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NIST IR 8438

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

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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 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 2021 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 2021 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 Agencies additionally were asked to list any rescinded GUS in lieu of VCS during the past fiscal year and to briefly describe their activities undertaken to carry out provisions described in Circular A-119. 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 2021, 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 2021, 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 2021 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.

Access Board (ACCESS) Fiscal Year 2021 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. 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 2021, 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 2021, 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,

Additionally, two Access Board members serve as statutory representatives on the Election Assistance Commission (EAC) Advisory Board and Technical Guidelines Development Committee (TGDC). The role of the EAC Advisory Board is to advise the EAC through review of the Voluntary Voting Systems Guidelines (VVSG) and the TGDC, chaired by the NIST director, assists EAC in developing the VVSG. On February 10th, 2021, the EAC formally announced adoption of the VVSG 2.0 and that the four EAC Commissioners had unanimously approved the VVSG 2.0 documents. For 2021, the EAC Advisory Board and TGDC meetings were held virtually, and work continued with updating VVSG 2.0 supplemental materials, including life cycle guidance for migrating from deprecated VVSG versions. In addition to the Advisory Board and TGDC, Access Board members and staff also attend other EAC public hearings.
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 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

Consumer Product Safety Commission (CPSC) Fiscal Year 2021 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, 2020 to September 30, 2021, CPSC staff provided technical support or was otherwise engaged in the development of voluntary safety standards for 78 different products or product areas. 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 Activity Report, otherwise known as the Vstar Report. This report shows, among other things, product or product areas 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 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):** 2

Table 1: Current Government Unique Standards FY2021

(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 2021 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 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 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 food safety practices. In FY 2021, AMS' Specialty Crops Program, Specialty Crops Inspection Division (SCI) and its licensed auditors performed 4,089 food safety audits (primarily GAP and GHP audits) on more than 100 different commodities in all 50 states and Puerto Rico.

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 National Organic Program (NOP) did not use any Government Unique Standards in lieu of Voluntary Consensus Standards in FY 2021. NOP also did not participate in any Voluntary Consensus

Standards Activities during FY 2021.

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. Moreover, 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.

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 international standards allows DP to have a direct role in the development and use of voluntary consensus standards.

Relevant Websites:
- ISO: https://www.iso.org/about-us.html
- ANSI U.S. TAG Listing: https://share.ansi.org/Shared%20Documents/Standards%20Activities/International%20Standardization/ ISO/US%20TAGs%20to%20ISO/All%20ISOTAGS_Nov2021.pdf
- 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 US 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. L&P 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 US and International standard development organizations to promote efficiency and competitiveness for American farmers, producers, processors, handlers, wholesalers, warehousing companies, and retailers. In the United States 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 2021, the US delegation to the United Nations Economic and Social Council, Economic Council for Europe, Steering Committee on Trade Capacity and Standards, Working Party on Agricultural Quality Standards, Specialized Section on the Standardization of Meat was led by LP staff members. UNECE is a voluntary international standards development organization. The meeting was held in a hybrid format as a result of the Covid Pandemic. In attendance were delegations from Australia, China, France, Germany, Poland, and the United States, as well as representatives from non-government organizations. These proceedings covered the collection of data from slaughterhouses, revision of the UNECE standard for porcine meat (marbling and fat), the development of a standard for animal protein derived from connective tissue, the development of international minimum sustainability guidelines for the meat sector, alignment of the Economic Commission for Europe cut codes with the Harmonized Commodity

Descriptions and Coding System, and the possible development of a livestock language. An AMS staff person was elected as the vice chairperson of this organization during the meeting session.
In 2021, LP continued its service as a member of the American National Standards Institute American Society for Quality (ANSI-ASQ) National Accreditation Board representing the interests of the U.S. agricultural industry. The ANSI-ASQ National Accreditation Board provides accreditation for ISO/IEC 17021 management systems certification bodies, ISO/IEC 17025 testing and calibration laboratories and forensic testing agencies, ISO/IEC 17020 inspection bodies and forensic inspection agencies, ISO Guide 34 reference material producers, ISO/IEC 17043 proficiency test providers, and industry-specific programs. Board participation included providing guidance for the international development of accreditation processes in accordance with these management systems standards.
USDA's Livestock and Poultry Program (LP has served as the ANSI delegated US Technical Advisory Group administrator for the International ISO subcommittee TC 34 Food Products/SC 6 Meat, poultry, fish, eggs, and their products since its establishment in 1980. In 2021, LP continued to provide funding to ANSI for operation and maintenance of this US TAG providing for open US industry, government, and academic access to the ISO standardization framework) led the development of international voluntary consensus standards for meat, poultry, fish, eggs and their products eggs, meat, and poultry. LP staff members served as the TAG chair and supported the administration of the US secretariat for TC 34/SC 6. LP coordinated the formulation of the US position for the international committee and attended all the committee meetings. The US TAG for TC 34/SC 6 supported the virtual participation of US experts including LP staff in seven SC 6 working groups: WG 19 Nomenclature and vocabulary, WG 20 Operating procedures of slaughtering, WG 21 Fermented meat products, WG 22 Frozen surimi, WG 23 Determination of additives, WG 24 Determination of pollutant and WG 25 Determination of glutamic acid content to publish seven international voluntary consensus standards in 2021 including ISO 13493:2021 Meat and meat products — Determination of chloramphenicol content — Reference method, ISO 13496:2021 Meat and meat products — Detection and determination of coloring agents, ISO 23722:2021 Meat and meat products — Vocabulary, ISO 23776:2021 Meat and meat products — Determination of total phosphorous content, ISO 23781:2021 Operating procedures of pig slaughtering, ISO 23854:2021 Fermented meat products — Specification, and ISO 23855:2021 Frozen surimi — Specification. TC 34/SC 6 is currently developing the following new standards: ISO/WD 937 Meat and meat products — Determination of nitrogen content (Reference method), ISO/WD 1442 Meat and meat products — Determination of moisture content (Reference method), ISO/WD 5553 Meat and meat products — Detection of polyphosphates, ISO/WD 7124 Eggs and egg products — Determination of fipronil and metabolites residues — Liquid chromatography-tandem mass spectrometry, ISO/WD 7158 Meat and meat products — Determination of nitrite and nitrate content-ion chromatography method.
At its last plenary meeting TC 34/SC 6 discussed laboratory cultured protein as food among meeting participants. LP stands ready to represent U.S. interests on the standardization of this emerging topic.
In 2008, as a response to a World Trade Organization lawsuit affecting the international trade of bioengineered food products LP provided collaborative funding to the American Oil Chemist’s Society (AOCS) for the establishment of ISO TC 34/SC 16 horizontal methods for molecular biomarker analysis to provide 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. The deliverables from this committee would eventually serve as international standard for GMO testing, including citation and recommendation for use in the US National Bioengineered Food Disclosure Standard. Although, USDA no longer provides direct funding to AOCS, because the committee has

become member supported, an LP staff person serves as the international executive committee manager and technical expert. The LP staff member leads all of the international committee proceedings. Currently TC 34/SC 16 has 8 working groups: WG 8 Meat speciation, WG 9 Subsampling of seeds and grains, WG 10 Rapid nucleic acid amplification methods, WG 11 Biobanking for agriculture and food production, JWG 12 Molecular biomarkers of agricultural fibers, WG 13 Microarray detection, WG 14 Genetically engineered content detection and quantification, and WG 16 Single laboratory validation of qualitative real time PCR methods. In 2021 TC 34/SC 16 published three standards: ISO/TS 21569-2:2021 Molecular biomarker analysis — Methods of analysis for the detection of genetically modified organisms and derived products — Part 2: Construct-specific real-time PCR method for detection of event FP967 in linseed and linseed products, ISO 22753:2021 Molecular biomarker analysis
— Method for the statistical evaluation of analytical results obtained in testing sub-sampled groups of genetically modified seeds and grains — General requirements, ISO 22949-1:2021 Molecular biomarker analysis — Methods of analysis for the detection and identification of animal species in food and feed products (nucleotide sequencing-based methods) — Part 1: General requirements. Standards under development in ISO TC 34/SC 16 include ISO/AWI 5354 Molecular biomarkers of agricultural fibers — Screening of genetically modified organisms (GMOs) in cotton and textiles, ISO/DIS 16577 Molecular biomarker analysis — Vocabulary for molecular biomarker analytical methods in agriculture and food production, ISO/CD 16578 Molecular biomarker analysis — Requirements for microarray detection of specific nucleic acid sequences, ISO/DTS 20224-8 Molecular biomarker analysis — Detection of animal- derived materials in foodstuffs and feedstuffs by real-time PCR — Part 8: Turkey DNA detection method, ISO/DTS 20224-9 Molecular biomarker analysis — Detection of animal-derived materials in foodstuffs and feedstuffs by real-time PCR — Part 9: Goose DNA detection method and ISO/FDIS 22942-1 Molecular biomarker analysis — Isothermal polymerase chain reaction (isoPCR) methods — Part 1: General requirements.
An LP staff member continues to serve as the US convener for ISO TC 276/WG 5 Biotechnology Data programming and integration.
In 2021 LP staff participated as a designated ISO expert in drafting and expert committees for ISO/IEC JTC 1/SC 29/WG 8 MPEG Genomic coding, ISO/TC 34/Food products, ISO/TC 34/SC 5 Milk and milk products, ISO TC 34/SC 9/WG 25/DIS 23418 Microbiology of the food chain — Whole genome sequencing for typing and genomic characterization of foodborne bacteria — General requirements and guidance; ISO/TC 34/SC 17 Management systems for food safety; ISO/TC 34/SC 20 Food loss and waste, ISO Strategic activity group on smart farming, ISO/TC 34/WG 14 Vitamins, carotenoids and other nutrients, ISO/TC 38 Textiles, ISO/TC 69 Applications of statistical methods, ISO/TC 93 Starch (including derivatives and by-products), ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems – biorisk and biosafety, ISO/TC 215 Health Informatics, ISO/TC 276 Biotechnology, and IEC Strategic Exploratory Group 12 Bio digital convergence.

LP staff represented the USDA at the two Interagency Committee on standards policy (ISCP) meetings and participated in the annual ANSI ISO Forum meetings.
In 2021 an LP staff member, served as an expert panel member for AOAC stakeholder method performance requirement (SMPR) for A2 Milk and as a working group chair for the AOAC stakeholder program on Agent Detection Assays.

USDA's Fair Trade Practices Program (FTPP), Packers and Stockyards Division (PSD) participated in Voluntary Consensus Standards Activities during FY 2021.
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 5 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*. National Institute of Standards and Technology Handbook 44, 2013.

2. Standard Practice for User Requirements for Livestock, Meat, and Poultry Evaluation Devices or Systems. American Society for Testing Materials 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's Fair Trade Practices Program's (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 National Institute of Standards and Technology (NIST) Handbook 44.

The National Type Evaluation Program (NTEP) is a verification program administered by the National Conference of Weights and Measures (NCWM) to ensure measurement devices are manufactured in accordance with United States standards. Standards, policies, and test procedures are developed by industry and technical experts who meet annually to maintain consensus. Devices who maintain 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 US 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 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):**
   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 2021 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 mission of the DOC is to create the conditions for economic growth, jobs creation, and opportunity within the US by ensuring fair trade nationally and internationally, providing the data necessary to support commerce and constitutional democracy, and fostering innovation by setting standards and conducting foundational research and development. Together with other bureaus of DOC, the five listed in this report support the strategic goals of accelerating US leadership, enhancing job creation, strengthening US 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 FY2021 to support these critical mission areas.

