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

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National Institute of Standards and Technology
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Standards Services

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

Each year 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 seek to minimize their reliance on GUS by using VCS whenever possible to achieve the following goals:

- reduce costs and regulatory burden;
- provide incentives and opportunities encouraging growth of U.S. enterprises;
- increase agency benefits from private sector expertise.

The FY 2020 summary, prepared by the National Institute of Standards and Technology (NIST), compiles the reports provided by 22 participating agencies listed in Appendix A. In these reports, agencies document any new use of GUS in lieu of VCS during FY 2020 and provide a rationale for each new use. Agencies also list any rescinded GUS in lieu of VCS during the past year. Agencies 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 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 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For FY 2020, federal agencies did not report any new GUS used in lieu of VCS, nor did federal agencies rescinded any GUS used in lieu of VCS.

Summary

In FY 2020, federal agencies did not add or rescind any GUS in lieu of VCS and report a total of 80 GUS currently used in lieu of VCS. 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 demonstrated interest in engaging 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 standards developed by the private sector.

In accordance with its coordination role as defined in the NTTAA and Circular A-119, NIST continues to assist federal agencies and their stakeholders with standards and conformity

assessment information, program support, guidance, and policy concerns. 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 Circular A-119. This report fulfills the annual reporting requirements of both the NTTAA and Circular A-119.

Appendix A: FY 2020 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 2020 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 (Access Board) is the only federal agency whose primary mission is accessibility for people with disabilities. 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 2020, 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 2020, 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, in February 2020, the EAC's Technical Guidelines Development Committee – on which two Access Board members serve as statutory members – published draft "Recommendations for Requirements for the Voluntary Voting System Guidelines 2.0" for public comment. In spring 2020, EAC held three virtual public hearings on these TGDC-recommended requirements in which the Access Board's two TGDC members participated.

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 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

Consumer Product Safety Commission (CPSC) Fiscal Year 2020 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, 2019 to September 30, 2020, CPSC staff provided technical support or was otherwise engaged in the development of voluntary safety standards for 78 different products. 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 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): 2

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

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

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

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

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 2020 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 the National School Lunch Program and other Federal food assistance 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, and fish. To support the procurement process, AMS maintains a series of purchase specifications that are used by contractors to deliver food products and by 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 2020, AMS' Specialty Crops Program, Specialty Crops Inspection Division (SCI) and its licensed auditors performed 4,150 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 2018. NOP also did not

participate in any Voluntary Consensus Standards Activities during FY 2018.

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

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

(6) 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/search/fullsite-search.html?query=d13.11&resStart=0&resLength=10&toplevel=products -and- services&sublevel=standards-and-publications&

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). As the U.S. member body to ISO, ANSI relies on U.S. TAGs to support the development of voluntary, consensus-based international standards used in the global marketplace. DP concurrently engages in and facilitates 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 related U.S. TAGs that serve as national mirror committees to related ISO technical committees and subcommittees, 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/ISOTAG_Nov2020.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 (LP) led the development of international voluntary consensus standards for eggs, meat, and poultry, and provided leadership in conformity assessment activities through active participation on global accreditation boards. For example, LP served as the Administrator and Chair of the U.S. Technical Advisory Group (TAG) to the International Organization for Standardization (ISO) Technical Committee 34, Subcommittee 6 for Meat, Poultry, Eggs, Fish, and their products. As Administrator, LP participated in virtual plenary sessions organized by the Chinese delegation to review standards, submitted ballot initiatives for consideration, and engaged in various Working Groups. Topics considered included: Meat and Meat Products Basic Terminology, Specifications for Fermented Meat Products, and Operating Procedures for Pig Slaughter. LP also participated in the review and amendment of Laboratory methods of analysis for Glutamic acid content, and Determination of total phosphorous content specifically related to SC6 products. As future collaboration grows for laboratory cultured protein among stakeholders participating in TC34SC16, LP stands ready to represent
U.S. interests on this emerging topic.

LP led the development of the United Nation's (UN) global standards for egg, poultry, and meat products to assist U.S. producers with marketing their products throughout the world. As the U.S. representative to the Specialized Section on the Standardization of Meat, LP was re-elected as the Vice Chair of the Specialized Section and was elected to the position of Vice-Chair of the UN Working Party on Agricultural Quality Standards. LP participated in the global workshop organized by the Specialized Section and provided technical expertise on a range of topics including imaging methods for meat quality, linking product descriptions with harmonized tariff codes, and international security and sustainability of standards during the COVID-19 pandemic.

LP served as a member of the ANSI-ASQ National Accreditation Board and represented the interests of the U.S. agricultural industry. Board participation included providing guidance for

the international development of accreditation processes in accordance with management systems standards.

LP led the development of international voluntary consensus standards for molecular biomarkers in food products including crop pathogen detection and identification, bioengineered foods, plant variety identification and meat speciation. As the committee manager of the International Organization for Standardization's (ISO) technical committee 34/subcommittee 16 for horizontal methods for molecular biomarker analysis LP provided oversight, coordination and expert input for over 30 ISO technical specifications and standards. LP participated in drafting and coordinated the publication of: ISO/TS 16393:2019 Molecular biomarker analysis -- Determination of the performance characteristics of qualitative measurement methods and validation of methods; ISO 20813:2019 Molecular biomarker analysis -- Methods of analysis for the detection and identification of animal species in foods and food products (nucleic acid-based methods) -- General requirements and definitions and ISO/DIS 21572-2019 Foodstuffs — Molecular biomarker analysis — Immunochemical methods for detection and quantification of proteins.

LP led the US development of ISO standards for bioinformatics in the life sciences. The US technical advisory group for ISO TC 276 WG 5 "Data processing and integration" aims to develop ISO deliverables for traceable, searchable, and interoperable data together with integrated data processing for biotechnology/life sciences. The main foci are definition of data and model formats and their interfaces; definition of metadata and relations of data and models; quality management of processed data and models.

