power Test Codes, Supplement on Instruments and Apparatus, part 5, Measurement of Quantity of Materials, Chapter 1, Weighing Scales
Rationale
It does not specify the number of initial calibration weights to be used nor a specific pretest weight procedure.
Voluntary Standard
ASTM E319-85 (Reapproved 1997), Standard Practice for the Evaluation of Single-Pan Mechanical Balances
Rationale
This standard is not a complete weighing procedure because it does not include a pretest procedure.
(14) Government Unique Standard
EPA Method 29 – Metals Emissions from Stationary Sources [Incorporated: 2001]
Voluntary Standard
ASTM D4358-94 (1999), Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy
Rationale
These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires

the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.

Voluntary Standard
ASTM E1741-95 (1995), Standard Practice for Preparation of Airborne Particulate Lead Samples Collected During Abatement and Construction Activities for Subsequent Analysis by Atomic Spectrometry
Rationale
These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three

ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.
Voluntary Standard
ASTM E1979-98 (1998), Standard Practice for Ultrasonic Extraction of Paint, Dust, Soil, and Air Samples for Subsequent Determination of Lead
Rationale
These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.
Voluntary Standard
CAN/CSA Z223.26-M1987, Measurement of Total Mercury in Air Cold Vapour Atomic Absorption Spectrophotometeric Method
Rationale
It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.

(15) Government Unique Standard
EPA Method 29 for the determination of the concentration of Hg [Incorporated: 2015]
Voluntary Standard
ASTM D6784-02 (2008), “Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)”
Rationale
The use of this voluntary consensus standard would be more expensive and is inconsistent with the final Hg standard that was determined using EPA Method 29 data.
(16) Government Unique Standard
EPA Method 29, “Metals Emissions from Stationary Sources” [Incorporated: 2017]
Voluntary Standard
ASTM D6784–02 (Reapproved 2008), ‘‘Standard Test Method for Elemental, Oxidized, Particle- Bound and Total Mercury Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)’’
Rationale
The use of this voluntary consensus standard would be impractical because this standard is only acceptable as an alternative to the portion of EPA Method 29 for mercury, and emissions testing for mercury alone is not required under 40 CFR part 63, subpart MM.
(17) Government Unique Standard
EPA Method 2C - Determination of Stack Gas Velocity and Volumetric Flow Rate in Small Stacks or Ducts (Standard Pitot Tube) [Incorporated: 2018]
Voluntary Standard
ASTM D3154 – 00 (2014), Standard Method for Average Velocity in a Duct (Pitot Tube Method)
Rationale
This standard appears to cover EPA’s Part 60 Methods 1, 2, 2C, 3, 3B, 4, but lacks in quality control and quality assurance requirements. Specifically, ASTM D3154 00 does not include the following: 1) proof that openings of standard pitot tube have not plugged during the test; 2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, heir calibration must be checked after

each test series; and 3) the frequency and validity range for calibration of the temperature sensors. (not for EPA Methods 1, 2, 2C, 3, 3B, 4)
(18) Government Unique Standard
EPA Method 3 – Gas Analysis for The Determination of Dry Molecular Weight [Incorporated: 2018]
Voluntary Standard
ASTM D3154 – 00 (2014), Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale
This standard appears to cover EPA's Part 60 Methods 1, 2, 2C, 3, 3B, 4, but lacks in quality control and quality assurance requirements. Specifically, ASTM D3154 00 does not include the following: 1) proof that openings of standard pitot tube have not plugged during the test; 2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, heir calibration must be checked after each test series; and 3) the frequency and validity range for calibration of the temperature sensors. (not for EPA Methods 1, 2, 2C, 3, 3B, 4)
(19) Government Unique Standard
EPA Method 301- Field Validation of Pollutant Measurement Methods from Various Waste Media [Incorporated: 2018]
Voluntary Standard
ASTM D4855-97 (2002) - Standard Practice for Comparing Test Methods
Rationale
This ASTM standard appears to be equivalent to EPA Method 301 in its statistical design and decision criteria but is less prescriptive than Method 301 for many procedures. For example, the ASTM does not require the use of a t-test explicitly to test the precision of the alternative method, but instead states that a t-test or F-test should be used, as appropriate. The primary difference between ASTM D4855-97 and EPA Method 301, that makes the ASTM standard not acceptable as a complete alternative to the EPA method, is that the ASTM standard addresses the testing of materials rather than environmental samples. Because of this difference, the ASTM standard does not prescribe the use of paired samples as in the EPA method. This feature of EPA Method 301 is critical to its success and the acceptability of an alternate standard.
(20) Government Unique Standard
EPA Method 306 - Chromium Emissions, Electroplating and Anodizing [Incorporated: 2002]
Voluntary Standard
ASTM D4358-94 (1999) - Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy
Rationale
This MACT standard (Petroleum Refineries) only cites Method 29. Therefore, the following EPA comment is only applicable for Method 29 not Method 12 and 306: Method 29 requires the use of hydrofluoric acid (HF) in its process of digestion of the sample. ASTM D4358-94 (1999) does not require the use of HF; therefore, it cannot be used in the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas the subject ASTM standard requires cellulose filters and other probable non-glass fiber media, and this further negates their use as Method 29 equivalent methods. (Same comment as provided for ASTM E1741 and ASTM E1979).