The **US Census Bureau (Census Bureau)**

The US Census Bureau (Census Bureau) completed the 2020 Census, delivering the small area geography and "basic tabulations of population" to each state as required by P.L. 94-171. 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) were applied in the Census Bureau's statistical surveys, economic analysis, and geographic programs. The collection and analysis of data for geographic programs continues with programs such as:

- The Census Bureau's 2020 urban-rural classification is a delineation of geographic areas, identifying both individual urban areas and the rural areas of the nation. The Census Bureau's urban areas represent densely developed territory, and encompass residential, commercial, and other non-residential urban land uses. The Census Bureau delineates urban areas after each decennial census by applying specified criteria to decennial census and other data. "Rural" encompasses all population, housing, and territory not included within an urban area.
- The 2020 Public Use Microdata Areas (PUMA) which occurs every ten years after the decennial census publishes the population count to allow State Data Centers from each state, the District of Columbia, and Puerto Rico to delineate PUMAs using specific standards and criteria (specifically using the census population counts and updated census tracts from the 2020 Census). Participation is voluntary and allows a 90-day review period for State Data Centers to delineate, review, and submit their PUMAs.

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 4 below). These standards and programs, in addition to ongoing research and innovation activities, were designed to improve public access, discoverability, integration, and data sharing, and to support the open government initiative and the provisions of OMB Circular A-016 <https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-016.pdf>. In 2021, the following activities exemplified the Census Bureau's application of VCS.

1. The Census Bureau applied the International Committee for Information Technology

Standards (INCITS) data standards in their contribution to the National Spatial Data Infrastructure (NSDI). Census Bureau staff continued participation in FGDC's Geospacial Data Act of 2018 (GDA) Covered Agency Report and GDA Lead Covered Agency report surveys as a requirement of the GDA to provide information on their use of the ISO standards for all geospatial data, including 34 National Geospatial Data Assets (NGDAs).

2. The Census Bureau's NGDA datasets represent a federal portfolio of geospatial datasets derived from the Topologically Integrated Geographic Encoding and Referencing (TIGER) System. The Census Bureau's TIGER/Line shapefiles for these NGDAs are accessible by the general public and discoverable on Census.gov, the Federal Geographic Data Committee's Geospatial Platform, and Data.gov.
3. The Census Bureau submitted responses, to the FGDC, for the NGDA Baseline Standards Inventory Survey in October 2020 and has renewed licensed subscriptions to the following voluntary consensus standards through 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 cataloguing.
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.

4. To support 2020 Census operations, the Census Bureau developed various web mapping applications using open web service formats including GeoServices Representational State Transfer (REST) Specification services and OGC's OpenGIS Web Map Service (WMS). These applications allowed users to interact with Census Bureau data in many ways including but not limited to selecting features and viewing their attributes, searching for features by name or geocode, and identifying features by selecting them from a map. The underlying services were exposed to allow other web developers to use the Census

Bureau's authoritative data in their own maps, too. A list of the web mapping applications is below:

- TIGERweb is a web-based mapping tool developed to allow users to visualize geospatial data derived from the U.S. Census Bureau's Master Address File (MAF)/TIGER database (MTDB) without geographic information system (GIS) software and without downloading TIGER data. It provides a simple way to select and view features and their attributes, to search for features by name or geocode, and to identify features by selecting them from an on-screen map. The spatial data within TIGERweb covers the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, and the Island Areas. TIGERweb includes attribute information from the Decennial Census, Economic Census, and the American Community Survey (ACS). The Census Bureau exposes TIGERweb's GeoServices REST Specification services and OGC's OpenGIS Web Map Service (WMS), which allows developers to integrate them into their own GIS or custom web-based applications.
- Response Outreach Area Mapper (ROAM) was developed to make it easier to identify hard-to-survey areas through the analysis of socioeconomic and demographic characteristic profiles of these areas using ACS estimates available in the Census Bureau's Planning Database. Learning about each hard-to-survey area allowed the Census Bureau to create a tailored communication and partnership campaign, and to plan for field resources including hiring staff with language skills specific to the local area. These and other efforts improved response rates. The Census Bureau exposes ROAM's GeoServices REST Specification services to allow for developers to integrate them into their own GIS or custom web-based applications.

5. The Census Bureau is now actively involved 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 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) as well as 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.

The International Trade Administration (ITA)

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

In FY2021, 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 US Technical Advisory Group (TAG) to ISO/TC293, Feed Machinery to support US 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 US 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 US exporters. In FY2021 ITA also worked with the National Institute of Standards and Technology (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 US engagement could benefit commercial goals.

ITA participates in the ANSI Unmanned Aircraft Systems Standards Collaborative. An ITA specialist continues to participate in the Smart Textiles Subcommittee of ASTM International (ASTM) Committee D13 on Textiles and a staff member of the Commercial Section in the US Embassy in Mexico City participates in the monthly sessions of Mexico's National Textile Standards Committee to monitor standards that could impact US textiles and apparel exporters.
In FY2021 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, electric vehicles, wine, blockchain and distributed ledger technology, and conformity assessment. ITA has joined inter-agency efforts led by the Department of State to shape 5G and telecommunications standardization taking place at the International Telecommunications Union (ITU), including preparations for the World Telecommunications Standardization Assembly (WTSA).
ITA engaged on standards issues with the ASEAN Consultative Committee on Standards and Quality, including organizing workshops, additive manufacturing (3D printing), and digital trade standards – particularly those related to cybersecurity and promoting digital trust - and work on standards for critical and emerging technologies through the Quadrilateral Security Dialogue (Quad) with Australia, India, and Japan, including on AI and advanced communications. ITA also supported standards engagement under the Pan-American Standards Commission (COPANT). Bilateral engagement on standards issues was ongoing with various trading partners including through the US-Brazil Commercial Dialogue, the US-Canada Regulatory Cooperation Council, the US-EU Executive Working Group, and the US-EU Trade and Technology Council (TTC), among others. ITA maintained Standards Attaches in Beijing, Brussels, Jakarta, Johannesburg, Mexico City, and Sao Paulo.

ITA is a part of the US delegation headed by the Office of the US 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-related trade concerns on the floor of the WTO TBT Committee against several countries in FY2021. During FY2021, ITA also participated as part of the US Government's delegation for trade agreement negotiations with the United Kingdom, specifically the TBT, Good Regulatory Practices (GRP), and Sectoral chapter negotiations. ITA regularly works with US 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 14) with the Office of the US Trade Representative (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 US innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve the quality of life. As specified in the National Technology Transfer and Advancement Act (NTTAA), in authorizing legislation, and in the Office of Management and Budget (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. 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.

During FY2021, NIST played leadership roles in the areas of advanced communications, Artificial Intelligence (AI), cybersecurity, and quantum computing, and developed a guidance document on using inclusive language in standards for NIST staff. An estimated 570 NIST staff members participated in just under 3,500 committee activities across 327 standards developing organizations.

Advanced Communications

NIST leads the government-wide Advanced Communications Technologies Working Group (ACTWG) chartered under the ICSP to facilitate coordination of Federal agency advanced communications technologies (ACT) standards activities. The working group meets monthly and has been gathering information through presentations by participating agencies.

In addition, over 50 people across NIST come together as part of an all-of-government approach to wireless standards and contribute to global standards and specification development organizations such as 3rd Generation Partnership Project (3GPP), Institute of Electrical and Electronics Engineers (IEEE), Internet Engineering Task Force (IETF), International Telecommunication Union Radiocommunication Sector (ITU-R), Alliance for Telecommunications Industry Solutions (ATIS), and International Organization for Standardization/International Electrotechnical Commission Joint Technical Committee 1 (ISO/IEC JTC1).

Working through public-private partnerships such as the NIST-led Next G Channel Model Alliance and the National Science Foundation (NSF)-led Resilient Intelligent Next Generation Systems Program, NIST experts work with Industry and the research community to provide communication measurements, methods, and tools to enable the rapid development and deployment of Next G standards and technologies. NIST's decades of standards-setting leadership reflects its continued commitment to wireless research and development and public-private partnerships.

Artificial Intelligence (AI)

The National Science and Technology Council (NSTC) Machine Learning/Artificial Intelligence (ML/AI) Subcommittee established the role of the US Government AI Standards Coordinator with responsibility to gather and share AI standards-related needs, strategies, roadmaps, terminology, use cases, and best practices in support of reliable, robust, and trustworthy AI in government operations, including:

- planned and ongoing standards approaches and engagement activities, including a robust feedback loop with Standards Developing Organizations (SDOs);
- specific horizontal or vertical areas for prioritization;
- requirements for input into proposed standards activities; and

— analyses of whether ongoing standards activities meet Federal Government needs and whether additional guidance is appropriate.
    - The Subcommittee selected the Chief of Staff of the NIST Information Technology Laboratory to fulfill the role of US Government AI Standards Coordinator.
    - As part of the U.S. Government AI Standards Coordinator responsibilities, the AI Standards Coordination Working Group (AISCWG) was established in April 2021, to facilitate coordination of government agency activities related to development and use of AI standards. The group operates under the charter of the ICSP. Participants include representatives across federal agencies with expertise and/or an agency stake in the development and implementation of AI standards. The AISCWG is responsible for assisting the ICSP in promoting effective and consistent federal policies leveraging AI standards cited in the AI Standards Plan.

The AISCWG raises awareness of federal agencies' standards needs based on their use of AI; fosters agency interest and participation in AI standards activities; fosters coordination of US Government positions regarding draft standards, standards work items, and other standards activities based on consensus processes; and establishes effective means of coordinating AI international standards activities with those of the private sector.

Delivering the needed measurements, standards, and other tools is a primary focus for NIST's AI efforts, and much of its work focuses on aspects of trustworthiness. Over the past two years, NIST has expanded and made noteworthy progress in carrying out research specifically addressing standards-oriented research. It has selected priority topics and activities based on its statutory mandates and the needs expressed by US industry, other federal agencies, and the global AI research community. Among other things, NIST recently:

- Initiated research efforts in explainable and interpretable AI, bias in AI, secure AI, user trust in AI, and evaluation of AI.
- Developed a series of reports on aspects of AI trustworthiness, including: *A Method for Evaluating User Trust in AI Systems*; *A Taxonomy and Terminology of Adversarial Machine Learning*; *Psychological Foundations of Explainability and Interpretability in AI*; and *A Proposal for Identifying and Managing Bias in AI*.
- Organized a series of ongoing workshops to build communities and advance scientific discussions, beginning with a series kickoff and consisting of one-, two-day, and multi-week sessions involving working sessions aiming to forge agreement on key terms and aspects of trustworthiness that can be incorporated into the development of standards.
- Organized a joint workshop with the Food and Drug Administration (FDA) and Defense Advanced Research Projects Agency (DARPA) on AI for Drug Development in August 2021.

Cybersecurity

NIST develops cybersecurity standards, guidelines, best practices, and other resources to meet the needs of US industry, federal agencies and the broader public. In FY2021, NIST staff actively participated in VCS committees addressing cybersecurity risk management and measurement, identity and access management, the Internet of Things, and privacy. NIST continued its effort to evaluate candidates for standardization of one or more quantum-resistant cryptographic algorithms.