LP led the establishment of a new US ISO technical advisory group for ISO TC 34 Food Products/SC 5 Milk and milk products. The US Dairy industry has not been involved in ISO standardization of dairy products even though many dairy analytical methods are under ISO stewardship. The new TAG will permit US stakeholders to participate in the development and maintenance of ISO Dairy standards.

LP provided a professional expert for the development and publication of the ISO International Workshop Agreement number 32 GMO cotton. In addition, LP provided an expert professional for the development of international voluntary consensus standards in several ISO technical committees including ISO TC34 Food Products, ISO TC 34/SC 17 Food Safety Management Systems, and ISO TC 34/SC 9 Microbiology of the food chain. LP representatives attended 6 international meetings to support ISO standardization development. ISO standards for food products are used throughout the world and referenced directly in USDA and AMS standards.

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

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): 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 2020 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 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. In coordination with other branches of DOC, the five branches 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 received by these five branches of DOC on how they engaged in international voluntary consensus standards and conformity activities during FY2020.

The **US Census Bureau (Census Bureau)** is completing the 2020 Census and will be delivering the small area geography and "basic tabulations of population" to each state as required by P.L. 94-171. Since the first Census Redistricting Data Program (RDP), conducted as part of the 1980 Census, the Census Bureau has included summaries for the major race groups as specified by the Statistical Program and Standards Office of the US Office of Management and Budget (OMB) in Directive 15 (as issued in 1977 and revised in 1997). During the 1990 Census RDP, voting age population (18 years and over) was added to the cross-tabulation of race and Hispanic origin. Programs and activities designed for the dissemination and analysis of statistical and geospatial data are being used in support of this effort.

Partnerships with tribal, state, county, and local governments, other federal agencies, commercial organizations, non-profit and academic institutions assisted in the collection and analysis of data for geographic programs such as the 2020 Boundary and Annexation Survey (BAS) and the 2020 Participant Statistical Areas Program (PSAP). Standards from organizations such as the International Organization for Standardization (ISO), the Open Geospatial Consortium (OGC), the Federal Geographic Data Committee (FGDC) and others that were developed through ANSI's voluntary consensus standards process, were applied in the Census Bureau's statistical surveys, economic analysis, and geographic programs.

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 3 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-119.

In 2020, the following activities exemplified the Census Bureau's application of VCS. The Census Bureau applied the International Committee for Information Technology Standards (INCITS) data standards for the criteria in their contribution to the National Spatial Data Infrastructure (NSDI). Census Bureau staff

participated in the FGDC's development of the National Geospatial Data Assets (NGDA) Baseline Standards Inventory Survey as a requirement of the Federal Data Strategy, Action 10, and the Geospatial Data Act of 2018 to query all covered agencies on their use of standards. The Census Bureau's leadership in the development and publication of two international standards for Addressing (ISO 19160-3 and 19160-2) continued in 2020.

The Census Bureau maintained 34 datasets considered NGDAs using standards developed by INCITS.

1. The Census Bureau's NGDA datasets represent a federal portfolio of geospatial datasets that meet specific requirements outlined in the 2018 Geospatial Data Act and are considered capital assets for decision making and public use. 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 public and discoverable on the Census.gov website (https://www.census.gov/), the Federal Geographic Data Committee's Geospatial Platform (GeoPlatform) (https://www.geoplatform.gov/), and Data.gov (https://www.data.gov/).

The Census Bureau maintained 34 NGDA datasets in 2020 to support the FGDC Governmental Units, and Administrative and Statistical Boundaries Theme (33 NGDAs), and the FGDC Transportation Theme (1 NGDA). Federal agency respondents were asked to identify open standards to enhance the use of and access to these datasets in support of the NSDI, as outlined in the OMB Circular A-16 Supplemental Guidance (https://www.whitehouse.gov/wp- content/uploads/2017/11/Circular-016.pdf). The Census Bureau submitted responses to the FGDC for the NGDA Baseline Standards Inventory Survey in October 2020 and is currently maintaining licensed subscriptions to twelve ISO standards through the ANSI. The list of standards that the Census Bureau consulted for their NGDAs baseline are listed below:

- 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 - Part1: Fundamentals*.

- INCITS/ISO 19115-2:2019 (2019): *Geographic information - Metadata - Part 2: Extensions for acquisition and processing*.

2. The Census Bureau's 2020 TIGER/Line shapefiles complied with the ISO 19115-2 and ISO 19139- 2 metadata-related standards.

3. The Census Bureau led the development of ISO *19160-3 Addressing – Part 3: Quality management for address data*, published in February 2020. 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 understands 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 gained 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) 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://legacy.trade.gov/td/standards/.

In FY2020, 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). An ITA representative also actively participated in the ISO/IEC Joint Technical Committee 1 Subcommittee 31 (JTC1/SC31), Automatic Identification and Data Capture Techniques. An ITA representative joined the US TAG for ISO/IEC JTC1 WG14 for Quantum Computing to gain greater understanding of standards development in the quantum information sciences. ITA regularly notifies relevant US stakeholders about opportunities to participate in new standards development activities that might have trade implications with the aim of heading off future market access issues for US exporters.

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

In FY2020 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, and conformity assessment. ITA has joined inter-agency efforts led by the US 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 on the internet of things (IoT), additive manufacturing (aka 3D printing), and conformity assessment.
Bilateral engagement on standards issues was ongoing with various trading partners and through the US-Brazil Commercial Dialogue, the US-India Commercial Dialogue, the US-Argentina Commercial Dialogue, the US-Canada Regulatory Cooperation Council, and the US-EU Executive Working Group, among others. ITA continues to maintain Standards Attaches in Beijing, Brussels, Jakarta, 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 WTO's Committee on Technical Barriers to Trade (TBT) that address specific standards-related trade concerns. Additionally, ITA coordinated several sets of US Government (USG) comments submitted to China on its standardization reform initiative and as input on the trade-related aspects of a Mexico survey on US standards. Throughout FY2020, ITA served on the USG delegations to the various trade agreement negotiations, 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 FTA TBT chapters.