(21) Government Unique Standard
EPA Method 306a - Chromium Emissions, Electroplating -- Mason Jar [Incorporated: 2002]
Voluntary Standard

ASTM D4358-94 (1999) - Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy
Rationale
This MACT standard (Petroleum Refineries) only cites Method 29. Therefore, the following EPA comment is only applicable for Method 29 not Method 12 and 306: Method 29 requires the use of hydrofluoric acid (HF) in its process of digestion of the sample. ASTM D4358-94 (1999) does not require the use of HF; therefore, it cannot be used in the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas the subject ASTM standard requires cellulose filters and other probable non-glass fiber media, and this further negates their use as Method 29 equivalent methods. (Same comment as provided for ASTM E1741 and ASTM E1979).
(22) Government Unique Standard
EPA Method 311 "Analysis of Hazardous Air Pollutant Compounds in Paints and Coatings by Direct Injection Into a Gas Chromatograph" [Incorporated: 2015]
Voluntary Standard
ASTM D6438 (1999)—Standard Test Method for Acetone, Methyl Acetate, and Parachlorobenzotrifluoride Content of Paints and Coatings by Solid Phase Microextraction-Gas Chromotography
Rationale
This methods is impractical as an alternative to EPA Method 311 because it targets chemicals that are VOC and are not HAP
(23) Government Unique Standard
EPA Method 3A – Carbon Dioxide and Oxygen Concentrations, IAP [Incorporated: 1999]
Voluntary Standard
ISO 12039:2001
ANSI/ASME PTC 19-10-1981(2010)
ISO 10396:(2007)
ASTM D5835-95 (2013) ASTM D6522-11
ASTM D6522
CAN/CSA Z223.2-M86 (R1999)
Rationale
ISO 12039:2001, Stationary Source Emissions-- Determination of Carbon Monoxide, Carbon Dioxide, and Oxygen--Automated Methods: This ISO standard is similar to EPA Method 3A, but is missing some key features. In terms of sampling, the hardware required by ISO 12039:2001

does not include a 3-way calibration valve assembly or equivalent to block the sample gas flow while calibration gases are introduced. In its calibration procedures, ISO 12039:2001 only specifies a two-point calibration while EPA Method 3A specifies a three-point calibration. Also, ISO 12039:2001 does not specify performance criteria for calibration error, calibration drift, or sampling system bias tests as in the EPA method, although checks of these quality control features are required by the ISO standard.
ANSI/ASME PTC 19-10-1981(2010) - Part 10 Flue and Exhaust Gas Analyses: (added to Annual Report in FY2018) This standard includes manual and instrumental methods of analyses for carbon dioxide (CO2), carbon monoxide (CO), hydrogen sulfide (H2S), nitrogen oxides (NOx), oxygen (O2), and sulfur dioxide (SO2). The VCS method analytes that include one or more of the same techniques as the EPA methods are as follows: CO2 [manual (3B, 6A and 6B) and instrumental (3A and 3C)]; CO [manual (3B) and instrumental (10 and 10B)], H2S [manual (15A and 16A) and instrumental (15, 16, and 16B)], NOx [manual (7 and 7C) and instrumental (7A, 7B, 7E, 20)], O2 [manual (3B) and instrumental (3A, 3C, 20)], and SO2 [manual (6, 6A, 6B, 20) and instrumental (6C)]. The manual methods are all acceptable

alternatives to the corresponding EPA test methods (3B, 6, 6A, 6B, 7, 7C, 15A, 16A, 20 (SO2 part of 20 only)). [Note that one of the standard's manual SO2 procedures incorporates EPA Method 6 in its entirety]. For the standard's instrumental procedures, only general descriptions of the procedures are included which are not true methods. Therefore, the instrumental procedures (3A, 3C, 6C, 7A, 7B, 7E, 10, 10B, 15, 16, 16B, 20 (NOx part of 20 only)) are not acceptable alternatives to the corresponding EPA methods.
ISO 10396:(2007) - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations: (added to Annual Report in FY2018) This standard is similar to EPA Methods 3A, 6C, 7E, 10, 20 (nitrogen oxides and oxygen parts of 20 only), ALT 004, CTM 022, but lacks in detail and quality assurance/quality control requirements. Specifically, ISO 10396 does not include the following: 1) sensitivity of the method; 2) acceptable levels of analyzer calibration error; 3) acceptable levels of sampling system bias; 4) zero drift and calibration drift limits, time span, and required testing frequency; 5) a method to test the interference response of the analyzer; 6) procedures to determine the minimum sampling time per run and minimum measurement time; 7) specifications for data recorders, in terms of resolution (all types) and recording intervals (digital and analog recorders, only). This standard is also very similar to ASTM D5835.

ASTM D5835-95 (2013) - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration: (added to Annual Report in FY2018) This standard is similar to EPA Methods 3A, 6C, 7E, 10, 20 (nitrogen oxides and oxygen parts of 20 only), ALT 004, CTM 022, but lacks in detail and quality assurance/quality control requirements. Specifically, ASTM D5835-95 does not include the following: 1) sensitivity of the method; 2) acceptable levels of analyzer calibration error; 3) acceptable levels of sampling system bias; 4) zero drift and calibration drift limits, time span, and required testing frequency;
5) a method to test the interference response of the analyzer; 6) procedures to determine the minimum sampling time per run and minimum measurement time; 7) specifications for data recorders, in terms of resolution (all types) and recording intervals (digital and analog recorders, only). This standard is also very similar to ISO 10396.
ASTM D6522-11 - Standard Test Method for the Determination of Nitrogen Oxides, Carbon Monoxide, and Oxygen Concentrations in Emissions from Natural Gas-Fired Reciprocating Engines, Combustion Turbines, Boilers and Process Heaters Using Portable Analyzers: (added to Annual Report in FY2018) ASTM D6522 has been determined to be technically appropriate for identifying nitrogen oxides, carbon monoxide, and oxygen concentrations when the fuel is natural gas.