Quantum Computing

NIST participates in and chairs INCITS/Quantum Computing committee serving as the US TAG to ISO/IEC JTC 1/WG14 *Information technology - Quantum computing*. This committee serves as a

focus of and proponent for JTC 1's standardization program on Quantum Computing by identifying gaps and opportunities in Quantum Computing standardization and developing deliverables in the area of quantum computing. The TC maintains relationships with other relevant SDOs, and other entities involved in QC standardization. The main focus of both the US TAG and JTC 1/WG14 is on its first developing deliverable, ISO/WD 4879 *Quantum computing – Terminology and vocabulary*. This document is developing the language that will be used among quantum computing professionals as products come into fruition. NIST has acted to ensure a strong and balanced US industry input by working with US industry organizations such as the Quantum Economic Development Consortium (QED-C) to solicit feedback and has also been added to the international editorial team that manages the written content. A second document, ISO/TR *Information technology – Introduction to quantum computing,* has been posted with an updated outline.

Inclusivity Language in Standards

NIST published a Guidance for NIST Staff on Using Inclusive Language in Documentary Standards (NISTIR 8366) for the benefit of NIST staff experts who participate in the development of documentary standards as expert collaborators and leaders. The publication provides guidance on how to reduce bias in terminology used in standards development.

National Oceanic and Aeronautic Administration (NOAA)

Standardization of data acquisition and data management practices are vital to NOAA's mission and the effective sharing of its data for use by the public, industry, and academia. NOAA seeks to establish 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) and SDOs (e.g., Open Geospatial Consortium). All NOAA line organizations participate in standards development activities, which are typically coordinated through NOAA's Environmental Data Management Committee (EDMC). NOAA also participates in the Commerce Data Governance Board (established in September 2019) and subsequent Commerce Geospatial Standards Users Group (established in May 2020).

In general, standards used in many NOAA activities are established in conjunction with other Federal agencies either through joint participation in national (e.g., FGDC) and international (e.g., United Nations committee of experts on Global Geospatial Information Management) organizations or by means of bilateral and multilateral agreements with other nations. The recent implementation of the Geospatial Data Act of 2018 (GDA)) and the Digital Accountability and Transparency Act (DATA Act) bring NOAA activities into sharper focus regarding standards within the FGDC. Likewise, the adoption by the US of the UN Global Geodetic Reference Frame (UN GGRF) has affirmed US commitment to international standards. These standardization activities apply to all phases of environmental data acquisition, processing, and distribution.

- NOAA has created and is developing an implementation for the NOAA Data Strategy, its first-ever NOAA Data Strategy and Implementation Plan. The purpose of the NOAA Data Strategy is to dramatically accelerate the use of data across the Agency and with other key partners, maximize openness and transparency, deliver on mission, and steward resources while protecting quality, integrity, security, privacy, and confidentiality. The overall strategy is designed to serve as a framework for consistency that builds upon existing laws and regulations related to how NOAA uses and manages data, while being flexible and adaptable to external influences such as new policies, Executive Orders, stakeholder input, and new technologies that drive innovation within the Agency.

- NOAA is updating its data governance approach through the creation of the new NOAA Data Governance Committee and the establishment of NOAA Line Office Assistant Chief Data Officers. The NOAA Data Governance Committee (DGC) coordinates the implementation of the NOAA Data Strategy, including oversight of policies that ensure NOAA data assets are strategically and efficiently managed on behalf of the NOAA enterprise. A series of DGC Working Groups and Task Teams will be established under the DGC to include Metadata, Data Catalogs, Data Licensing, and Data Innovation.

- The Big Data Program (BDP) is an enterprise service that eliminates friction and provides public access to NOAA's open data via the cloud partner's platforms and outside the NOAA FISMA boundary. Ten-year Indefinite Delivery, Indefinite Quality (IDIQ) contracts with Amazon, Google, and Microsoft ensure public access to NOAA data with no egress charges incurred for the user or the agency. These partners and NOAA have also begun to transform data from environmental data standards (e.g., netcdf4) to more generalized and cloud-optimized standards (e.g., Cloud-Optimized GeoTIFF) of interest to the wider data science community. As of Q4 FY21, the BDP disseminated more than 220 datasets, equaling over 14 petabytes of data, including atmospheric, satellite, oceanic, fisheries, climate data and much more through the BDP public-private partnerships. The BDP also works with the cloud partners to understand users' needs, based on interactions and communications, and is developing an approach that also incorporates other DoC data, to address specific climatic and societal challenges.

- NOAA shares thousands of its datasets through the Environmental Research Division Data Access Program (ERDDAP) service (https://coastwatch.pfeg.noaa.gov/erddap/index.html) and the Weather and Climate Toolkit https://www.ncdc.noaa.gov/wct/) which allows for the delivery and translation of data among multiple formats. NOAA data providers use the open-standard Data Access Protocol v2.0 to support interoperable data access.

- In October 2019, NOAA's National Geodetic Survey (NGS) published a framework for defining and maintaining the State Plane Coordinate System of 2022 (SPCS2022). This standards framework is key to guide the transition from the North American Datum of 1983 (NAD 83) to the 2022 Terrestrial Reference Frames (TRFs). SPCS2022 will replace SPCS 83 (NAD 83). NGS recognizes that there is significant interest within the geospatial community as to how SPCS2022 is defined, and many wish to have a voice in the development of SPCS2022. As this framework also specifies the characteristics and requirements for SPCS2022, the intent is to define SPCS2022 such that it is a technically sound and practical projected coordinate system for the modernized National Spatial Reference System (NSRS).

- NOAA and Census co-lead the planning and implementation of all requirements under the Geospatial Data Act (GDA) of 2018. Key examples of progress include: the creation of a Commerce Geospatial Strategy and Implementation Plan; chartering and leading the Commerce Geospatial Working Group, Commerce Standards Users Group, and Commerce Imagery Users Group; successfully submitting all required GDA reports including the annual Commerce Covered Agency and 6 Geospatial Theme reports; and participating in bi-annual audits of Commerce's performance under the GDA. All of these efforts include strategic and tactical direction to Commerce bureaus to adopt data standards in the execution of their missions.

- NOAA published the NOAA Data Strategy and is in final review of the NOAA Data Strategic Action Plan as of March 2022. The purpose of the NOAA Data Strategy is to dramatically accelerate the use of data across the agency and with other key partners, maximize openness and transparency, deliver on mission, and steward resources while protecting quality, integrity, security, privacy, and confidentiality. The overall strategy is designed to serve as a framework for consistency that builds upon existing laws and regulations related to how NOAA uses and manages data, while being flexible and adaptable to external influences such as new policies, Executive Orders, stakeholder input, and new technologies that drive innovation within the agency. The strategic action plan serves as a roadmap for implementation of the NOAA Data Strategy. This action plan will establish a modernized and unified NOAA data enterprise in support of the missions across NOAA, including close coordination with the NOAA science and technology focus areas.

- NOAA has expanded its use of the international OpenSearch standard and schema.org community metadata standards to support data discovery. These standard metadata have continued to be utilized by Google in their free-text DataSetSearch capability (https://toolbox.google.com/datasetsearch) which has now become a regular Google service. NOAA has continued to provide feedback to Google on the rankings of NOAA datasets.

- NOAA's newest satellites all use the open-standard Network Common Data Form (NetCDF-4) format rather than an agency-developed data format. NOAA has supported the collaborative development and is currently using standards for NetCDF-4 profile to handle in situ data from stationary and moving sensors. NOAA promotes the use of ISO- 19115-2 metadata standards and encourages use of Climate and Forecast Conventions (CF) and Attribute Conventions for Dataset Discovery (ACDD) community standards for naming conventions in NetCDF file production for satellite data. NOAA's National Centers for Environmental Information (NCEI) has defined multiple NetCDF templates to guide those submitting data to NCEI in the NetCDF data format. Use of NetCDF and these templates reduces the data analysis overhead as many scientific data analysis applications readily support the NetCDF data format.

- NOAA uses the ISO 19115: “Geographic information – Metadata” family of geospatial metadata standards and participates in US representation in ISO TC211 Geographic information/Geomatics, with Census Bureau serving as the lead for DOC. NOAA continues its gradual transition to the newest version of ISO 19115.

- NOAA uses ISO 26324: “Information and documentation -- Digital object identifier system” to assign unique, resolvable, and persistent identifiers to archival datasets and technical reports.

- NOAA National Weather Service meteorological data and reports comply with World Meteorological Organization (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.

- Light Detection and Ranging (lidar) is a remote sensing method that uses light in the form of a pulsed laser to measure ranges (variable distances) to the Earth. NOAA has adopted the American Society of Photogrammetry and Remote Sensing (ASPRS) Lidar Exchange

Format (LAS) standard format for lidar data and the open-source LAZ (laszip.org) for the compression of lidar data.

- NOAA/US Integrated Ocean Observing System (IOOS) requires adherence to standards as a part of its core capabilities and supports development of those standards. IOOS contributes to the Attribute Convention for Data Discovery (ACDD) via Earth Science Information Partners (ESIP), a broad-based, distributed community of data and information technology practitioners, and promulgating scientific metadata standards via https://ioos.github.io/ioos-metadata. IOOS also supports the development of Darwin Core and EML for biodiversity data and the development of ISO 19115 as the schema required for describing geographic information and services by means of metadata. IOOS Regional Associations must practice open data sharing via the Global Earth Observing System of Systems (GEOSS), use of ERDDAP and Thematic Real-Time Environmental Distributed Data Services (THREDDS) servers for data discovery and access, and provide metadata using relevant standards and the IOOS metadata profile – https://ioos.github.io/ioos- metadata/. The IOOS Catalog is the master inventory of IOOS Data Management and Communications (DMAC) datasets and data access services. Data providers are expected to register their datasets in the Catalog using standards given in https://ioos.noaa.gov/data/contribute-data/catalog-registration/. IOOS provides directions for setup and a gold standard ERDDAP at https://github.com/ioos/erddap-gold-standard. For full details in IOOS' use of standards see https://ioos.noaa.gov/data/data-standards/ and https://ioos.noaa.gov/data/data-standards/data-publishing/. IOOS also coordinates efforts to establish authoritative QA/QC procedures for the U.S. IOOS core variables, as necessary, including detailed information about the sensors and procedures used to measure the variables via Quality Assurance/Quality Control of Real-Time Oceanographic Data (QARTOD).

- NOAA remained a Principal Member of the Open Geospatial Consortium (OGC), and various data providers have adopted key OGC standards, including the Catalog Service for Web (CS/W), Web Map Service (WMS), Web Coverage Service (WCS), Web Feature Service (WFS), and Sensor Observation Service (SOS). NOAA participates in OGC Working Groups to help evolve the suite of voluntary-consensus standards.

- NOAA uses GitHub to allow the standardization of NOAA code sharing with the scientific and data communities.

- NOAA has submitted data to NIH's Genbank, following established standards. GenBank is part of the International Nucleotide Sequence Database Collaboration, which comprises the DNA DataBank of Japan (DDBJ), the European Nucleotide Archive (ENA), and GenBank at the National Center for Biotechnology Information (NCBI) (https://www.ncbi.nlm.nih.gov/genbank/).

- NOAA's Office of Coast Survey (OCS) and the Center for Operational Oceanographic Products and Services (CO-OPS) represent the US in the International Hydrographic Organization (IHO) and on several regional hydrographic commissions. OCS surveys and nautical charts are produced to IHO standards that ensure consistent nautical charts so that mariners can confidently use charts compiled by any member organization across the world. OCS engages heavily in the IHO working groups on standards for digital data formats, data display, and product authentication (https://iho.int/en/standards-and- specifications). CO-OPS adheres to IHO standards in providing water level and current information for the marine navigation community.

- NOAA's Center for Operational Oceanographic Products and Services represents the US on the Global Sea Level Observing System Group of Experts (GLOSS GE). This group establishes best practices and standards for the collection, processing, and dissemination of water level data for climate studies. CO-OPS transmits its long-term data sets to GLOSS data centers along with data from many of the world's water level organizations so that the climate research community has access to high quality water level records in a standard format on a single database.