Finally, ITA co-manages the Industry Technical Advisory Committee on Standards and Technical Trade Barriers (ITAC 14) with USTR which provides input to the Secretary of Commerce and USTR on standards-related policy matters.

National Institute of Standards and Technology (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 into their programs, procurement and regulatory activities. NIST's 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 Standards.gov to serve as a standards and conformity assessment related resource for Federal agencies, industry, and the public.

<u>NIST response to the COVID-19 Pandemic</u>

In FY2020, the novel Corona virus, SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or COVID-19 created a global pandemic crisis, requiring immediate actions by US private and public sectors to contain COVID-19 and protect the US population. NIST participated in documentary standards development activities that directly addressed public health concerns. More information on NIST's response is located at https://www.nist.gov/coronavirus.
In tandem with other federal agencies and private sector standards development organizations, SCO coordinated free electronic access to over 80 international standards, developed by five organizations, that

addressed critical medical and personal protective equipment (PPE). Access to these standards permitted US manufacturers to more quickly retool their production processes to meet the demand for PPE and medical equipment.

SCO led NIST's participation in ASTM International's ASTM F23 (Committee on Personal Protective Clothing and Equipment) to quickly develop the ***Standard Specification for Barrier Face Coverings*** (e.g., face masks). Over 50 organizations participated to create the specification establishing minimum design, performance, labeling, and care requirements for reusable barrier masks for use by the public. NIST helped ensure that the standard's technical requirements were appropriate yet not excessive.
A multi-disciplinary team at NIST developed a way to increase the sensitivity of the primary test used to detect the SARS-CoV-2 virus. The team used a mathematical technique for perceiving comparatively faint signals in diagnostic test data to better detect the presence of the virus. The model was able to amplify a modest signal resulting from a low number of particles in a nasal swab test so that the presence or absence of the virus could be more easily perceived.

NIST is managing the technical working group, Joint ISO/TC 212 - ISO/TC 276 WG: Quality practice for detection of SARS-CoV-2. The committee is drafting a new technical specification that will explain what to consider in designing, making, and deploying analytical tests for detecting SARS-CoV-2 using nucleic acid amplification methods. The standard can guide medical laboratories in maximizing their testing accuracy and reliability by making the best use of commercially available in-vitro diagnostics when testing for COVID-19, and when developing their own tests for detecting the virus.

NIST published an ITL Bulletin (March 2020), "Security for Enterprise Telework, Remote Access, and Bring Your Own Device (BYOD) Solutions" in response to the significant telework increase in 2020. The Bulletin provides guidelines on telework and remote access to help organizations mitigate security risks associated with the enterprise technologies used for teleworking, such as remote access servers, telework client devices, and remote access communications.

NIST and the White House Office of Science and Technology Policy (OSTP) developed a program to improve search engines for accessing COVID-19 research data. This effort used AI to improve search capabilities.

<u>Additional FY2020 NIST activities</u>
In addition to targeted measurement research and coordinated standards participation in response to the COVID-19 pandemic, in FY2020, more than 440 NIST staff participated formally in over 1,750 standards activities in more than 112 different organizations. In addition to participation in standards developing organizations (SDOs), NIST staff held key roles on ANSI boards and committees that oversee the US standardization system that 'accredits' SDO's and serves as the US Member body to ISO and IEC

committees. Below is a sampling of NIST's activities in the development of documentary standards addressing core issues in advanced communications, cybersecurity, AI, and privacy.

Advanced communications

NIST provides leadership and technical expertise in key advanced communications related standards bodies. Over 30 NIST experts lead and participate in 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 Radiocommunications Sector (ITU-R), Alliance for Telecommunications Industry Solutions (ATIS), ISO- IEC/JTC1, and Wireless Innovation Forum Spectrum Sharing Committee (WinnForum). In FY2020, NIST contributions to 3GPP were focused on the evaluation of key functionalities of 5G New Radio specifications in support of mission critical public safety communications. NIST has also contributed its millimeter-wave propagation measurement and models to ITU-R to extend two recommendations on outdoor and indoor propagation guidelines.

Cybersecurity

NIST's National Cybersecurity Center of Excellence (NCCoE) is a collaboration of industry organizations, government agencies, and academic institutions working together to address relevant private sector cybersecurity issues. In FY2020, NCCoE launched "5G Cybersecurity: Preparing a Secure Evolution to 5G". This project will demonstrate how commercial and open-source products can leverage cybersecurity standards and recommend practices to mitigate identified risks and meet industry sectors' compliance requirements.

NIST staff participated within a variety of international and domestic SDOs addressing cybersecurity including INCITS, ISO, IEC, IETF, World Wide Web Consortium (W3C), and IEEE to leverage NIST's technical capabilities in research and standardization processes in areas like IT security, testing and validation, biometrics, security devices, Internet of Things (IoT), cloud computing, cryptography, identity and access control, critical infrastructures and others.

NIST also supported promotion and adoption of the NIST Cybersecurity Framework (CSF) both domestically and internationally and engaged with relevant SDOs for mapping CSF cybersecurity control objectives to industry standards, guidelines, and practices designed to promote the protection of critical infrastructure. NIST was instrumental for the creation of projects like *ISO/IEC 27100 Information technology — Cybersecurity — Overview and concepts*, and *ISO/IEC CD TS 27101 Information technology — Security techniques — Cybersecurity — Framework development guidelines*, as well as the completion of *ISO/IEC TR 27103:2018 Information technology — Security techniques — Cybersecurity and ISO and IEC standards*, which leverages Version 1.0 of the Cybersecurity Framework and incorporates additional ISO/IEC JTC 1 SC 27 Information security, cybersecurity and privacy protection standards.

Artificial Intelligence (AI)

NIST research in AI is focused on the security and trustworthiness of AI systems via research and participation in international standards developing efforts such as ISO/IEC JTC 1/SC 42 Artificial Intelligence.