CAN/CSA Z223.2-M86 (R1999) - Method for the Continuous Measurement of Oxygen, Carbon Dioxide, Carbon Monoxide, Sulphur Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Streams: (added to Annual Report in FY2018) This standard is unacceptable as a substitute for EPA Methods 3A, 6C, 7E, 10, 10A, and 20 (nitrogen oxides and oxygen parts of 20 only), since it does not include quantitative specifications for measurement system performance, most notably the calibration procedures and instrument performance characteristics. The instrument performance characteristics that are provided are non- mandatory and also do not provide the same level of quality assurance as the EPA methods. For example, the zero and span/calibration drift is only checked weekly, whereas the EPA methods requires drift checks after each run.
(24) Government Unique Standard
EPA Method 3B – Gas Analysis for the determination of emission rate correction Factor for Excess Air [Incorporated: 2018]
Voluntary Standard
ASTM D3154 – 00 (2014), Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale
This standard appears to cover EPA's Part 60 Methods 1, 2, 2C, 3, 3B, 4, but lacks in quality control and quality assurance requirements. Specifically, ASTM D3154 00 does not include the following: 1) proof that openings of standard pitot tube have not plugged during the test; 2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, heir calibration must be checked after each test series; and 3) the frequency and validity range for calibration of the temperature sensors. (not for EPA Methods 1, 2, 2C, 3, 3B, 4)
(25) Government Unique Standard
EPA Method 4 – Determination of Moisture Content in Stack Gas [Incorporated: 2018]
Voluntary Standard
a. ASTM D3154-00 (2014) Standard Method for Average Velocity in a Duct (Pitot Tube Method)
b. ASME B133.9-1994 (2001) - Measurement of Exhaust Emissions from Stationary Gas Turbine Engines

Rationale
a. This standard appears to cover EPA's Part 60 Methods 1, 2, 2C, 3, 3B, 4, but lacks in quality control and quality assurance requirements. Specifically, ASTM D3154 00 does not include the following: 1) proof that openings of standard pitot tube have not plugged during the test; 2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, heir calibration must be checked after each test series; and 3) the frequency and validity range for calibration of the temperature sensors. (not for EPA Methods 1, 2, 2C, 3, 3B, 4)

b. Not a quantitative method, per se, although a good primer for this source category that includes technical descriptions of manual and instrumental sampling procedures, as well as performance specifications for instrumental methods. This standard has many good references, including the EPA Methods and Performance Specifications. Only use for engines and turbines. Not a method. (not for EPA Methods 2, 3A, 4, 5).
(26) Government Unique Standard
EPA Method 5 [Incorporated: 2015]
Voluntary Standard
ASME B133.9-1994 (2001)
ISO 9096:1992 (2003)
ANSI/ASME PTC-38-1980 (1985)
ASTM D3685/D3685M-98 (2005) CAN/CSA Z223.1-M1977
Rationale
The use of these voluntary consensus standards would not be practical with applicable law due to a lack of equivalency, documentation, validation data and other important technical and policy considerations.
(27) Government Unique Standard
EPA Method 515.4 – Chlorinated Acids in DW by LL Fast CG/ECD [Incorporated: 2003]
Voluntary Standard
ASTM D5317-98 -- Standard Test Method For Determination of Chlorinated Organic Acid Compounds in Water by Gas Chromatography With an Electron Capture Detector
Rationale
ASTM D5317-98 specifies acceptance windows for the initial demonstration of proficiency for laboratory fortified blank samples that are as small as 0 percent to as large as 223 percent recovery for picloram, with tighter criteria for other regulated contaminants. Therefore, this method permits unacceptably large control limits, which include 0 percent recovery.

Voluntary Standard
Standard Method 6640 B for the chlorinated acids
Rationale
The use of this voluntary consensus standard would have been impractical due to significant shortcomings in the sample preparation and quality control sections of the method instructions. Section 1b of Method SM 6640 B states that the alkaline wash detailed in section 4b2 is optional. The hydrolysis that occurs during this step is essential to the analysis of the esters of many of the analytes. Therefore, this step is necessary and cannot be optional. In addition, the method specifies that the quality control limits for laboratory-fortified blanks are to be based upon plus or minus three times the standard deviation of the mean recovery of the analytes, as determined in each laboratory. Therefore, this method permits unacceptably large control limits, which may include 0 percent recovery.
(28) Government Unique Standard
EPA Method 531.2 – N-Methylcarbamoylozimes/ates, Aqueous In/HPLC [Incorporated: 2003]
Voluntary Standard
Standard Method 6610, 20th Edition
Rationale
Standard Method 6610, 20th Edition has recently been approved for compliance monitoring. Standard Method 6610, 20th Supplemental Edition permits the use of a strong acid, hydrochloric acid (HCL), as a preservative. The preservatives in all of the other approved EPA and Standard Methods procedures for these analytes are weak acids that adjust the pH to a specific value based upon the pKa of the preservative. The use of HCL would require accurate determinations of the pH of the sample in the field and could be subject to considerable error and possible changes in pH upon storage. Although not specifically observed for oxamyl or carbofuran during the development of similar methods, structurally similar pesticides have been shown to degrade over time when kept at pH 3. Therefore, approval of this method is impractical because it specifies the use of a strong acid (HCL) when positive control of the pH is critical.
Voluntary Standard
Standard Method 6610, 20th Supplemental Edition
Rationale
Standard Method 6610, 20th Edition has recently been approved for compliance monitoring. Standard Method 6610, 20th Supplemental Edition permits the use of a strong acid, hydrochloric acid (HCL), as a preservative. The preservatives in all of the other approved EPA and Standard Methods procedures for these analytes are weak acids that adjust the pH to a specific value based upon the pKa of the preservative. The use of HCL would require accurate determinations of the pH of the sample in the field and could be subject to considerable error and possible changes in pH upon storage. Although not specifically observed for oxamyl or
carbofuran during the development of similar methods, structurally similar pesticides have been shown to degrade over time when kept at pH 3. Therefore, approval of this method is impractical because it specifies the use of a strong acid (HCL) when positive control of the pH is critical.

(29) Government Unique Standard
EPA Method 5i - Low Level Particulate Matter, Stationary Sources [Incorporated: 2001]
Voluntary Standard
ASTM D6331-98
Rationale
This standard does not have paired trains as specified in method 5 and does not include some quality control procedures specified in the EPA method and which are appropriate to use in this rule.