- NOAA's National Geodetic Survey (NGS) represents the US on the UN Committee of Experts on Global Geospatial Information Management (UN-GGIM)'s Subcommittee on Geodesy (UN SCoG). The Subcommittee is developing a Global Geodetic Reference Frame (GGRF) to provide a globally consistent approach to geodesy involving a common reference system, geodetic infrastructure, standards, and education/training. The UN GGRF was adopted by the US Government along with the governments of other nations. As such, the US Government has agreed to abide by these international standards - including the adoption of a modernized NSRS that is based on the International Terrestrial Reference System (ITRS) and the International Height Reference System (IHRS). NGS is working to modernize and improve the US NSRS to do just that. A new geopotential datum and four terrestrial reference frames aligned with the UN GGRF are planned for release in 2022 and will replace the current vertical and horizontal datums. NGS also participates in the UN-GGIM:Americas regional committee to ensure that the updated NSRS is regionally consistent with the Sistema de Referencia Geocéntrico para Las Américas (SIRGAS) Reference System for the Americas, which is also based on the UN GGRF.

- NGS also represents the US on the ISO TC 211 on Geographic information/Geomatics. Definitional parameters for US reference frames, datums, and geoid models were loaded into the ISO Geodetic Registry (ISOGR), guided by ISO 19127/19135. The ISOGR is intended as a tool for GIS application developers and US Government Agencies to provide look-up tables to make reference frame transformations simpler and authoritative. ISO TC 211 also authored two standards: *ISO 19111:2019 Geographic information — Referencing by coordinates* and *ISO 19161-1:2020 Geographic information— Geodetic references — Part 1: International terrestrial reference system (ITR*S). The first updates datums and reference frames to account for time-varying movement (i.e., not just earthquakes - the whole frame moves). The second specifies adoption of the International Association of Geodesy's (IAG) International Terrestrial Reference System (ITRS), which is a component of the UN GGRF. NGS also participates in ISO TC 172 SC6 *Optics and photonics, Geodetic and surveying instruments* on geodetic instrumentation standards to ensure that appropriate standards are maintained for equipment and usage of equipment to meet positional accuracy requirements desired in the NSRS. NGS also participates in the OGC as well as ISO to ensure US FGDC standards are consistent with - if not based on entirely - internationally accepted standards following the guidance of the Geospatial Data Act of 2018 (GDA). Additionally, NGS leads efforts in the International Federation of Surveyors (FIG) to implement these standards and hold appropriate training and education seminars to effect transfer of this knowledge.

- NOAA's National Centers for Environmental Information (NCEI) has defined multiple Network Common Data Form (NetCDF) templates to guide those submitting data to NCEI in the NetCDF data format. Use of NetCDF and these templates reduces the data analysis

overhead as many scientific data analysis applications readily support the NetCDF data format.

- NOAA's National Centers for Environmental Information (NCEI) uses the ISO 14721 Open Archival Information System (OAIS) Reference Model standard as the basis for archival activities supporting NOAA environmental data. In addition to being the foundation for on premise activities, it is being used as the guide for current development of a Cloud archive workflow.

National Telecommunications and Information Administration (NTIA)

NTIA contributes to the development and application of national and international telecommunication standards by leading, participating in, and making technical contributions to various voluntary national and international telecommunication standards committees, such as the 3rd Generation Partnership Project (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) founded 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 2021, NTIA-ITS staff held 32 positions in seven standards bodies, including eight Chair/Co-chair/Vice-chair positions. NTIA-ITS staff filled key leadership positions in the ITU-R, including Head of the U.S. Delegation to Study Group (SG) 3 (Radiowave Propagation), International Chair and U.S. Chair of SG3 Working Parties 3K and 3L (Point-to-area propagation and ionospheric propagation and radio noise), and U.S. Chair of Working Party 3J (Propagation fundamentals). NTIA-ITS staff also filled key leadership positions in the ITU-T, including Head of U.S. Delegation to Study Group 13 (Future Networks) and Study Group 11 (Signaling Requirements, Protocols and Test Specifications). NTIA-ITS also continued its technical leadership and contributions to communications standards for emerging 5G technologies through participation in 3GPP and in that capacity, and at the behest of the National Security Council, is responsible for driving collaboration between U.S. Departments/Agencies participating in 3GPP. Finally, NTIA-ITS provided technical leadership and contributions to IEEE standards for local/personal/metropolitan area networks (LAN/PAN/MAN) through participation in IEEE 802. NTIA-ITS leads US 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 2021, NTIA-ITS contributed one of the 11 U.S. technical contributions to Study Group 3. NTIA-ITS proposed an update to Recommendation ITU-R P.528 (a propagation prediction method for aeronautical mobile and radionavigation services using the VHF, UHF and SHF bands) to support requests from the International Civil Aviation Organization (ICAO). As a result of the NTIA-ITS contribution, ICAO will be able to use P.528 in their frequency management system. NTIA-ITS submitted an update to the previously proposed replacement software to support

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, which were active during the intersessional period. Correspondence Group CG-3K-3M-9 on aeronautical propagation produced and submitted to Working Part 3K a new revision to ITU-R P.528 (a propagation prediction method for aeronautical mobile radionavigation services using VHF, UHF and SHF bands). NTIA-ITS submitted multiple input contributions to this work, both theoretical text and software. This update supports WRC-23 sharing studies for possible new International Mobile Telecommunications (IMT) services.
Correspondence Group CG-3L-7 on radio noise produced and submitted to Working Party 3L a new revision on ITU-R P.372 (radio noise). NTIA-ITS also submitted multiple input contributions to this new revision, including supporting software.
Correspondence Group CG-3J-11 on reference standard atmospheres continues to work towards integrating updated weather prediction model data to improve atmospheric models for radio-wave propagation prediction methods.

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, and 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. NTIA-OIA also provides U.S. leadership in the ITU-T Telecommunications Specification Advisory Group (TSAG). Additionally, NTIA-OIA has also followed work in the Internet Engineering Task Force (IETF).

Direct participation by NTIA in the 3rd Generation Partnership Project (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 attends 3GPP Working Groups for Services (SA1), System Architecture (SA2), and Security (SA3). Additionally, NTIA-ITS attends the Radio Access Network Working Group 1 (RAN1) focused on the physical layer for LTE and 5G. Additionally, NTIA-OIA participates in 3GPP at a Plenary level Technical Specification Group (TSG) SA and RAN.

In FY 2021, NTIA-ITS's focus was on four topics in 3GPP: spectrum sharing, non-terrestrial network, unmanned aerial systems and vehicle-to-everything communications. With the aim of contributing to the standards, NTIA-ITS proposed a study item related to spectrum sharing among incumbent and commercial users in SA1 working group.
NTIA's Office of Spectrum Management (NTIA-OSM) attends 3GPP Technical Specification Group Radio Access Networks Working Groups 1 (RAN 1) and 4 (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.

For a number of years, NTIA-ITS has provided technical guidance to other government agencies in advocating for standardization of service features specific to public safety, emergency communications, and transportation. A continued focus in FY 2021 was to ensure that NTIA and other interested agencies obtained 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. NTIA's overall goals also include monitoring regional adversary participation efforts to subvert the open consensus-based standards processes and developing and promulgating expertise in cutting edge mobile broadband technology trends.

United States Patent and Trademark Office (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 US 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 2021 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 8,343 VCS approved for use within the Department of Defense. Each of these 8,343 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.

Thousands more 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 2021, DoD adopted 53 VCS in several areas, including: Construction Building Materials; Non-Destructive Testing and Inspection; Welding, Soldering, and Brazing; Parachutes; Electrical Insulators and Insulation Materials; Metal Castings; Electrical and Electronic Equipment and Components; Plastics and Fabricated Materials; Oils and Greases; Chemical Testing; Hardware and Abrasives; Human Factors; and Configuration Management. DoD also canceled 236 military unique documents and replaced 12 of them with VCS.

DoD uses VCS for many different purposes and has had a long history of working with VCS bodies and industry to ensure DoD's needs can be met using VCS. As an example, in Fiscal Year 2021, a team from the U.S. Army's DEVCOM Ground Vehicle Systems Center led an effort to modify existing performance specifications to support the abatement of Hexavalent-Chromium/Cadmium as a corrosion protective coating on fasteners commonly used on the Army's fleet of ground combat systems. This team edited sixty-one (61) VCS documents to reflect the preferred and alternate use of Zinc-Nickel plating. They then sent these edits to the appropriate commercial industry review boards for approval. Further, this

team received approval from the American Society of Mechanical Engineers (ASME) to change ASME B18.24 to accommodate the use K-Factor (torque modifiers) requirements, and from SAE International and Aerospace Industry Association (AIA), both of which have begun updating their standards for the use of Zinc-Nickel plating. Implementation of the changes will improve personnel safety, significantly reduce environmental impact, improve system maintainability and reliability, and reduce cost. Creating options to eliminate hazardous materials in the Army's fleet will have the potential to save millions of dollars in disposal costs.

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):**

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

Department of Energy (DOE) Fiscal Year 2021 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 2021, 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. 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 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 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

Department of Health and Human Services (HHS) Fiscal Year 2021 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, in our Quality Indicators, and in AHRQ's United States Health Information Knowledgebase. 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 with partners in a voluntary and consensus 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), was established to lead the accreditation program which launched in September 2011. CDC has been involved as a partner and funder of this

initiative to provide support to PHAB's accreditation and continuous improvement activities. As part of this effort, PHAB engaged hundreds of public health practitioners in developing and testing all elements of the program, including the standards and accreditation assessment process. The PHAB standards and assessment process meet the definitions of OMB Circular A-119, regarding voluntary consensus standards and conformity assessment processes.

Until the establishment of PHAB, there had been no national accreditation program for public health departments. The program is intended to "improve and protect the health of the public by advancing the quality and performance of public health departments.". The first cohorts of health departments were accredited in early 2013. As of the end of FY 2021:

- PHAB has accredited 394 health departments—39 states, five tribes, and 350 local health departments (including 283 individually accredited local health departments and 67 county health departments through a centralized state application).
- 89% of the U.S. population is served by an accredited health department (HD).
- PHAB began reaccrediting sites in 2018; 51 sites have been reaccredited.
- 506 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. The initial national consensus standards were released in July 2011 (Version 1.0) and an update (Version 1.5) was released in 2014. CDC participated in PHAB efforts to support requirements for reaccreditation, published manuscripts about its support of accreditation in a journal, and has been collaborating to explore a variety of topics to inform updates to the Standards and Measures. In FY21, CDC supported PHAB in producing and vetting the Version 2022 Standards and Measures, which are being finalized to reflect public comments and planned for release in 2022. CDC's interest and support regarding this accreditation program is evidenced through its accreditation page at https://www.cdc.gov/publichealthgateway/accreditation/.

Evaluation data to date show very positive findings about benefits and impact. A PHAB survey in July 2020 found that more than 80% of accredited health departments indicated that, overall, accreditation has helped their response to the COVID-19 pandemic. Annual evaluation findings also consistently report short- and long-term benefits to participating in accreditation. June 2021 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 (85%), and improved collaboration across units within the health department (88%) one year after accreditation. Four years after accreditation, the program has helped health departments use health equity as a lens for identifying and addressing health priorities (73%) and strengthened the utilization of resources (68%). More information about the positive impact of the accreditation program can be found by reviewing data and reports available through PHAB's website.