Privacy

In FY 2020, NIST published Version 1.0 of the NIST Privacy Framework: *A Tool for Improving Privacy through Enterprise Risk Management* (Privacy Framework). The Privacy Framework is a voluntary tool developed in collaboration with stakeholders intended to help organizations identify and manage privacy risk. The Privacy Framework can be mapped to standards supporting its implementation and identify gaps in existing guidelines, and in turn help drive the development of new or revised standards to fill those gaps. In FY 2020 NIST also actively engaged in international standards development organizations to advance the development of risk-based standards to help organizations protect individuals' privacy. Three examples of standardization efforts that benefitted from NIST's expertise are the ISO Project Committee 317, which focuses on developing ISO 31700, *Consumer protection: privacy by design for consumer goods and services*; the ISO/IEC 27557, *Organizational privacy risk management*; and the IEEE P7002, *Data Privacy Process*.

Biotechnology

As the administrator of the US Technical Advisory Group (TAG) for the ISO Technical Committee (ISO/TC) 276 on Biotechnology, NIST coordinates US responses to the suite of international biotechnical standards developed through ISO. NIST's role is to implement the guidance of ANSI to ensure that each standard is developed through consensus, due process, and openness. The US TAG stakeholders assembled by NIST includes participating and observing member organizations representing producers, users/consumers, government, academia, and professional entities. More information may be found here: https://www.nist.gov/programs-projects/us-tag-isotc276-biotechnology .

Conformity assessment

In September 2020, NIST revised 15 CFR Part 287 *Guidance on Federal Agency Conformity Assessment Activities* - 15 CFR Part 287 *Guidance on Federal Agency Conformity Assessment Activities*. Section 12 of the NTTAA of 1995 directs NIST to "coordinate technical standards activities and conformity assessment activities of Federal, State, and local governments with private sector technical standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures". NIST originally issued the guidance found in 15 CFR 287 on August 10, 2000 in response to OMB Circular A- 119 (February 10, 1998) directing the Secretary of Commerce to issue guidance to Federal agencies to ensure effective coordination of Federal conformity assessment activities. The January 2016 revision to OMB Circular A-119 re-emphasizes NIST's role in issuing guidance to agencies as well as Federal agencies' responsibilities with respect to conformity assessment. NIST has revised this guidance to reflect development in conformity assessment concepts and evolution in Federal agency strategies and coordination in using and relying on conformity assessment.

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). 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.

- Through its Big Data Project, NOAA has signed contracts with Amazon, Google, and Microsoft to distribute NOAA's open data through those partners' cloud platforms at no cost to the data consumer. 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. To date, NOAA has distributed over 80 federal datasets through the Big Data Project public-private partnership, using cloud platform standards (e.g., S3, BigQuery) for data access and dissemination.

- 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 has provided leadership for the creation of the Federal Data Strategy (strategy.data.gov) and the national response to the Geospatial Data Act. Both efforts include strategic and tactical direction to Agencies to adopt data standards in the execution of their missions.

- NOAA has created and is developing an implementation for the NOAA Data Strategy. 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 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, Geostationary Operational Environmental Satellite system (GOES) - GOES- 16, GOES-17, and the polar orbiting NOAA-20, all use the open-standard Network Common Data Form (NetCDF-4) format rather than agency-developed data formats. 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 the WMO Information System (WIS) Global Information System Centres (GISC) which includes 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) is contributing 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 data metadata standards via ioos.github.io/ioos-metadata. IOOS requires adherence to standards as a part of its core capabilities. This includes open data sharing via the Global Earth Observing System of Systems (GEOSS) the use of ERDDAP and Thematic Real-Time Environmental Distributed Data Services (THREDDS) servers for data discovery and access, 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/contribute-data/

- NOAA remained a Principal Member of the OGC in FY2020, 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 United States 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 United States 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 United States 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 WG6 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 Open Geospatial Consortium (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 date 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.

National Telecommunications and Information Administration (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 3GPP, ITU-R, ITU-T, IEEE Standards Association, and ATIS. In addition, NTIA's Institute for Telecommunication Sciences (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.

In FY 2020, ITS staff held 28 positions in eight standards bodies, including 10 Chair/Co-chair/Vice-chair positions. ITS staff filled key leadership positions in the ITU-R, including Head of the US Delegation to Study Group (SG) 3 (Radiowave Propagation), International Chair and US Chair of SG3 Working Parties 3K and 3L (Point-to-area and ionospheric propagation), and US Chair of Working Party 3J (Propagation fundamentals). ITS staff also filled key leadership positions in the ITU-T, including Head of US Delegation to Study Group 13 (Future Networks) and Study Group 11 (Protocols and Test Specifications). ITS staff hold the Co-Chair position for the ATIS 5G Supply Chain Working Group. 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 US Departments/Agencies participating in 3GPP. Finally, ITS provided technical leadership and contributions to IEEE standards for local/personal/metropolitan area networks (LAN/PAN/MAN) through participation in IEEE 802.

ITS leads US efforts at the ITU-R Study Group 3 (SG3), the technical group that focuses exclusively on radiowave propagation. At SG3, ITS contributes inputs and ensures the technical accuracy and correctness of international radiowave propagation standards. SG3 Recommendations on radiowave 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 2020, ITS contributed five of the 22 US technical contributions to SG3. 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 ITS contribution, ICAO will be able to use P.528 in their frequency management system. ITS 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'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 in conjunction with technical support from ITS, has been participating heavily in the 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; ITS led the US delegation in those study groups. NTIA's work in ITU-T focuses on industry-led, bottom-up, consensus-based standards and appropriately working with US government colleagues to help ensure the ITU-T avoids duplication of efforts with other standards development organizations such as 3GPP.