(30) Government Unique Standard
EPA Method 6 - Determination of Sulfur Dioxide Emissions from Stationary Sources [Incorporated: 2018]
Voluntary Standard
a. ISO 7934:1998 (2016) - Stationary Source Emissions Determination of the Mass Concentration of Sulfur Dioxide Hydrogen Peroxide/Barium Perchlorate/Thorin Method
b. ISO 11632:1998 (2016) - Stationary Source Emissions Determination of the Mass Concentration of Sulfur Dioxide Ion Chromatography
Rationale
a. This standard is only applicable to sources with 30 mg/m3 SO2 or more. Also, this standard does not separate SO3 from SO2 as does the EPA methods; therefore, ISO 7934:1998 is not valid if more than a negligible amount of SO3 is present. Also, it does not address ammonia interferences.

b. Sampling procedures are similar to EPA Method 6, but lacks in detail and quality control procedures, such as calibration checks and leaks tests.
(31) Government Unique Standard
EPA Method 7E [Incorporated: 2015]
Voluntary Standard
ANSI/ASME PTC 19-10-1981-Part 10 ISO 10396:1993 (2007)
ASTM D5835-95 (2007)
CAN/CSA Z223.2-M86 (1999)
Rationale
The use of these voluntary consensus standards would not be practical with applicable law due to a lack of equivalency, documentation, validation data and other important technical and policy considerations.

(32) Government Unique Standard
EPA Method 9 [Incorporated: 2016]
Voluntary Standard
ASTM D7520-09 “Standard Test Method for Determining Opacity of a Plume in the Outdoor Ambient Atmosphere”
Rationale
The use of this voluntary consensus standard would not be practical due to a lack of equivalency, documentation, validation data and other important technical and policy considerations. The EPA did not receive comments during the notice and comment period that caused us to alter the standards and methods in the final permits.
(33) Government Unique Standard
EPA Method ALT 004 [Incorporated: 2002]
Voluntary Standard
ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration
Rationale
Similar to Methods 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance and quality control requirements. Very similar to ISO 10396.
Voluntary Standard
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations
Rationale

Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.
(34) Government Unique Standard
EPA Method CTM 022 [Incorporated: 2002]
Voluntary Standard
ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration
Rationale
Similar to Methods 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance and quality control requirements. Very similar to ISO 10396.

Voluntary Standard
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations
Rationale
Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.
(35) Government Unique Standard
EPA Performance Specification 2 (nitrogen oxide portion only) [Incorporated: 2001]
Voluntary Standard
ISO 10849:1996, Determination of the Mass Concentration of Nitrogen Oxides--Performance
Rationale
Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.
(36) Government Unique Standard
EPA Performance Specification 2 (sulfur dioxide portion only) [Incorporated: 2001]
Voluntary Standard
ISO 7935:1992, Stationary Source Emissions--Determination of the Mass Concentration of Sulfur Dioxide--Performance Characteristics of Automated Measuring Methods"
Rationale
Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.
(37) Government Unique Standard
SW846-6010b [Incorporated: 2002]
Voluntary Standard
ASTM C1111-98 (1998) - Standard Test Method for Determining Elements in Waste Streams by Inductively Coupled Plasma-Atomic Emission Spectrometers
Rationale
This standard lacks details for instrument operation QA/QC, such as optimizing plasma operating conditions; upper limit of linear dynamic range; spectral interference correction; and calibration procedures, which include initial and continuous calibration verifications. Also lacks internal standard and method of standard addition options for samples with interferences.
Voluntary Standard
ASTM D6349-99 (1999) - Standard Test Method for Determining Major and Minor Elements in Coal, Coke, and Solid Residues from Combustion of Coal and Coke by Inductively Coupled Plasma-Atomic Emission Spectrometers

Rationale

This standard lacks details for instrument operation QA/QC, such as optimizing plasma operating conditions, upper limit of linear dynamic range, spectral interference correction, and calibration procedures, that include initial and continuous calibration verifications. Also lacks details for standard preparation, and internal standard and method of standard addition options for samples with interferences.
(38) Government Unique Standard
Validated Method 8327: Per-and Polyfluoroalkyl Substances (PFAS) Using External Standard Calibration and Multiple Reaction Monitoring (MRM) Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) [Incorporated: 2019]
Voluntary Standard
ASTM D7979-19: Standard Test Method for Determination of Perfluorinated Compounds in Water, Sludge, Influent, Effluent and Wastewater by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS)
Rationale
For the reasons set forth below, EPA determined that PFAS analytical methods should be validated by multiple laboratories, rather than by a single lab, for use under the Resource Conservation and Recovery Act (RCRA) and other EPA programs, e.g., the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The ASTM D7979 standard is not multi-lab validated for the matrices of concern for RCRA and CERCLA.
Multi-lab validation accomplishes several purposes: First, it is a means to assess accuracy and reproducibility of data independent of the organization that developed the method. Second, it reduces uncertainty regarding the method used to produce the data to support decision making. By assuring accuracy and reproducibility of the data and confidence in the method, methods that are multi-lab validated provide additional assurance to EPA decision-makers and the public that resulting data used to protect human health and the environment are robust, reliable and of known quality.

EPA test methods that support RCRA and are used by other Federal programs can be found in the EPA publication, Test Methods for Evaluating Solid Waste: Physical/Chemical Methods, also known as SW-846. Under RCRA's SW-846 methods program, the methods development and validation process for Validated Method 8327 and other methods contained in SW-846 includes posting a method on EPA's public website for public comment, comment adjudication and relevant method revisions
(39) Government Unique Standard
WaterSense Specification for Spray Sprinkler Bodies Appendix B: Spray Sprinkler Body Performance test method [Incorporated: 2017]

Voluntary Standard
ASABE/ICC 802-2014, "Landscape Irrigation Sprinkler and Emitter Standard"

Rationale
WaterSense used ASABE/ICC 802-2014 (section 303.5.2) as the basis for its sprinkler performance test. However, no product testing was done by the ASABE/ICC standard development committee prior to publishing the standard. When WaterSense did this testing many changes had to be made to eliminate redundant steps, correct deficiencies in the method and provide sufficient detail to run the test consistently at any laboratory. WaterSense
has submitted the revised method to the ASABE/ICC 802 committee for consideration in the revision of the standard.