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. (see: 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

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 (CDC) established the CDC Diabetes Prevention Recognition Program (DPRP) (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 (see https://www.niddk.nih.gov/about-niddk/research- areas/diabetes/diabetes-preventionprogram-dpp/Documents/DPP_508.pdf). The current standards, though still grounded in the earlier research, incorporate innovations from further translational studies, best practices, and expert opinion.

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 to show that they are having an impact on preventing or delaying type 2 diabetes. CDC reviews these data and provides feedback to each organization. DPRP evaluation data to date show that evaluated participants attended an average of 18 core sessions and 8 core maintenance in the National DPP lifestyle change program. Participant risk reduction, determined using participant outcomes associated with weight, physical activity minutes, and HbA1c, was seen in 51.8% of all evaluated participants. This risk reduction included 47.7% who achieved at least a 5% weight loss; 35.6% who achieved at least a 4% weight loss combined with at least 150 min/week, on average, of physical activity; and 0% to date who had at least a 0.2% reduction in HbA1c*. As of January 5, 2022, there are 2,114 CDC-recognized organizations that have collectively enrolled 584,994 participants nationwide since the program's inception.

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 51 staff contributing their expertise to approximately 22 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 2 major committee organizations (i.e., ANSI and ISO). 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.

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 implementation of interoperability standards for health data through the United States Core Data for Interoperability (USCDI). NCHHSTP subject matter experts (SMEs) contributed to the following USCDI version 3 use cases: patient demographics-country of usual residence and immunization administered date. Further, NCHHSTP SMEs promoted use of USCDI value sets for sexual orientation and gender identity (SOGI) data elements when collaborating with CDC's Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) to have these SOGI data elements included as optional data elements within the National Notifiable Disease Surveillance System (NNDSS).

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.

3) 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): www.nacha.org
- The Designated Standards Maintenance Organization (DSMO): www.hipaa-DSMO.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 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) 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: http://www.cms.gov/QualityMeasures/
2) National Quality Forum: http://www.qualityforum.org/

4) 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 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 FY2021, 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 2021
Date Federal Register Notice
March 3, 2021 FR Notice (List #54) [Docket No. FDA-2004-N-0451]
https://www.fda.gov/media/146431/download
April 29, 2021 FR Notice (List #55) [Docket No. FDA-2004-N-0451]
https://www.fda.gov/media/148113/download

Access to the current FDA List of Recognized Consensus Standards, as published and updated in the Federal Register, can be found at
http://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

- **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*

- **Biocompatibility standards-specific guidance:** *Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*

The docket number: for these guidances are under docket FDA-2019-D-3805 published on September 25, 2020.

Under the ASCA Pilot, at the end of FY21, CDRH has provided ASCA recognition to 5 Accreditation Bodies and granted ASCA-accreditation to 77 testing laboratories under the scope of standards and methods included in the ASCA Pilot.

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 to issue certifications for FDA-regulated food, which includes human food, pet food, and non-medicated animal feed. FSMA established the "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications," program at 21 CFR part 1 subpart M. The regulation describes 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 regulation, 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."
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 FY21, the FDA has recognized 4 accreditation bodies which have accredited 13 certification bodies. FDA maintains an online registry of recognized accreditation bodies and accredited certification bodies.

FSMA also gives us express authority to establish a laboratory accreditation program for the analyses of human and animal foods. FDA issued a proposed rule in November 2019 that would implement this program. The proposed rule would establish 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. As proposed, FDA would recognize accreditation bodies that would then accredit laboratories to conduct food testing. The proposed rule would incorporate by reference two voluntary consensus standards: ISO/IEC 17011:2017 would form the foundational

requirement for accreditation bodies, and ISO/IEC 17025:2017 would form the foundational requirement for food testing laboratories. The comment period closed in July 2020; FDA expects to issue a final rule establishing this program in late 2021.

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, has been an ISO/IEC 17043 accredited proficiency testing provider 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 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 capacity/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), ORA/ORS Laboratories also conduct analytical work aimed at updating and harmonizing USP pharmaceutical analysis monographs using USP reference materials.
ORA/ORS laboratories are accredited to ISO/IEC 17025 standards. The FDA Forensic Chemistry Center (FCC), the ORS forensics specialized lab, is accredited to the standards of ANSI-ASQ National Accreditation Board (ANAB) / American Society of Crime Lab Directors or ASCLD.
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 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. In addition, the ORA/ORS labs specialized in pharmaceutical testing are also audited by the

Pharmaceutical Inspection Convention and Pharmaceutical Co-operation Scheme (PIC/S) for conformance to established PIC/S standards.
ORA/ORS Laboratories are also active members of the Integrated Consortium of Laboratory Networks (ICLN) and CODEX International; 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 is aimed to advance 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 can 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
- Flexible Funding Model
- National Integrated Food Safety System – Laboratory Capacity Building
- Voluntary National Retail Food Regulatory Program Standards
- Animal Feed Regulatory Program Standards

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 v 3 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

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. In September 2017, CBER awarded a one-year contract to Nexight Group and the Standards Coordinating Body (SCB) 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. The deliverables for this contract included written reports and webinars. In October 2018, this contract was extended through March 2019 to build on the foundation set by the original contract. The deliverables for the extended contract include the conduct of a two-day workshop on the development of documentary standards and reference materials applicable to regenerative medicine products. The goals of the workshop were to 1) build awareness of standards development processes and the value of engaging in standards development; 2) share knowledge of in-process standards advancement or development efforts; 3) identify experts who could be tapped to support/engage in future standards development; 4) identify working group members willing to commit to advance individual potential standards. In September 2020, FDA initiated another contract with Nexight Group and SCB to further support the development of standards for regenerative medicine products. Under the contract Nexight Group/SCB will conduct feasibility assessments for specific standards identified as needed standards by industry stakeholders. They will also develop an educational curriculum for the implementation of existing standards applicable to regenerative medicine products.
In March 2019, CBER published a final Guidance Document: Standards Development and the Use of Standards on Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation . This guidance document provides information to CBER stakeholders on CBER's policy for utilizing voluntary standards to satisfy regulatory requirements such as product characterization and potency.
In addition to biologics, CBER has regulatory oversight for products that meet the definition of a medical device. As such, CBER participates in the S-CAP medical devices managed by CDRH and the ASCA Pilot Program.

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. 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 detailing the FHIR mapping of all Phase 1 PQ/CMC data elements is in the clearance process.

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.

2) 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 is currently undertaking the process to complete the requirements for the ONC 2015 Edition Cures Update, per ONC's timeline in the Federal Register.
The IHS has utilized and incorporated numerous information technology standards promulgated by development organizations and specified in the various ONC Final Rules in order 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/

6) National Institutes of Health (NIH) National Cancer Institute (NCI)
The Nanotechnology Characterization Laboratory (NCL) 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 more than 70 assays for nanomaterial characterization, termed NCL's Assay Cascade. All NCL assays are published on the NCL website and free to download: https://ncl.cancer.gov/resources/assay-cascade-protocols. Over 450 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:

- ITA-29: Detection of nanoparticles' ability to stimulate toll-like receptors using HEK-Blue reporter cell lines

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." Efforts are also ongoing to bring 10 NCL protocols through ASTM as Standard Methods or Standard Guides. These efforts are continuing into 2022. 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)
- Method "In vitro Analysis of Nanoparticle Hemolytic Properties" (a revision of **ASTM E2524-08**

(2013) previously developed by the NCL)

- Method "In vitro Analysis of Nanoparticle Effects on CFU-GM" (a revision of **ASTM E2525-08**

(2013) previously developed by the NCL)

- Method "Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells" (a revision of ASTM **E2526-08** (2013) previously developed by the NCL)

National Library of Medicine (NLM)

The National Library of Medicine (NLM) has been a center of information innovation since its founding in 1836. The world's largest biomedical library, NLM maintains and makes available a vast print collection and produces electronic information resources on a wide range of topics. NLM also supports and conducts research, development, and training in biomedical informatics and health information technology. In addition, the Library coordinates the 8,000-member Network of the National Library of Medicine that promotes and provides access to health information in

communities across the United States.

NLM is active at a national level 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,[1] which is an outgrowth of NLM's work on the PubMed Central journal article archive. Another example is NLM's participation in the development of NISO's new Recommended Practice: *PIE-J: Presentation & Identification of E-Journals*.[2] Pie-J provides guidance to publishers of electronic journals on the presentation and identification of electronic journals to ensure long-term online accessibility to scholarly journals even after titles and publishers change.
For more than four decades, NLM has conducted and supported groundbreaking research and development related to the representation, interpretation, and use of biomedical knowledge in electronic forms including electronic health records (EHRs). NLM has been the central coordinating body for clinical terminology standards within the Department of Health and Human Services (HHS) since 2004. In this role, NLM is the official depository and distribution center for clinical terminologies, responsible for integrating them within the Unified Medical Language System (UMLS) Metathesaurus and for developing and maintaining mappings between designated standard clinical terminologies and important related terminologies, including the HIPAA code sets. NLM works with (and, in some cases, provides funding to) vocabulary developers, message standards development organizations, other Federal agencies, and users of standards to fulfill its role as the central coordinating body for clinical terminology standards and to respond to recommendations from the Health Information Technology Advisory Committee. Clinical terminology standards and resources supported or produced by NLM includes:

- **UMLS Metathesaurus** – Produced by NLM, this resource incorporates many different vocabularies, classifications, and code sets. While not a standard in and of itself, it is an important resource to help the research and healthcare community understand the breadth of available standards and how they relate to one another;
- **LOINC (Logical Observations Identifiers Names and Codes)** – NLM funds the ongoing 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 (Radiology codes) and LOINC codes, and mappings between IEEE instrument codes and LOINC codes. LOINC works closely with HL7 FHIR. It includes a standard FHIR vocabulary server and the LOINC content is all provided on FHIR's own vocabulary server. LOINC supports sets of variables, including laboratory panels such as CBC, and survey instruments. LOINC panels provide information needed to generate a FHIR questionnaire (data collection form) and can support all the special features of FHIR questionnaires, i.e., skip logic, pre-population

from FHIR medical records, etc. FHIR questionnaires can be generated on the fly as web data input forms;

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[1] http://www.niso.org/apps/group_public/project/details.php?project_id=93
[2] https://www.nlm.nih.gov/bsd/policy/piej_niso_practices.html

- **SNOMED CT** – NLM is the US representative to SNOMED International and as such pays the annual fee that permits U.S.-wide use of SNOMED CT (comprehensive clinical healthcare terminology; accessible within the UMLS Metathesaurus and in native format from NLM) and creation and distribution of the U.S. Edition of SNOMED CT;
- **RxNorm** – NLM produces and distributes RxNorm (terminology for clinical drugs; accessible both within the UMLS Metathesaurus and separately from NLM). 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. NLM provides several web-based programs 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. These programs are quite popular. For example, the RxNav API receives more than 1.6 billion API queries annually.
- **UCUM (Unified Code for Units of Measure)** – Developed by the Regenstrief Institute with funding from NLM UCUM is a 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.

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 systems over the past 20 years:

- **Consolidated Health Informatics** (CHI; active 2001 - 2007) - eGov project designated the suite as

U.S. Government-wide clinical standards for use in U.S. Federal Government healthcare systems.