Direct participation by NTIA in the 3GPP, the dominant cellular communications standards development organization, allows NTIA to advance US commercial, economic, and government interests by providing technical input to promote strong unbiased standards that support fair competition in next generation/5G cellular technologies. ITS attends 3GPP Working Groups for Services (SA1), System Architecture (SA2), and Security (SA3). Additionally, ITS attends the Radio Access Network Working Group 1 focused on the physical layer for LTE and 5G (RAN 1). NTIA's Office of Spectrum Management (OSM) attends 3GPP Technical Specification Group Radio Access Networks Working Groups 1 (RAN 1) and 4 (RAN 4). 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, 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 2020 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 2020 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 ensuring costs are contained within the acquisition environment. In Fiscal Year 2020, DoD adopted 50 VCS in several areas, including: Thermal Joining of Metals, Electrical Insulators and Insulation, Bolts, Obsolescence Management, and Electrical Connectors. DoD also canceled 141 military unique documents and replaced 9 of them with VCS.

DoD uses VCS for many different purposes. As an example, in Fiscal Year 2020, Naval Sea Systems Command, adopted a series of standards through the American Welding Society (AWS) that contains the essential welding variables for carbon steel in the thickness range of 1/8 inch [3 mm] through 1-1/2 inch [38 mm], using manual gas tungsten arc welding. The standards cite the base metals and operating conditions necessary to make the weldment, the filler metal specifications, and joint designs for groove and fillet welds. These standard welding procedures were developed primarily for naval applications. DoD also adopted IEC 64202 on Obsolescence Management. This document will provide DoD the requirements and guidance applicable to any organization that is dependent on another organization to obtain value from the usefulness of the items that it provides a cost-effective obsolescence management process and the activities used to implement the process are applicable throughout all phases of an item's life cycle.

Lastly. DOD adopted a series of Aerospace Standards from SAE International. These standards offer technical requirements for a variety of hardware items, which are used in various DoD weapon systems such as: bolts, washers, and electrical insulation sleeving.

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):** This agency reports voluntary consensus standards usage on a category basis

Department of Energy (DOE) Fiscal Year 2020 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 2020, 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 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.

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 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 Health and Human Services (HHS) Fiscal Year 2020 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.

a. 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.

b. 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

c. 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 co-funder (with the Robert Wood Johnson Foundation) of this initiative. 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 2020:
• PHAB has accredited 361 health departments—36 states, four tribes, and 331 local health departments (including 264
individually accredited local health departments and 67 county health departments through a centralized

state application
• 82% of the U.S. population is served by an accredited health department (HD).
• PHAB began reaccrediting sites in 2018; 32 sites have been reaccredited.
• 510 HDs, including 41 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 that can inform the Version 2.0 updates to the Standards and Measures, which are planned for release in 2022. CDC's interest and support regarding this accreditation program is evidenced through its accreditation page at http://www.cdc.gov/stltpublichealth/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 benefits to participating in accreditation. April 2020 evaluation data indicate that the program has stimulated quality improvement (96% of accredited health departments agree), improved accountability (80%), improved the capacity of the department to provide high quality programs and services (82%), and strengthened the utilization of resources (71%). More information about the positive impact of the accreditation program can be found by reviewing data and reports available through PHAB's website and in May/June 2018, an issue of the Journal of Public Health Practice and Management was dedicated to the Impact of Accreditation and included several manuscripts authored by federal partners. Evaluation findings are also summarized through this Morbidity and Mortality Weekly Report (MMWR) manuscript, which was co-authored by PHAB and CDC: (https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a3.htm?s_cid=mm6531a3_e).

d. 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.

e. National Center for Health Statistics (NCHS)

The National Center for Health Statistics (NCHS) Classifications and Public Health Data Standards Staff (CPHDSS) continues to serve as the focal point for assessing and supporting a wide array of public health data standards and standards development activities to support the mission of NCHS. CPHDSS participates in health data standards activities to provide public health representation in the development, maintenance and implementation of national healthcare standards to meet the needs of population health that supports vital records reporting and specific survey data requirements for NCHS data systems. NCHS has had successful outcomes over the past year in its standards activities including: development of an Implementation Guide for use by Jurisdictions and their Health IT system vendors that will support the reporting of natality using a new specification based on emerging industry approaches, but informed

by years of lessons around requirements, successes and challenges gained through defining and implementing historically mature standards. Additionally, the National Health Care Surveys have continued to progress their standards development to fulfill the reporting requirements for the public health objectives under Promoting Interoperability (PI) regulations; and, the development, enhancement and expansion of standards for reporting and interoperability.

Details of activities and reports about the Center's eVital Standards Initiative are available within the newly established Vital Statistics Modernization Community of Practice (CoP): https://www.cdc.gov/nchs/nvss/modernization/cop.htm. A complete list of eVital standards is available at http://www.cdc.gov/nchs/nvss/evital_standards_intiatives.htm. Under this initiative, CDC/NCHS is working with the National Association for Public Health Statistics and Information Systems (NAPHSIS), state representatives and other vital records stakeholders to develop vital records standards to enable electronic data exchanges among electronic health record systems, U.S. vital records systems and potentially other public information systems for birth, death and fetal death events. NCHS also provides support for state pilot testing and trial implementation to promote the refinement and adoption of e- Vital Standards-based interoperability. Information on accessing the national standards for vital records reporting is available at https://www.cdc.gov/nchs/nvss/evital/accessing_evital_standards.htm. Additional informational products including presentations, posters and papers are readily accessible to interested stakeholders.

NCHS is engaged in the development and use of the new Health Level 7 International (HL7) Fast Healthcare Interoperability Resources (FHIR) standard. This work aims to leverage the latest web standards and focuses on implementation to improve the timeliness of mortality and natality reporting as well as the initial development and use of FHIR with Health Care Surveys. NCHS is also working with our state vital records agencies through the NVSS Community of Practice to explore how national standards can be utilized for the Center to provide coded cause of death and race and ethnicity information in response to states' death reporting information. These standards for both mortality and natality were tested with state vital records offices and their electronic death and birth registration system vendors at HL7 FHIR Connect-a-thons. Regarding the National Health Care Surveys (NHCS), in 2020 NCHS participated as a use case for a FHIR reference architecture known as Making EHR Data More Available for Research and Public Health that Reference Architecture (MedMorph). It refers to 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. Health Care Surveys is a specific use case within this framework and will have FHIR profiles developed for survey reporting. These efforts support the interoperability among various public health systems and Health IT systems.