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

Summary
The FCC references many standards in support of the Commission's regulatory responsibilities. These standards, referenced in the FCC rules, range from referencing measurement methods and conformity assessment procedures to radio carriage requirements for oceangoing vessels to promote safety of life. In addition, standards are used to promote compatibility between radios and to achieve coordination among Commission licensees. In all cases, the Commission, through its public rulemaking process, has proposed and adopted voluntary consensus standards (e.g., ANSI, IEEE, 3GPP, etc.) under which licensees and permitees must operate and under which it carries out conformity assessment activities.

Voluntary Consensus Standards Examples
For example, the Hearing Aid Compatibility Report and Order (FCC 21-28) amended Section 20.19 of the commission rules by adopting the C63® Accredited Standards Committee's standard for "Compatibility between wireless handsets and Hearing Aids" version ANSI C63.19-2019 to replace ANSI C63.19-2011. The updated C63® project started in 2015 and was approved by the C63® standards committee in 2019. The ANSI C63.19-2019 standard was adopted by the commission in June 2021 to include improvements for VOIP cellular IP networks, better user experience for hearing aids with t-coil, and adding volume control to improve voice performance for persons with hearing aids and persons who are hard-of-hearing who do not use hearing aids. The order FCC 21-28 established a transition period to allow cellular handsets to continue to use the ANSI C63.19-2011 standard up to June 4th, 2023. After that time, cellular handsets that are hearing aid compatible must meet the ANSI C63.19-2019 standard.

Another example is the successful use of the Telecommunications Industry Association Telecommunications System Bulletin 10-F, "Interference Criteria for Microwave Systems." This standard, referenced within several Commission rule parts has become the cornerstone for applicants and licensees to successfully coordinate the use of microwave communications systems.
Also, on October 2, 2017 the European standard for wireless microphones ETSI EN 300 422- 1 V1.4.2 (2011-08): "Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wireless Microphones in the 25 MHz to 3 GHz frequency range; Part 1: Technical characteristics and methods of measurement, was incorporated by reference in Section 15.38 of the FCC rules. This standard is used for the evaluation of the out-of-band emissions of wireless microphones.

When making measurements to demonstrate compliance with the FCC rules it is required to use the appropriate measurement methods as specified in the applicable section of the FCC rules. For example, for Part 15 devices see Section 15.31 for a list of required measurement standards. Other measurement procedures that have been found acceptable by the Commission, in accordance with Section 2.947, may also be used. See Measurement Procedures and 47 CFR Section 2.947.

Conformity Assessment.
Radio Frequency (RF) devices are required to be properly authorized under 47 CFR Part 2 prior to being marketed or imported into the United States. The Office of Engineering and Technology (OET) administers the equipment authorization program under the authority delegated to it by the Commission. This program is one of the principal ways the Commission ensures that RF devices used in the United

States operate effectively without causing harmful interference and otherwise comply with the Commission's rules. All RF devices subject to equipment authorization must comply with the Commission's technical requirements prior to importation or marketing. See Equipment Authorization Approval Guide

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2021. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY): 0

Federal Trade Commission (FTC) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The Federal Trade Commission ("FTC" or "Commission") is an independent agency of the United States Government charged with enforcing competition and consumer protection laws. The Commission's primary contact with voluntary consensus standards and the organizations that produce them is in connection with the enforcement of the Federal Trade Commission Act, which prohibits unfair methods of competition and unfair or deceptive acts and practices in or affecting commerce. Consistent with its statutory authority, the Commission occasionally has promulgated consumer protection regulations that incorporate voluntary consensus standards. *See, e.g.*, 16 C.F.R. § 306.5 (provision of FTC's "Fuel Rating Rule"); 16 C.F.R. § 460.5 (provision of FTC's "R-Value Rule"). FTC staff monitors complaints about products and may conduct investigations, including testing, to ensure accurate labeling or advertising.
The Commission does not participate in the standards development activities of voluntary consensus standards bodies.

To carry out the provisions of OMB Circular A-119, the FTC has designated the Deputy General Counsel for Legal Counsel as its Agency Standards Executive. The FTC's Office of the General Counsel, under the direction of the Agency Standards Executive, provides advice to FTC staff regarding implementation of revised OMB Circular A-119.

2. Please list the government-unique standards (GUS) your agency <u>began using in lieu</u> of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 0

Government Publishing Office (GPO) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The use of standards at GPO has ensured consistency in our manufacturing process and the ability to maintain the highest quality in the production of our documents. The use of standards is very important in our procurement / acquisition process and defining our needs. When dealing with vendors, standards provide a level playing field for them when bidding on our Agency requirements. We use VCSs by reference to inform potential bidders and offerors of our minimum requirements.

We also use standards to ensure consistency and accuracy in the services that we provide to our customers.

To formulate compliance policies and procedures that govern air quality, waste management, wastewater discharge, pollution prevention, health and safety, GPO relies on VCSs and applicable Federal and District regulations.

Standards-based cataloging rules and procedures ensure consistent record creation, search, retrieval, and transfer of records in catalogs across libraries internationally (e.g., NISO Z39.50).