- **Healthcare Information Technology Standards Panel** (HITSP; active 2005 - 2010) - identified the suite in various interoperability specifications for use throughout the U.S. healthcare spectrum. The suite was required for use in U.S. Federal Government healthcare systems, recommended for use in the private sector.
- **Health Information Technology for Economic and Clinical Health (HITECH) Act** - In July 2010 the suite were named as standards to support stage 1 meaningful use in the "Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology" Final Rule. Subsequent final rules for EHR certification criteria (2011, 2014, and 2015 Editions) each expanded the requirements for use of the suite to support meaningful use.
- **United States Core Data for Interoperability (USCDI)** – Established by the Office of the National Coordinator for Health Information Technology (ONC) as part of the Cures Act Final Rule, USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. A USCDI data element is the most granular level at which a piece of data is exchanged. The USCDI specifies the set of coding systems that are required for use in US electronic medical record systems to support interoperable health information exchange. In this system, SNOMED CT, LOINC, and RxNorm and UCUM are all required for use for designated purposes.

- **Interoperability Standards Advisory (ISA)** – Established by the Office of the National Coordinator for Health Information Technology (ONC), ISA is the model by which ONC coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications for use in healthcare systems. ISA specifies LOINC, SNOMED CT, and RxNorm and UCUM as the preferred coding system for designed purposes.
- **Health Level Seven (HL7) Standards for Genetics** – LOINC has been selected as the core structure of three HL7 standards genetics including 1) HL7 V2 specification for cytogenetics, 2) laboratory reporting of genetic variants, and 3) HL7 FHIR specification for clinical genetic reports.
- **LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests** – Announced by HHS on June 4, 2020, LIVD is new laboratory data reporting guidance for COVID-19 testing. LIVD uses LOINC and SNOMED CT 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). It was an essential ingredient in the quick (few days) generation of COVID-19 test codes produced by the collaboration between CDC, FDA, Regenstrief (LOINC), SNOMED International, APHL and the IVD industry connectivity consortium.
- **Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)** – NLM has been an active proponent of the FHIR standard that is now supported at the National Institutes of Health (NIH) level to support data science (see https://datascience.nih.gov/fhir-initiatives). Both the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) include requirements for use of FHIR in recent rulemaking related to the 21st Century Cures Act. NLM's specific focus is on exploring the creation of FHIR-compliant API for clinical research use, starting by standardizing phenotype data for several large population cohort studies archived within the database of Genotypes and Phenotypes (DbGap). NLM has also developed several software tools to facilitate use of FHIR (https://lhcforms.nlm.nih.gov). Users and developers downloaded some of these tools nearly 100,000 times in 2021. NLM's National Center for Biotechnology Information (NCBI) maintains databases of genetic variants (ClinVar, dbSNP) that are required coding systems for HL7 FHIR genetic reporting (http://ncbi.nlm.nih.gov).

In addition, SNOMED CT is the standard for selected data elements in international genetic information resources, including the NIH Genetic Testing Registry and the ClinVar database of clinically significant human variations. It is also being used in an increasing number of clinical research studies.

NLM, on behalf of HHS, is the U.S. Member of the International Health Terminology Standards Development Organisation (IHTSDO; using the trading name SNOMED International) which owns, maintains, and distributes SNOMED CT internationally and promotes global standardization of health information. As the US Member, NLM produces and distributes:

- **US Edition to SNOMED CT** – combination of the U.S. Extension and the International Release of SNOMED CT. The U.S. Edition to SNOMED CT is the version of SNOMED CT cited as CMS Promoting Interoperability program requirements. The US Extension is a formal extension of the International Release that allows NLM to provide both rapid access to SNOMED CT concepts needed by U.S. stakeholders, as well as standard terminology needed for U.S. clinical use cases (e.g. regulatory or legislatively mandated terms specific to the U.S.) that are not generally useful in other countries.
- **CORE Problem List Subset of SNOMED CT** – updated 4 times per year (with each new release of SNOMED CT and the UMLS Metathesaurus). The Subset is designed to facilitate the use of SNOMED CT for coding of problem list data in EHRs and to enable more meaningful use of EHRs to improve patient safety, health care quality, and health information exchange. Development and distribution of this initial subset was used as a model for development of other frequency- based subsets to facilitate implementation of SNOMED CT, LOINC, and RxNorm throughout the

U.S. including:

  - SNOMED CT Route of Administration
  - Nursing Problem List Subset of SNOMED CT
  - Universal Laboratory Order Codes from LOINC and Common UCUM Codes (both created in conjunction with the Regenstrief Institute)
  - RxNorm Current Prescribable Content
- **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:
  - **SNOMED CT to ICD-10** – updated and expanded in conjunction with the IHTSDO
  - **SNOMED CT to ICD-10-CM** – builds on and makes use of the tools and policies developed for the IHTSDO mapping project.
  - **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 CMS.
- **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.

As the U.S. Member of the IHTSDO NLM also:

- **Makes available the U.S. SNOMED CT Content Request System (USCRS**) in support of the U.S. Extension to SNOMED CT. USCRS is a mechanism for U.S. stakeholders to request changes to SNOMED CT (e.g. new concepts or enhancements to existing concepts). The long-term goal is to allow the establishment of a network for U.S. contributions to the development of SNOMED

CT by both government agencies and private sector organizations and enable collaboration with other IHTSDO member countries in the development of SNOMED CT content and subsets.

- **Facilitates alignment and harmonization** - NLM continues working with the IHTSDO to facilitate alignment and harmonization between SNOMED CT and other key health terminologies, most notably with LOINC.

NLM provides access to several additional resources to make standards more accessible:

- **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 mapped 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), 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.
- **Value Set Authority Center (VSAC)** - NLM, in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare & Medicaid Services (CMS) created VSAC, which was launched in early FY2013. The system has since been expanded to include an authoring tool that allows users to author value sets in a collaborative environment. NLM continues working with ONC and CMS to enhance and expand VSAC to meet the community's 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.
- **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.

NLM works closely with the HHS Office of the National Coordinator for Health Information Technology (ONC) to ensure NLM's vocabulary harmonization and standards efforts are in sync with those of ONC and the Health Information Technology Advisory Committee (HITAC). NLM participates in the HITAC and has participated in its predecessors, the Health IT Policy Committee and the Health IT Standards Committee as a member. HITAC assumes responsibility for evaluating vocabularies and information models needed to achieve greater interoperability across healthcare systems, to "Promote Interoperability", and other federal requirements. NLM also participates in the Federal Health IT Coordinating Council.
NLM participates in the International Organization for Standards (ISO) Health Informatics Technical Committee (ISO/TC 215) to provide advice at the national (ANSI) and international (ISO) levels. This groups scope is "standardization in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.
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.

The United States Core Data for Interoperability (USCDI) 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 a Draft USCDI Version 1 (USCDI v1) and the associated data classes and data elements for public comment as part of the ONC Cures Act notice of proposed rulemaking. ONC created an annual process for updating the USCDI based on public input. In 2021, ONC published USCDI Version 2 after going through the annual process and is now working on developing USCDI Version 3. 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. As part of ONC's ongoing charge to coordinate across federal and industry stakeholders, this year it was determined that it was necessary to adjust the SVAP timeline. Instead of the comment period being from September to November as was done in 2020, starting in 2021, the comment period will be held from January to May of each year. ONC will announce approved standards for SVAP in June each year with them becoming effective for Certification Program use in August of that year. To facilitate the timeline shift, the 2021 comment period, due to end September 30, 2021 was extended to May 2, 2022. Additionally, the announcement of next version of approved standards for SVAP will be delayed by approximately six months, from January 2022 to June 2022. With the updated timeline, and since the entire SVAP process will conclude within the same calendar year, the naming convention will be modified to match the year in which the SVAP is approved by the National Coordinator. Hence, the next release of standards approved via SVAP will be named as "Approved Standards for 2022" instead of 2021. Please see the SVAP Approved Standards on the ONC Certification Program SVAP webpage.

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/sites/isa/files/2021-07/USCDI-Version-2-July-2021-Final.pdf
https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf
https://www.healthit.gov/isa/standards-version-advancement-process
https://www.healthit.gov/topic/standards-version-advancement-process-svap
https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
https://www.healthit.gov/sites/default/files/facas/2021-01-13_Draft%20USCDI_Version_2_Presentation.pdf
https://www.healthit.gov/isa/ONDEC https://www.healthit.gov/topic/standards-version-advancement-process-svap

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 Core Set of Measures.

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

2021 Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set): https://www.medicaid.gov/medicaid/quality-of-care/downloads/2021-adult-core-set.pdf

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

Department of Homeland Security (DHS) Fiscal Year 2021 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.
Specific Component-level responses are summarized below:

- In 2020, OMB Circular A-119 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 American National Standard Institute (ANSI) voluntary consensus standards for radiation and nuclear detections systems used in homeland security. In 2020 CWMD sponsored the publication of a revision to ANSI N42.42 American National Standard Data Format for Radiation Detectors Used for Homeland Security and of amendments to ANSI N42.32 American National Standard Performance Criteria for Alarming Personal Radiation Detectors for Homeland Security and ANSI N42.34 American National Standard Performance Criteria for Handheld Instruments for the Detection and Identification of Radionuclides. As directed by the Safe Port Act of 2006, CWMD chaired the interagency Technical Capability Standard (TCS) Working Group to produce government-unique standards and completed the publication of a new Technical Capability Standard for Radiation Portal Monitor Systems with Energy Analysis Capability and a revision to the Technical Capability Standard for Handheld Instruments Used for the Detection and Identification of Radionuclides. The Standards Program established a CWMD webpage to provide open access to the DHS Technical Capability Standards for the general public. CWMD also participated with the U.S. Committee for International Electrotechnical Commission (IEC) international standards for radiation detection systems. In 2020 the IEC published: a new standard for Mobile Radiation Detection Systems, a revision to the standard for Spectroscopic Personal Radiation Detectors, and an amendment to the standard for Data Format.
- CWMD sponsored ANSI Series N42 standards for radiation detection for homeland security are available at: https://ieeexplore.ieee.org/browse/standards/get-program/page

- DHS Technical Capability Standards are available at: https//:www.dhs.gov/publication/technical-capability-standards-radiological-detection.
- 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; and ICC 1300, Standard for the Vulnerability-Based Seismic Assessment and Retrofit of One- and Two-Family Dwellings.
- 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 as a means 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 http://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for- Prevention-Policy-CG-5P/Commercial-Regulations-standards-CG-5PS for further information.

- The DHS Science & Technology Directorate (S&T) delivers effective and innovative insight, methods, and solutions for the critical needs of the homeland security enterprise – working to meet the requirements of other DHS Components and DHS stakeholders. In 2020, S&T worked to expand the access to standards across the Department through increased collaboration with the DHS Library, as well as procuring a subscription to IHS for those in DHS in the National Capital Region. S&T is also developing a standards portal, Coordination and Access Portal for Standards (CAPS), which will greatly enhance the Department's standards access and collaboration capabilities. Additionally, S&T worked closely with NIST to develop a framework and toolkit of training modules, resources, and documents on standards development and conformity assessment, as it relates to the DHS mission and their standards needs. The toolkit will enable the DHS Standards Executive to tailor and execute a DHS standards training program specific to the operational needs of the various DHS components.

The Office of Science and Engineering (OSE) Biometrics and Identity Technology Center (BI-TC) also participates as a SME in the International Committee for Information Technology Standards (INCITS), specifically the (1) M1 Biometrics Committee and the (2) B10 Identification Cards and Related Devices

Committee. BI-TC also participates as a SME in the International Organization for Standardization (ISO), SC37 Biometrics Subcommittee.