Efforts have continued the development of an HL7 FHIR implementation guides for vital records management and reporting. In April 2020, the HL7 Birth and Fetal Death FHIR implementation guide was drafted with the support and feedback of a workgroup consisting of state vital records representatives, electronic birth registration system vendors and natality subject matter experts. This effort was to prepare a ballot for publication during the HL7 January 2021 ballot cycle. In October 2020 the HL7 Vital Records Death Reporting FHIR implementation guide was published as a standard for trial use. Ongoing maintenance and development for this standard has continued throughout 2020. Additionally, maintenance has continued for the development of the HL7 V2.6 and Integrating the Healthcare Enterprise (IHE) standard for vital records. The HL7 VR messaging and document standards and the IHE VR standards have been enhanced to support interoperability for the complete flow of information from the provider to the jurisdiction, and bi-directional reporting of death events between the jurisdiction and NCHS including mortality coding as well as race and ethnicity coding. These standards support implementers whose legacy systems are still using these specific versions of standards and may have the ability to transform between various standards. For example, some systems may transform V2 to FHIR when transporting data among disparate systems. It is for these reasons the maintenance of other standards is paramount. These various types of standards within the standards developing community provide the foundation to support new emerging standards such as FHIR. The legacy standards development NCHS has participated in during previous years has provided the groundwork for efficiently creating other standards.

In addition to FHIR standards and architecture involvement, the Division of Health Care Statistics at NCHS is transitioning from data collection by medical record abstraction to accepting electronic submission of clinical data from health care provider's electronic health records (EHRs). To support this effort, in 2020 NCHS developed an updated HL7 Consolidated Clinical Document Architecture (CDA) implementation guide, which is expected to be released in 2021. This HL7 CDA National Health Care Surveys implementation guide includes Release 1.2 and 3 and is intended initially to be the national electronic standard for the implementation of the meaningful use and promoting interoperability (PI) objective for specialized reporting to NCHS. Implementers of this IG will be able to submit data to fulfill

the requirements of the surveys by automatic extraction of the data from the providers' EHR or data repository. Information on these standards is available on http://www.cdc.gov/ehrmeaningfuluse/national_health_care_surveys.html.

In 2020 communication and outreach efforts were initiated to get Health Care Survey reporting into Health IT vendor's Real World Testing plans as mentioned within the Office of the National Coordinator for Heath Information Technology (ONC) regulations: https://www.healthit.gov/condition-ccg/real- world-testing

NCHS continues to provide support for the development, maintenance and expansion for various standards and their content profiles and has expanded into the reference architecture realm to better support the transactions among external disparate systems. These standards provide a mechanism to utilize information obtained from health IT systems for public health reporting.

f. 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.

g. 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 identifying and adopting national standards and operating rules to increase the electronic exchange of health information between covered entities. Covered entities include all health plans, certain health care providers and health care clearinghouses, and these organizations are defined in the Health Insurance Portability and Accountability Act of 1996 (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 encouraging 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.

NSG staff participate in workgroups of the standards setting organizations listed below. 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:

1) Health Level 7 (HL7): www.HL7.org
2) National Council for Prescription Drug Programs (NCPDP): www.ncpdp.org
3) Accredited Standards Organization, Insurance (X12N): www.x12.org
4) Council for Affordable Quality Healthcare (CAQH) Committee for Operating Rules for Information Exchange (CORE) CAQH
CORE: www.caqh.org
5) NACHA (the Electronic Payments Association): www.nacha.org
6) The Designated Standards Maintenance Organization (DSMO): www.hipaa-DSMO.org

NSG also monitors the activities of NIST, and the Office of the National Coordinator. This year, NSG collaborated with the Office of the National Coordinator to post the administrative transaction standards on the Interoperability Standards Advisory. This gives greater visibility to the voluntary consensus standards developed by the SDOs. View the advisory here: https://www.healthit.gov/isa/.

The Quality Measurement and Value-Based Incentives Group (QMVIG) in the Centers for Clinical Standards and Quality (CCSQ) at CMS also selects and implements performance measures for healthcare provider quality reporting, public reporting, and value-based purchasing programs. CMS prefers to use quality measures that have gone through a consensus endorsement process and can be considered consensus-based standards. The National Quality Forum (NQF), a not-for-profit private sector organization, meets the NTTAA definition of a consensus-based organization, is currently contracted by CMS to perform a transparent consensus development process to endorse performance measures. The process includes: a comprehensive open call for measures; review of scientific and statistical evidence; review and discussion by a balanced panel of external experts and stakeholders; opportunities for public and expert comment and feedback; and an appeals process for stakeholder objections. 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/

h. Food and Drug Administration (FDA)

FDA is responsible for advancing public health by helping to bring safe and effective medical products and foods to the U.S. public; and helping the public get the 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 (VCS) 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 setting 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 reviewers with assessment of products and product applications;
• 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:
http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm193332.htm

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

i. 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 decides to recognize a standard and 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 FY2020, 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 2020:
Date Federal Register Notice
March 30, 2020 FR Notice (List #53) [Docket No. FDA-2004-N-0451]
https://www.govinfo.gov/content/pkg/FR-2020-03-30/pdf/2020-06520.pdf October 24, 2019 FR Notice (List #52) [Docket No. FDA-2004-N-0451] https://www.fda.gov/media/131993/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. Center for Food Safety and Applied Nutrition (CFSAN).

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" (link to guidance here)

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 FY20, the FDA has recognized 4 accreditation bodies which have accredited 8 certification bodies. A

registry of recognized accreditation bodies and accredited certification bodies is available on the Accredited Third- party Certification Program webpage (link to page here).

FSMA also gives us express authority to establish a laboratory accreditation program for the analyses of foods. FDA issued a proposed rule in November 2019 that would implement this program (link to proposed rule here). 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 early 2022.