Below, please find the GPO reported links:

CS https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/ppr.pdf?sfvrsn=2

- New link: Printing Procurement Regulations_7-22 (gpo.gov)

CS https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/qatap-rev-09-19.pdf
CS https://www.gpo.gov/docs/default-source/forms-and-standards-files-for- vendors/contractterms2018.pdf
CS https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/310-3-contract-terms-microforms262f0930b44a64308413ff00001d133d.pdf
CS https://www.gpo.gov/docs/default-source/forms-standards-pdf-files/jcpregs.pdf
CS https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/jcp-code-o-90-paper.pdf
CS https://www.gpo.gov/docs/default-source/forms-standards-pdf-files/o-91_update.pdf
CS https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/vol_13.pdf Updated in 2016 / can be deleted once all term contracts have met their end of option years. New spec in current paper book dated September 2019
CS http://www.gpo.gov/pdfs/customers/sfas/vol12/vol_12.pdf
CS https://www.gpo.gov/docs/default-source/forms-standards-pdf-files/guidelines_attending_presssheetinspections.pdf?sfvrsn=2
CS https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/contractors_holding_psi.pdf?sfvrsn=2
CS http://www.gpo.gov/gporestarget.pdf

LSCM/PST https://www.fdlp.gov/cataloging-and-classification/cataloging-guidelines
PST http://www.loc.gov/standards/mods/
PST http://www.loc.gov/standards/mets PST
https://www.loc.gov/standards/premis/

Below is all new from Standards Inventory:

Printing Procurement Regulation (PPR), Last Revised 07/22
Printing Procurement Regulations_7-22 (gpo.gov)

GPO Contract Terms - Quality Assurance Through Attributes Program, Revised 09/2019
https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/qatap-rev-09-19.pdf

GPO Contract Terms - Solicitation Provisions, Supplemental Specifications, and Contract Clauses, Revised 01/2018
https://www.gpo.gov/docs/default-source/forms-and-standards-files-for- vendors/contractterms2018.pdf

GPO Contract Terms - Quality Assurance Through Attributes Program for Microforms, Revised 02/2017 https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/310-3-contract-terms-microforms262f0930b44a64308413ff00001d133d.pdf

Government Printing and Binding Regulations, published by the JCP, Updated 02/1990
https://www.gpo.gov/docs/default-source/forms-standards-pdf-files/jcpregs.pdf

JCP-O-90 Printable Plastic Film (Synthetic Paper) --Current as of 10/2018
www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/jcp-code-o-90-paper.pdf

JCP O-91 Uncoated (Tear Resistant) Synthetic Paper - This link is to a spec from March 14, 2016 https://www.gpo.gov/docs/default-source/forms-standards-pdf-files/o-91_update.pdf

Government Paper Specification Standards, 09/2019, No. 13,
https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/vol_13.pdf

Government Paper Specification Standards, 03/2011, No. 12
http://www.gpo.gov/pdfs/customers/sfas/vol12/vol_12.pdf

Guidelines for GPO Staff Performing Press Sheet Inspections, Revised 2015--Hardcopy Available from the GPO, Print Procurement, APS, QCPP

Guidelines for Agency Representatives Attending Press Sheet Inspections. Revised 06/15
https://www.gpo.gov/docs/default-source/forms-standards-pdf-files/guidelines_attending_presssheetinspections.pdf?sfvrsn=2

Guidelines for Contractors Holding Press Sheet Inspections--Hardcopy Available from the GPO, Print Procurement, APS, QCPP. Revised 01/15

https://www.gpo.gov/docs/default-source/forms-and-standards-files-for-vendors/contractors_holding_psi.pdf?sfvrsn=2

GPO Resolution Target
http://www.gpo.gov/gporestarget.pdf

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 0

General Services Administration (GSA) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

OMB Circular A-119 assists our Agency to review our standards use on a recurring basis, and continuously assess the potential to expand use of non-government standards/ voluntary consensus standards when practical for the Government. This leads to increased efficiency in our work processes and contributes to greater reliability on product quality.

Standards play a significant role in the Federal Supply program. They are used to establish baselines for product quality, performance and features; allow competitive procurement of functionally equivalent products and; when necessary ensure interchangeability of products produced under different contracts and across different contract periods. The most significant aspect of our use of standards is to ensure the safety and durability of the products purchased for government use.

GSA maintains a Standards website: http://www.gsa.gov > Buy Through Us > Purchasing Programs > Requisition Programs > GSA Global Supply > Supply Standards > Index of Federal Specifications, Standards, and Commercial Item Descriptions

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 3

(1) Government Unique Standard

Federal Specification KKK-A-1822E - Federal Specification for Ambulances [Incorporated: 2003]

Voluntary Standard

ASTM F2020 - Standard Practice for Design, Construction, and Procurement of Emergency Medical Services Ambulances

Rationale

The ASTM Standard Practice for Design, Construction, and Procurement of Emergency Medical Services (EMSS) Ambulances (ASTM F2020) is not practical for use, and therefore GSA uses the Federal Specification for Ambulances (KKK-A-1822E). GSA has determined the ASTM document is not practical for use for the following reasons:

1) GSA has determined that ASTM F2020 contains specific practices that are technically and economically impractical to use for the acquisition of commercial based vehicles because the

document is financially burdensome and technically ineffective. Specifically at issue is the ASTM Standard Specification for Medical Oxygen Delivery Systems for EMS Ground Vehicles, F1949-99 which is inclusive to ASTM F2020.

2) GSA has determined that ASTM F2020 is impractical because it is defined as a standard practice which is ambiguous and an ineffective substitution for specifications or requirements for use in GSA contract documents. ASTM F1949-99, a Standard Specification for Medical Oxygen Delivery Systems for EMS Ground Vehicles is included in ASTM F2020. ASTM F1949-99 is defined as a "standard specification".

3) GSA has determined that ASTM F2020 is impractical because ASTM International does not provide interpretations and written guidance to their publications which is inadequate and less useful. ASTM members may only offer personal opinions. ASTM offers no mechanism to support timely resolution of conflicts between contractor and procurement organizations on technical subject matter. GSA provides interpretations, clarifications and engineering determinations when required. This is one of the most important concerns presented by the Ambulance Manufacturers Division (AMD).