- The DHS Intelligence Training Academy (ITA) designs, develops, assesses, and delivers homeland security intelligence training through a diverse set of training, education, and professional development programs for the Homeland Security Enterprise (HSE) and DHS Intelligence Enterprise (IE). Since inception, the ITA has delivered 901 training programs and trained 16,730 students across the HSE, IE, and Intelligence Community (IC). In FY2020, ITA renewed its accreditation to Federal Law Enforcement Training Accreditation (FLETA) standards.
- USCIS has developed and is implementing data standards in its technology systems, which are used to perform the mission. USCIS has 107 approved data standards, 20 of which are DHS-approved data standards. 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. In the next year, USCIS will manage data standards in Collibra in accordance with DHS.
- 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.
- 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

- CBP/ES: The Agency does not have a standards-specific website. The following is the list of voluntary consensus standards in use by the HRM, Occupational Safety and Health Division. However, no employees of the HRM, Occupational Safety and Health Division are currently participating as board members in the development of these consensus standards:

ANSI Z136.1 – Safe Use of Lasers
ANSI Z136.6 – Safe Use of Lasers Outdoors
ANSI/HPS N43.17-2009 - Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation
ANSI/HPS N43.3-2008 – Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV
ANSI/HPS N43.5-2005 – Radiological Safety Standard for the Design of Radiographic and Radioscopic Non-Medical X-Ray Equipment Below 1 MeV
ANSI/HPS N43.14-2011 - Radiation Safety for Active Interrogation Systems for Security Screening of Cargo, Energies Up to 100 MeV

NCRP Report No.160, Ionizing Radiation Exposure of the Population of the United States. NCRP Report No. 116, Limitation of Exposure to Ionizing Radiation.
NCRP Report No. 141 – Managing Potentially Radioactive Scrap Metal
NCRP Report No. 147 – Structural Design for Medical X-Ray Imaging Facilities

NCRP Report 151 – Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities
NCRP Commentary No. 16 – Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems
NCRP Commentary No. 20 – Radiation Protection and Measurement Issues Related to Cargo Scanning with Accelerator-Produced High Energy X-Rays
NCRP Commentary No. 22 – Radiological Health Protection Issues Associated with Use of Active Detection Technology Systems for Detection of Radioactive Threat Materials
NCRP Commentary No. 21 – Radiation Protection in the Application of Active Detection Technologies
NCRP Commentary No. 18 – Biological Effects of Modulated Radiofrequency Fields ICNIRP – Guidelines for Limiting Exposure to Electromagnetic Fields (100 kHz to 300 GHz)
International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines, 2020 for limiting exposure to electromagnetic fields (100 kHz to 300 GHz)
Federal Aviation Administration (FAA) Advisory Circular 70-1, Outdoor Laser Operations (2004)
FAA Order 7400.2, Procedures for Handling Airspace Matters (2012)

CBP/OS RESPONSE:
LSS utilizes consensus standards from the following organizations to ensure that the technical, electrical, and mechanical performance along with the safety of radiation detection, non-intrusive inspection (NII) systems and digital technology acquired and examined by the agency meet CBP requirements:
ANSI American National Standards Institute
IEEE Institute of Electrical and Electronics Engineers Standards Association NFPA National Fire Protection Association
ASTM ASTM International (formerly American Society for Testing and Materials) ASME American Society of Mechanical Engineers
CFTT National Institute of Standards (NIST) Computer Forensics Tool Testing Program IACIS International Association of Computer Forensic Examiners
SWGDE Scientific Working Group on Digital Evidence
SANS SANS Institute Best Practices

- TSA as a government component focused on developing capabilities (i.e. hardware, software and processes) that concentrates on safe-guarding aviation security, TSA/RCA drives standards in two distinct ways:

    - Voluntary Consensus Standards Development and
    - Performance Standard Development

During the past fiscal year, TSA has actively engaged with an ANSI-accredited Standards Development Organization called NEMA (National Electrical Manufacturers Association). As described in the OMB Circular A-119, NEMA serves as the “Voluntary Consensus Standards Body”, whom facilitates the development of the Digital Imaging and Communication in Security (DICOS)

standard for metadata (i.e. metadata and image format) associated with airport security images. These images result from security examination of a passenger, a passenger's checked bags, or a passenger's carry-on bags. TSA/RCA has appointed the Capability Development & Integration Branch to facilitate this engagement with NEMA to develop DICOS v3.0. Representative from this branch server on three (3) Technical Working Group Committees to help promote a "Voluntary Consensus Development" process that encourages efficiencies, expand opportunities for industry stakeholders, conserve resources, as well as, serves our agencies mission. As the version number implies, TSA has worked with NEMA for several years to evolve the DICOS standard from version 1 to version 2A (currently published: NEMA), to our current work with version 3.0. TSA/RCA also develops **performance standards**, which specifies requirements in terms of required results with criteria for verifying compliance, but without stating the methods for achieving required results. These requirements are developed and packaged in a variety of ways, depending on their stage in the development cycle:

- CASP – Capability Analysis Study Plan
- CAR – Capability Analysis Report
- ORD – Operational Requirement Document
- FRD – Functional Requirements Document
- *This also includes our* Detection Requirements for Explosive material (to include Prohibited Items).

TSA/RCA performs a rigorous process of developing and refining these standard requirements, thru the "Voluntary Consensus Standard Body" referred to as the DHS Joint Requirements Council (JRC), to ensure the requirements support the government's desired interests. Through this process, representatives from the TSA/RCA Requirements Development Branch resolve objections through adjudication, where all comments have fair consideration. Once deliberated, and approved, the performance requirements migrate through a formal approval process via our senior leadership. Lastly, TSA/RCA has long since recognized the high level of complexity and proprietary nature of our aviation security environment. The isolated configuration of our security systems has forced TSA to rely solely on a small group of industry technology providers. Over the past fiscal year, TSA/RCA has worked with National labs, and a matrix of industry stakeholders to execute multiple "conformity assessment activities" to promote standard communication between systems, standard data generation, standard image displays and overall open architecture development. The Checkpoint Automation (CPAM) initiative serves as a lead project to conduct requirements engineering, systems design, and Research and Development (R&D) to define and develop an integrated and open checkpoint screening architecture. CPAM has defined "Open Data" and "Standardization" as the key pillars of the CPAM initiative to guide open architecture initiatives and enable TSA to leverage Original Equipment Manufacturers' and 3rd-Party Vendors' in implementation of best-of-breed solutions. CPAM's continued work with industry leaders and small businesses to develop best-of- breed solutions has served as a "Voluntary Consensus Development Process" for developing performance standards (i.e. requirements) and standards for universal implementation.

- 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), WiFi Alliance, and OASIS Open. Within those bodies, CISA participates to monitor, support, and influence standards development activities relevant to agency mission objectives.

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

Department of Housing and Urban Development (HUD) Fiscal Year 2021 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 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):** 1

Table 1: Current Government Unique Standards FY2021

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(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 FY2021: In 2021, HUD published a final rule updating the Manufactured Home Construction and Safety Standards on January 12, 2021. HUD continues working with the Home Innovation Research Lab 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 2021 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 $5 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 (http://elips.doi.gov/ELIPS/DocView.aspx?id=1208), 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: http://www.fws.gov/stand/. 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 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

Department of Justice (DOJ) Fiscal Year 2021 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 2021, 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.

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

- **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 and recently presented at the ICANN73 conference in March 2022.
    - **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 chaired the semi-annual meeting of E30 in October 2021, as well as chairing (3) meetings of the Executive Committee between

October and December 2021. 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) 2021, approximately 80 models of ballistic-resistant body armor were submitted for testing. In addition to initial testing, follow-up inspection and testing was conducted on approximately 330 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: http://nij.gov/standards.

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. During 2021, 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 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

Department of Labor (DOL) Fiscal Year 2021 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 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):** 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 2021 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 engagement in standards policy, standards development organizations, and our use of standards within the agency supports U.S. government's standards policy, which recognizes the importance of Voluntary Consensus Standards and gives great weight to a more flexible "bottom up approach," where 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 negotiator of 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, the telecommunications Ministerial of the Asia-Pacific Economic Cooperation (APEC), and the regional efforts of the Organization of the American States (OAS) through its Inter-American Telecommunication Commission (CITEL); is the linchpin for commercial advocacy; and is the principal center for designing and implementing economic sanctions.
The Bureau's mission is to advance America's prosperity and other national interests by supporting U.S. businesses overseas, fostering good governance through economic transparency, accountability, and sustainability, and fostering inclusive economic growth and prosperity.
The Bureau of Economic and Business Affairs houses the Department's Standards Executive. The Standards Executive coordinates standards policy within the agency, represents the agency 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.

The Office of International Communications and Information Policy (CIP) 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 governments (currently 193) and non-governmental organizations and entities from the private sector (currently over 700) 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, CIP 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. CIP coordinates development of the government's technical, policy, and regulatory positions based on advice provided by government agencies and U.S. industries. CIP also encourages the participation of U.S. companies in these activities.

Web site: Bureau of Economic and Business Affairs

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 (architects, engineers, and contractors, etc.), 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 has used the International Code Council (ICC) Codes as its base code for a number of years, with amendments, and 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, as appropriate. The Foreign Affairs Manual in provision 15 FAM 900 incorporates a number of 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. 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 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):** 1

(1) Government Unique Standard
General 2021 OBO Design Standards (annual update)

Rationale
OBO prefers to leverage industry codes and standards to the degree they support OBO's mission of delivering safe, secure, functional, and resilient facilities. However, in some cases it is necessary to amend, modify, or focus industry codes and standards to address considerations such as for

coordination with Department security requirements and SECCA laws. In other cases it is useful to 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 2021 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 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:

- Through the Department's Non-Traditional and Emerging Transportation Technology (NETT) Council, released the "Hyperloop Standards Desk Review" (https://www.transportation.gov/policy- initiatives/nett/hyperloop-standards-desk-review). This document assessed the status of hyperloop standard development; provided a preliminary mapping of existing standards and regulations to specific hyperloop systems components, including a standards gap analysis; and identified stakeholder perspectives on the applicability of existing standards to domestic testing and deployment.
- In response to petition, the Federal Railroad Administration (FRA) issued a final rule of particular applicability (RPA) to establish safety standards for the Texas Central Railroad high-speed rail (HSR) system, applying Central Japan Railway Company's *Tokaido Shinkansen* technology, and its associated design and engineering principles. These standards are not intended for general application in the railroad industry. FRA incorporated by reference six Japanese Industrial Standards (JIS) and three ASTM International (ASTM) standards, along with ASTM test procedures.
- The National Highway Traffic Safety Administration (NHTSA) took two actions related to child safety. NHTSA issued a Final Rule adding design and performance specifications for a test dummy representing a 3-year-old child, to improve side impact protection. This rule incorporated revised SAE Recommended Practice J211, "Instrumentation for Impact Tests—Part 1—Electronic Instrumentation", and SAE J1733, "Sign Convention for Vehicle Crash Testing.'' NHTSA issued a Notice of Proposed Rulemaking to amend Federal Motor Vehicle Safety Standard (FMVSS) No. 213, ''Child restraint systems,'' by updating the standard seat assembly on which child restraint systems are tested. The revision also updates SAE Recommended Practice J211.