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, ORA Office of Regulatory Science 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.

j. 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 December of 2019, 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 refence materials included influenza antigens and sheep antisera for influenza vaccine potency testing, as well as tetanus and diphtheria antitoxin for flocculation for DTaP vaccines. Accreditation was received for both ISO standards in April 2020 from the American Association for Laboratory Accreditation (A2LA) .

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 December 2019 and received A2LA accreditation in April 2020. The scope of accreditation for the LIB covers the "ELISA Competition Assay for Quantitative Determination of Relative Potency of Allergenic Extracts."

In September 2020, a virtual internal audit was conducted for CBER to independently assess that DBSQC and LIB risk management, governance and internal control processes are operating effectively to the international standards ISO/IEC 17025 and 17034.

Identification of Medicinal Products (IDMP) is a suite of five standards developed within the International Organization for Standardization (ISO). These standards provide an internationally-

accepted framework to uniquely identify and describe medicinal products with consistent documentation, coding and exchange of product information between global regulators, manufacturers, suppliers and distributors. The IDMP suite of standards are a result of a need to standardize the definition of medicinal product and substance information to facilitate the unique identification and exchange of such information in the context of pharmacovigilance. As FDA focuses on the challenges of the global supply chain and foreign sourcing of medicinal products, FDA continues to participate in the development of and to promote the adoption of international harmonized IDMP to ensure the safety of medications throughout the world.

The 21st Century Cures Act was signed into law 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.

k. 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 currently in clearance; (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. This work will continue apace with each other into 2021 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 on using HL7 FHIR as the exchange standard to represent PQ/CMC structured data for

submissions. In 2020, the Center has initiated the standardization of the remaining information for eCTD Module 3.

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 TC215, and to collaborate with other regulators for harmonized approach for IDMP development.

l. 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/

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

The Nanotechnology Characterization Laboratory (NCL) is part of the National Cancer Institute (NCI)'s Alliance for Nanotechnology in Cancer and falls under the umbrella of the NCI's Cancer Imaging Program within the Division of Cancer Treatment and Diagnosis. The NCL is operated by Leidos Biomedical Research (contractor) as part of the Frederick National Laboratory for Cancer Research. 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. These assays have been tested against a wide variety of nanomaterial platform types and are updated as necessary. This year, six new protocols were added to our catalogue. These include:
• STE-4: Detection of ß-Glucan Contamination
• PCC-18: Quantitation of APIs in Polymeric Prodrug Formulations
• PCC-19: Asymmetric-Flow Field-Flow Fractionation
• PCC-20: Particle Concentration & Size using the Spectradyne nCS1
• PCC-21: Measuring Size and Number Concentration of Metallic Nanoparticle using single particle-ICP- MS
• ITA-27: Multiplex Enzyme-Linked Immunosorbent Assay (ELISA) for Detection of Human Cytokines in Culture Supernatants

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. Efforts were initiated in 2020 to bring 12 NCL protocols through ASTM as Standard Practice or Standard Guides. These efforts are continuing into 2021.

n. 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, 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. 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;
- 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);
- 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). LOINC, SNOMED CT, and RxNorm 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 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 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).
- 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 a number of software tools to facilitate use of FHIR (https://lhcforms.nlm.nih.gov). 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.

o. 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. 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 also charged the Health Information Technology Advisory Committee (HITAC) to create a taskforce to consider the Draft USCDI v1 and the related update timeline and expansion process. In consideration of the input received from public comment in response to ONC's proposed rule and from the HITAC task force, the USCDI v1 was adopted as a standard in the ONC Cures Act Final Rule published May 1, 2020.

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 v1 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 will advance interoperability by permitting developers of certified health IT to implement newer versions of standards and specifications than currently adopted in regulation. ONC established an annual public comment process for SVAP-eligible standards and implementation specifications. Following a detailed review and assessment of comments received during the comment period for 2020 SVAP-eligible standards and implementation specifications (September – November 2020), ONC finalized a list of standards and implementation specifications that can be advanced to under the ONC

Health IT Certification Program. Please see the SVAP Approved Standards for 2020 on the ONC Certification Program SVAP webpage.
To support HHS's ongoing response efforts to the outbreak of Coronavirus Disease 2019 (COVID-19), ONC has partnered with the Centers for Disease Control and Prevention (CDC) to share various resources for reporting and tracking COVID-19, as well as general clinical guidance to the health IT community and healthcare providers. Health IT now plays a crucial role in the collecting and reporting of COVID-19 data. Additionally, electronic health information exchange can facilitate effective strategies to combat COVID-19.

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/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf
• https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification
• 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/coronavirus

p. 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 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):** 1

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

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

Rationale
FDA is not using the ISO standard because the applicability of these requirements is limited to only portions of asepticall filtration, freeze-drying, sterilization in place, cleaning in place, or barrier-isolator technology. There are also significant substance that are not included in the document.

Department of Homeland Security (DHS) Fiscal Year 2020 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 FY2020 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 group 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.

3. **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 Housing and Urban Development (HUD) Fiscal Year 2020 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 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 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): 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 FY 2020: HUD is working with the Home Innovation Research Lab to support the Manufactured Housing Consensus Committee. HUD published a final rule on January 12, 2020 which updated 24 CFR 3280.

Department of the Interior (DOI) Fiscal Year 2020 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 a critical component to the successful execution of regulatory functions associated with our four primary missions of resource protection, resource management, recreation, and serving communities. We evaluate, adopt and apply standards across a wide array of disciplines to include scientific research, engineering, safety, contract administration, information technology, data management, law enforcement, and facilities management. As of the time of this report, not all data have been submitted, however below are several examples of how standards have contributed to mission success at the DOI.