4) The AMD has determined through consensus that it is impractical to replace the Federal Specification for Ambulances, KKK-A-1822E with the ASTM Standard Practice, F2020. GSA initiated a survey to collect public responses from a wide range of constituent users of the Federal Ambulance Specification. The National Association of Emergency Medical Technicians (NAEMT), the International Association of Fire Chiefs (IAFC), the National Association of State EMS Directors (NASEMSD) and the National Association of EMS Physicians universally accept and support the continued use of the Federal Specification. The AMD and constituent users have determined that it is impractical to replace the Federal Specification for Ambulances, KKK- A-1822E with the ASTM Standard Practice, F2020 because rule promulgation is complex and costly. Staff and administration resources would need to be diverted in each state EMS office to implement the change in statutes, public health codes, rules and regulations.

5) GSA has determined that ASTM F2020 is impractical because it is complex to GSA procurement efforts. While the current ASTM document recites many of the requirements from the Federal Specification, a future ASTM document would likely have diverging requirements unacceptable to the Government. This was verified by a member of the ASTM F2020 subcommittee at the September 4, 2003 meeting of the Federal Interagency Committee on Emergency Medical Services.

(2) Government Unique

Standard FF-L-2937

[Incorporated: 2006] **Voluntary**

Standard

UL 768

Rationale

Federal Specification FF-L-2937 – Combination Lock, Mechanical used in lieu of UL 768 Combination Locks. The lock covered by the GUS is used for the protection of classified information and weapons. The

UL specification did not meet identified government needs for dialing tolerance and bolt end pressure.

(3) Government Unique Standard

MIL-G-9954 - Glass Beads for Cleaning and Peening [Incorporated: 2000]

Voluntary Standard

SAE/AMS 2431 - Peening Media, General Requirements

Rationale

This government-unique standard contains specific size & performance required for Air Force critical applications that are not present in the voluntary standards.

National Archives and Records Administration (NARA) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

When NARA used standards during rulemaking in FY 2022, we complied with Executive Order 12866, "Regulatory Planning and Review;" Executive Order 13563, "Improving Regulation and Regulatory Review;" Executive Order 13610, "Identifying and Reducing Regulatory Burdens;" Executive Order 13609, "Promoting International Regulatory Cooperation;" Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs"; and OMB Circular A-4, "Regulatory Analysis."

NARA promulgated no rules in FY 2022 using Government unique standards (GUS).

NARA uses both voluntary consensus standards (VCS) and GUS in our procurement activities. NARA's Office of the Chief Acquisition Officer relies on program office personnel (technical experts) to identify, manage, and review the standards used in procurements of products and services within their own program areas. NARA's standards-related activities are available here:

https://www.archives.gov/preservation/technical
https://www.archives.gov/records-mgmt/storage-standards-toolkit
https://www.archives.gov/records-mgmt/prmd/standards-development.html
https://www.archives.gov/files/federal-register/write/handbook/ibr.pdf

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 0

National Aeronautics and Space Administration (NASA) Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

Proven, consensus-based standards are critical in defining engineering, safety and mission assurance, and health and medical requirements for NASA missions. These technical standards include, but are not limited to, voluntary consensus standards (VCS) cited in NASA directives and technical standards, other government agency standards, NASA technical standards, and NASA-endorsed standards. As NASA technical standards are developed and revised, more VCS are incorporated where appropriate. Many examples of NASA Technical Standards citing use of VCS, and access to those VCS, can be found on the NASA Technical Standards System Web site at https://standards.nasa.gov. NASA requires, prior to proposing development, revision, or revalidation of a NASA technical standard, a determination be made whether a VCS exists or is in development that meets or can be tailored to meet NASA's needs. NASA technical discipline experts also evaluate the opportunity to replace an existing NASA technical standard with a VCS or propose conversion to a VCS, thereby reducing duplicate standards. NASA follows the process required for VCS specified in OMB Circular A-119: openness, balance, due process, appeals process, and consensus. NASA also promotes the use of VCS by identifying and approving NASA- endorsed technical standards, a "pick list" of technical standards to consider first when selecting program and project requirements. These activities facilitate selection and use of VCS in lieu of NASA technical standards or other government agency standards in compliance with OMB Circular No. A-119. NASA directly cites OMB Circular A-119 and the preference for use of VCS and participation in VCS bodies' activities in NASA directives (NASA Policy Directive (NPD) 7120.4, NASA Engineering and Program/Project Management Policy, and NASA Procedural Requirements (NPR) 7120.10, Technical Standards for NASA Programs and Projects).

NASA encourages participation in VCS developing bodies and collects data on participation in development and revision of VCS. During this reporting period, 124 NASA representatives participated in 425 VCS development/revision activities in 30 Standards Developing Bodies. NASA's participation in VCS development/revision activities increased from 257 participants in FY2021 to 425 in FY2022, an increase of over 65 percent.

A NASA representative chairs the ISO TC20/SC14 Subcommittee for Space Systems and Operations in support of promoting use of VCS. The committee's scope of work is the standardization for manned and unmanned space vehicles, their design, production, maintenance, operation, and disposal, and the environment in which they operate. Six working groups provide an international forum for addressing the standardization needs and concerns of organizations and personnel involved with the development and operation of space systems. NASA currently supports the development/revision of over 13 ISO TC20/SC14 international consensus standards.

NASA cites as requirements for test methods 4 ASTM standards, 10 American Welding Society (AWS) standards, 26 SAE International (SAE) standards, 2 Government Electronics and Information Technology Association (GEIA) (SAE International) standards, 2 National Aerospace Standards (NAS) standards, and 1

Battelle Memorial Institute standard. As new revisions are developed, more VCS are incorporated where appropriate. NASA-STD-6012A, recently revised, cites 1 AWS, 14 ASTM, and 10 SAE standards.