- The Pipeline and Hazardous Materials Safety Administration (PHMSA) completed a significant rulemaking in response to 24 petitions, to update, clarify, or provide relief from various regulatory requirements while increasing or maintaining hazardous materials transportation safety, and harmonizing regulatory standards internationally to support safe trade. As part of this rulemaking, PHMSA incorporated or updated nine voluntary consensus standards from the American Pyrotechnics Association, American Society of Mechanical Engineers, Compressed Gas Association, Association of Energy Service Companies and Institute of Makers of Explosives; and recognized two European Union publications.
- The Federal Motor Carrier Safety Administration (FMCSA) issued a Notice of Proposed Rulemaking to amend its Hazardous Materials Safety Permits regulations to incorporate by reference the updated consensus Commercial Vehicle Safety Alliance (CVSA) handbook containing inspection procedures and Out-of-Service Criteria for inspections of shipments of transuranic waste and highway route-controlled quantities of radioactive material.
- The Federal Highway Administration (FHWA) issued a Notice of Proposed Rulemaking focused on revision to the design standards and standard specifications applicable to new construction, reconstruction, resurfacing, restoration, and rehabilitation projects on the National Highway System (NHS). The proposed rule would incorporate by reference the latest versions of design standards and standard specifications previously adopted and incorporated by reference and would remove the corresponding outdated or superseded versions of these standards and specifications.
- DOT provided significant input to the revision of the *United States Standards Strategy* by the American National Standards Institute (ANSI), affirming that the U.S. is committed to a sector-based approach to voluntary standardization activities, both domestically and globally.

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.

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 FY 2021 the United States Environmental Protection Agency (EPA) continued to comprehensively 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).

We highlight the following as examples:

A. Participation in the development of global standard to assess greenhouse gases from transportation

EPA is participating in the International Organization for Standardization (ISO) Working Group 14 under Subcommittee 7 (Greenhouse gas management and related activities) of ISO Technical Committee 207 (Environmental Management), ISO/TC 207/SC 7/WG 14. The objective of this Working Group is to develop a global voluntary consensus protocol to assess greenhouse gases from transportation. The concept draws from the EPA SmartWay partnership (www.epa.gov/smartway) as well as the expertise of the Global Logistics Emissions Council, the World Resource Institute, related prior ISO projects, and related programs and research efforts in other countries including France and Germany.

The standard, when completed, will provide a global framework for rigorous calculation and evaluation of transportation-related climate pollutants. Such transparency will provide market leverage to reduce carbon from goods movement and can inform national and international policy. It can also create a more level playing field for U.S. businesses competing in the global market. These aims advance EPA's mission of environmental protection while incorporating a considered balance of stakeholder perspectives. Toward this end, EPA SmartWay, working through the American National Standards Institute (ANSI) and the U.S. Technical Advisory Group (USTAG) to ISO/TC 207/SC 7/WG 14 conducted outreach to U.S. freight transportation and other stakeholders to seek their input. EPA also hosted the international kick-off meeting of this Working Group in November 2019 at the EPA National Vehicle and Fuel Emissions Laboratory at Ann Arbor, Michigan.

In addition to contributing significantly to the research and development of the main sections and annexes of the standard, EPA was instrumental in advocating for and leading the development of an informative annex on black carbon. EPA has strong interest in reducing this potent short-lived climate forcer, both to reduce climate risk, and because black carbon is a constituent of particulate emitted by the older diesel fueled vehicles often used in goods movement. Particulate emissions are especially concerning for communities– often disadvantaged or underserved - that tend to live in proximity to freight hubs and routes. EPA also led the drafting of an annex on hydrofluorocarbons (HFC's) and devised a methodology to measure HFC emissions within the trip- and hub- based framework of the standard.

Two years into a planned three-year timeline, the project has undergone several Working Group drafts and a committee draft. The next milestone is to prepare, publish and translate the draft international standard (DIS) by April 2022 for review and balloting by June 2022. There will then be an opportunity to review the DIS comments in preparation of the final draft international standard (FDIS) by August 2022. Final publication of the standard is anticipated by November 2022.

B. Promoting International Methods for Lead Paint Analysis in Developing Countries

EPA has been working with international partners through the Global Alliance to Eliminate Lead Paint (Alliance) to promote international standards for lead paint sampling and analysis in developing countries. The Alliance is a cooperative initiative jointly led by the World Health Organization (WHO) and the United Nations Environment Programme (UNEP) to prevent children's exposure to lead from paints containing lead and to minimize occupational exposures to lead paint.

The United States banned lead in household paint in the 1970s, but over 100 countries globally still allow the manufacture, import and sale of lead in household paint. The goal of the Alliance is to promote lead paint laws in all countries.

As a result of the work of the Alliance, many countries are now taking steps to eliminate lead paint through the establishment of laws that set low limits on lead in paint to protect human health and the environment. To help with the development of effective and enforceable national laws around the world, EPA spearheaded the creation of model law guidance that provides suggested legal language that countries can use when drafting their own national laws. The guidance includes a list of internationally accepted standards, including test methods for lead paint analysis, (view the model law here: https://www.unep.org/resources/publication/model-law-and-guidance-regulating-lead-paint). This includes test methods developed by the International Organization for Standardization (ISO) and ASTM International (ISO 6503, 1513 and 1514, and ASTM E1645-16, E1979-17, E1613 and D3335-85a).

Since the model law guidance was published, an increasing number of countries are using it to draft and enact their own national lead paint laws, most of which include requirements for internationally accepted methods to test for lead in paint.

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): 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.

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.

(7) Government Unique Standard
EPA Method 15 – Determination of Hydrogen Sulfide, Carbonyl Sulfide, and Carbon Disulfide Emissions from Stationary Sources [Incorporated: 2018]

Voluntary Standard
ASTM D4323-84 (2009) - Standard Test Method for Hydrogen Sulfide in the Atmosphere by Rate of Change of Reflectance

Rationale
This standard is not acceptable as an alternative to EPA Method 15 since it only applies to concentrations of H2S from 1 ppb to 3 ppm without dilution, which is likely to be lower than the levels at source conditions. Also, many quality control items are missing in ASTM D4323, such as checks for calibration drift and sample line losses. The calibration curve is also determined with only one point, as opposed to a multi-point curve of EPA Method 15.

(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.

(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
ASTM D3154-00 (2014) Standard Method for Average Velocity in a Duct (Pitot Tube Method)
ASME B133.9-1994 (2001) - Measurement of Exhaust Emissions from Stationary Gas Turbine Engines

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)
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
ISO 7934:1998 (2016) - Stationary Source Emissions Determination of the Mass Concentration of Sulfur Dioxide Hydrogen Peroxide/Barium Perchlorate/Thorin Method
ISO 11632:1998 (2016) - Stationary Source Emissions Determination of the Mass Concentration of Sulfur Dioxide Ion Chromatography

Rationale
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

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"

(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 man 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

Federal Communications Commission (FCC) Fiscal Year 2021 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.**

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: In the Hearing Aid Compatibility Report and Order (WT Docket No. 07-250) the Commission set a date of March 31, 2011 for the standards development organization, Accredited Standards Committee C63® - Electromagnetic Compatibility, to update the standard used to determine if a digital wireless phone is capable of operating effectively with hearing aids based on certain performance measurement standards contained in the 2007 version of ANSI C63.19, "American National Standard for Methods of Measurement of Compatibility between Wireless Communication Devices and Hearing Aids" (ANSI C63.19-2007). The applicability of this edition of the standard is limited to those air interfaces and frequency bands (800-950 MHz and 1.6-2.5 GHz) for which technical standards are stated in the standard governing wireless hearing aid compatibility. On February 16, 2021, the Commission adopted a Report and Order (FCC 21-28, WT Docket No. 20-3), effective June 4, 2021, updating its rules (§ 20.19 Hearing aid-compatible mobile handsets) to incorporate and use of the latest Hearing Aid Compatibility standard (ANSI C63.19-2019), providing a two-year transition period to the exclusive use of the updated standard. The updated standard increased the requirement to cover air interfaces frequency bands 614 MHz to 6 GHz, and added a volume control requirement to accommodate people with hearing loss, including those who do not use hearing aids.
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

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

Government Publishing Office (GPO) Fiscal Year 2021 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
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 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/

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

General Services Administration (GSA) Fiscal Year 2021 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 > Buying & Selling > Purchasing 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 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): 3**

Table 1: Current Government Unique Standards FY2021

(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 2021 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 2021, 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 2021 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 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

National Aeronautics and Space Administration (NASA) Fiscal Year 2021 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.**

NASA directly cites Office of Management and Budget (OMB) Circular No. A-119 and the preference for use of voluntary consensus standards (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, which is currently in revision and continues to promote use of VCS). 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 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 encourages participation in VCS developing bodies and collects data on participation in development and revision of VCS. During this reporting period, 112 NASA representatives participated in 257 VCS development/revision activities in 35 Standards Developing Bodies. NASA's participation in VCS development/revision activities increased from 81 participants in FY2020 to 112 in FY2021, an increase of over 38 percent. Some increase in the number of VCS development/revision activities and participation in Standards Developing Bodies was realized. NASA is well represented on AIAA committees to promote development/revision and use of VCS, as these standards are applied on many NASA program 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-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-114, Moving Mechanical Assemblies for Space and Launch Vehicles; AIAA-S-136 -202x, Safety Standard for Space Lithium Batteries; and AIAA-S-144 -201X, Qualification and Acceptance Tests for Commoditized Space Battery Cells.

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 50 international consensus standards.

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.

NASA is serving on SAE and ASTM International Committees in support of developing additive manufacturing metals and non-metallic standards. In a recent development of NASA-STD-6030, Additive Manufacturing Requirements for Spaceflight Systems, NASA leveraged use of many VCS from Standards Developing Organizations, e.g., ASTM D7028, Standard Test Method for Glass Transition Temperature (DMA Tg) of Polymer Matrix Composites by Dynamic Mechanical Analysis (DMA); ASTM E8/E8M, Standard Test Methods for Tension Testing of Metallic Materials; ASTM E21, Standard Test Methods for Elevated Temperature Tension Tests of Metallic Materials; ASTM E399, Standard Test Method for
Linear-Elastic Plane-Strain Fracture Toughness of Metallic; ASTM E466, Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials; ASTM E606/E606M, Standard Test Method for Strain-Controlled Fatigue Testing; ASTM E1450, Standard Test Method for Tension Testing of Structural Alloys in Liquid Helium; SAE AS9100, Quality Management Systems – Requirements for Aviation, Space, and Defense Organizations; and SAE AS9120, Quality Management Systems – Requirements for Aviation, Space, and Defense Distributors. Similarly, NASA-STD-6016C, Standard Materials and Processes Requirements for Spacecraft, cites as requirements four ASTM standards, ten American Welding Society (AWS) standards, twenty-six SAE International (SAE) standards, two Government Electronics and Information Technology Association (GEIA) (SAE International) standards, two National Aerospace Standards (NAS) standards, and one Battelle Memorial Institute standard.

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, VCS cited in NASA directives and technical standards, other government agency standards, NASA technical standards, NASA-endorsed standards, and related standards information such as lessons learned and application notes relative to specific standards. Access to authorized personnel Agency-wide is provided to over 61 VCS Standards Developing Bodies via subscription and on a pay-per-document basis with the capability to order additional standards as the need arises. As new revisions are developed, more VCS are incorporated where appropriate. Many more examples of NASA Technical Standards citing use of VCS can be found on the NASA Technical Standards System Web site at https://standards.nasa.gov under the NASA Technical Standards link.

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):**

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

Nuclear Regulatory Commission (NRC) Fiscal Year 2021 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 OMB 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 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 2021, the NRC hosted the fifth NRC Standards Forum. The goals of the NRC Standards Forum are for participants to help identify and prioritize standards for standards development organizations for development or revision and to initiate or support collaboration among participants in writing or updating 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 2021 Standards Forum can be found at https://www.nrc.gov/about-nrc/regulatory/standards-dev/standards- forum/2021.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 Web site 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 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):** 2

(1) Government Unique Standard

NRC NUREG-1556, "Consolidated Guidance about Materials Licenses" [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 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 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.

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