NASA is well represented on AIAA committees to promote development/revision and use of VCS, as these standards are applied on many NASA programs and projects in lieu of NASA standards. Some examples are the AIAA Aerospace Pressure Vessels Committee; AIAA S-080, Space Systems - Metallic Pressure Vessels, Pressurized Structures, and Pressure Components; AIAA S-081, Space Systems - Composite Overwrapped Pressure Vessels (COPVs); AIAA S-082 202x, Space Systems - Composite Overwrapped Pressure Vessels with a Composite Liner; AIAA S-110, Space Systems - Structures, Structural Components, and Structural Assemblies; AIAA-S-113, Criteria for Explosive Systems and Devices on Space and Launch Vehicles; AIAA-S-136 -202x, Battery Safety Standard for Space Applications; AIAA-S-144-202X, Code Verification in Computational Fluid Dynamics; AIAA G-095, Guide to Safety of Hydrogen and Hydrogen Systems; and AIAA R-091A-2020, Calibration and Use of Internal Strain-Gage Balances with Application to Wind Tunnel Testing.

NASA serves as the secretariat for Consultative Committee for Space Data Systems (CCSDS) leading the Spacecraft Onboard Interface Services (SOIS) committee with multiple standards development activities. The SOIS approach is to standardize the interfaces between items of spacecraft equipment by specifying well-defined standard service interfaces and protocols which allow standardized access to sensors, actuators, and generic spacecraft functions, allowing spacecraft applications to be developed independently of the mechanisms that provide these services.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

This agency reports voluntary consensus standards usage on a categorical basis.

Nuclear Regulatory Commission Fiscal Year 2022 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

The U.S. Nuclear Regulatory Commission (NRC) uses voluntary consensus standards as an integral part of our regulatory framework. Standards contain technical requirements, safety requirements, guidelines, characteristics, and recommended practices for performance. The benefits of being actively involved in developing and using standards include improved safety, cost savings, improved efficiency and transparency, and regulatory requirements with high technical quality. Some standards are incorporated by reference into NRC regulations. The NRC's regulations may be found at https://www.nrc.gov/reading-rm/doc-collections/cfr/ index.html. The NRC staff also issues documents providing guidance on acceptable methods for complying with NRC regulations such as Regulatory Guides (RGs). These guidance documents frequently endorse and reference voluntary consensus standards as acceptable methods for compliance with NRC regulations. RGs are cataloged here https://www.nrc.gov/reading-rm/doc-collections/index.html#reg.

The NRC implements the Office of Management and Budget Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," consistent with the provisions of the National Technology Transfer and Advance Act (NTTAA) of 1995 (Public Law 104-113) through formal guidance to the NRC staff.
Guidance to the NRC staff on standards work is provided in NRC Management Directive (MD) 6.5, "NRC Participation in the Development and Use of Consensus Standards." MD 6.5 and its associated directive handbook were initially published in 1998 and were revised and reissued in 2016. MD 6.5 describes the NRC's process with respect to the participation in the development and use of consensus standards. This process consists of three primary steps:
(1) identifying and prioritizing the need for new and revised technical standards, (2) participating in codes and standards development, and (3) endorsing codes and standards.

As an initiative to enhance agency use of standards and to exchange standards information with external stakeholders, in September 2022, the NRC hosted the sixth NRC Standards Forum.
The goals of the NRC Standards Forum are to facilitate discussions on codes and standards needs within the nuclear industry and explore how to collaborate in accelerating the development of codes and standards and the subsequent NRC endorsement of codes and standards. Our intent is to shorten the lengthy standards development cycle by encouraging collaboration among stakeholders including researchers producing technical information and standards writers who build upon their findings. The Standards Forum meetings are usually held once a year. A summary and related documents for the September 2022 Standards Forum can be found at https://www.nrc.gov/about-nrc/regulatory/standards-dev/standards-forum/2022.html.

The NRC is working, and intends to continue working, with multiple standards development organizations to close technical and regulatory gaps through development and application of consensus standards. These standards may be applied to regulatory activities for existing light-water reactors or new nuclear plant designs including advanced reactor technologies and small modular reactors. Standards continue to provide a critical element in our safety mission. For more information, the NRC website on

standards development is at: https://www.nrc.gov/about-nrc/regulatory/standards-dev.html.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2022. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 2

(1) Government Unique Standard

NRC NUREG-1556, "Consolidated Guidance about Materials Licenses" [Incorporated: 2011].

Voluntary Standard

(American National Standards Institute (ANSI)) N 13.2-1969, Guide for Administrative Practices in Radiation Monitoring.

Rationale

(ANSI) N 13.2-1969, "Guide for Administrative Practices in Radiation Monitoring," had been endorsed in Regulatory Guide 8.2, with the same title, issued in February 1973. The standard has not been revised since its inception, and it now refers to obsolete technical practices and outdated requirements. Therefore, Revision 1 of RG 8.2, published in May 2011, removed endorsement of ANSI N 13.2-1969. Guidance is now provided through two referenced NRC reports, that could be considered Government-unique standards: NUREG-1556, "Consolidated Guidance about Materials Licenses," and NUREG-1736, "Consolidated Guidance:
10 CFR Part 20—Standards for Protection against Radiation."

(2) Government Unique Standard

NRC NUREG-1736, "Consolidated Guidance: 10 CFR Part 20—Standards for Protection against Radiation" [Incorporated: 2011].

Voluntary Standard

(ANSI) N 13.2-1969, "Guide for Administrative Practices in Radiation Monitoring."

Rationale

(ANSI) N 13.2-1969, "Guide for Administrative Practices in Radiation Monitoring," had been endorsed in RG 8.2, with the same title, issued in February 1973. The standard has not been revised since its inception, and it now refers to obsolete technical practices and outdated requirements. Therefore, Revision 1 of RG 8.2, published in May 2011, removed endorsement of ANSI N 13.2-1969. Guidance is now provided through two referenced NRC reports, that could be considered Government-unique standards: NUREG-1556, "Consolidated Guidance about Materials Licenses," and NUREG-1736, "Consolidated Guidance: 10 CFR Part 20— Standards for Protection against Radiation."