The DOI and its bureaus and offices continued to participate in the InterNational Committee on Information Technology Standards Technical Committee L1 (INCITS L1), Geographic Information Systems, which is the means by which segments of the geospatial community participate in American National Standards Institute (ANSI) and International Organization for Standardization (ISO) geospatial standardization activities. INCITS L1 serves as the U.S. Technical Advisory Group to ISO Technical Committee 211, Geographic information/Geomatics. DOI also continues to be an active participant in the Open Geospatial Consortium (OGC), an international industry consortium of over 460 companies, government agencies and universities participating in a consensus process to develop publicly available interface standards.

The Bureau of Reclamation participates in voluntary consensus standards (VCS) development, and develops standards while in consideration of existing VCS and other industry standards. Water management, design and construction, hydro/power facilities measurement, power distribution, and dam safety risk analysis are among many areas of developmental participation. Reclamation's structure and facilities design, and developed technical references utilize voluntary consensus standards, most of which were developed with Reclamation's participation. Links to these standards can be found here:

Technical Service Center Manuals and Standards https://www.usbr.gov/tsc/techreferences/mands/mands.html
Consequence Estimating Methodology
https://www.usbr.gov/ssle/damsafety/documents/RCEMMethodology2015.pdf

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. Many of BOR's standards used in the hydro-power sector can be found here: Facility Rating Methodology and Standards
https://www.usbr.gov/power/reliability/Facility%20Rating%20Methodology%20Rev1.1with%20BOR%20cover.pdf
Hydro-power Facilities Instructions, Standards and Techniques (FIST) Manuals
https://www.usbr.gov/power/data/fist_pub.html

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 Federal Geographic Data Committee (FGDC) endorsed the Wetlands Mapping Standard in July 2009. The purpose of this standard is to support accurate mapping and classification of wetlands, while ensuring mechanisms for their revisions and update as directed under OMB Circular A-16, Revised. It is designed to direct the current and future digital mapping of wetlands. This mapping standard will be used for all wetland mapping nationally including Federal Agencies, States, Tribes, especially if that mapping data will be uploaded into NWI/The National Map as a data layer. Specifically, if Federal funding is involved, then use of the proposed Standard is required. For all other efforts, use of the standard is strongly encouraged. More information about the Wetlands Mapping Standard is available – at the following link:
https://www.fgdc.gov/standards/projects/FGDC-standards-projects/wetlands-mapping.

The FWS has adopted the Dublin Core Metadata Element Set (endorsed by the International Standards Organization) to describe the FWS collection of digital photos, videos, and other media that are currently stored in the FWS National Conservation Training Center (NCTC). This enhancement will reduce data anomalies and improve interoperability for data exchanges between NCTC and other systems.

The Office of Surface Mining (OSM) has defined geospatial standards for coal mining boundaries (surface and underground) that have been adopted as international standards by the American Society for Testing and Materials (ASTM). These standards have improved miner and public safety, reduced the cost of regulatory compliance, and map generation, and improved the electronic permitting process by reducing the time required to review regulatory permit requests. The incorporation of consensus Government geospatial standards (approved by the Federal Geographic Data Committee FGDC) has resulted in improving the quality and reducing the cost of geospatial products produced by the
U.S. Geological Survey (USGS). The adoption of geospatial standards has enabled the Bureau of Ocean Energy Management (BOEM) and Bureau of Safety and Environmental Management (BSEE) to integrate multiple geospatial layers within a single digital map viewer. This improved marine spatial planning efforts by permitting the standardization of previously incompatible geospatial data across federal, state, and local government uses, which improved the ability to identify the best location for renewable energy projects.

For the Bureau of Land Management (BLM) most of its data can be linked to a location and so it is critical we are consistent with geospatial metadata standards as set forth by the FGDC and the International Organization for Standards (ISO). The Department of the Interior uses Motorola R56 Standards and Guidelines for Communications Sites to ensure the design, construction, operation and maintenance, and inspection of all departmental radio communications sites meet minimum standards resulting in consistent safety and maintenance practices across the Department.

The National Park Service (NPS) was a leading partner in the development and recent FGDC endorsed Federal Trails Data Standards (FTDS) that provides for common descriptive data attributes among the many agencies that manage and administer national trails. The FTDS is available on the FGDC website at the following link: https://www.fgdc.gov/standards/projects/trail-data-standard/trail-data-standards. In addition, the NPS has implemented an internal Geospatial Information System (GIS) Data Layer Standards Process that allows NPS programs to efficiently develop and publish data content and exchange standards for sharing among programs and for developing consistent NPS-wide data sets. The internal NPS processes augment consensus standards developed by the FGDC and other programs and agencies to accommodate NPS- specific requirements. Use of both internal and external consensus standards allows the NPS to reduce costs for data and improve sharing among NPS parks and programs as well as other agencies and the public. The National Park Service has adopted the NPS Bibliographic Metadata Exchange Standard, which consists of a proposed NPS enterprise core bibliographic element set based on qualified Dublin Core (DC). The purpose of establishing an enterprise level core bibliographic metadata element set, NPS Bibliographic Metadata Element Set (NPS-BMES), and application profile, NPS Bibliographic Metadata Application Profile (NPSBibMAP), is to facilitate efficient exchange, harvesting (via ‘exposure’ of metadata in xml format), aggregation, and federated searching (promoting wide discovery) of NPS managed bibliographic data. The NPS-BMES is based on a subset of the ‘qualified’ level of the

Dublin Core Metadata Element Set (DCMES) standard, while the NPS-BibMAP is based on the Dublin Core Library Application Profile (DC-Lib). To support the mission for the Bureau of Indian Affairs in establishing a secure environment to maintain a stable “baseline” for protecting the Information Technology (IT) assets that enhance the quality of life and promote economic opportunities for the American Indians, Indian tribes, and Alaska Natives, NIST standards are used to accomplish our mission.

Security and Privacy standards are used to lower risks to an acceptable level, and to demonstrates due diligence towards safeguarding Indian Affair’s sensitive information and information systems.

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 Justice (DOJ) Fiscal Year 2020 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;
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 2020. While not an exhaustive inventory of activities, these three examples demonstrate the Department's active participation in improving and applying standards to deliver the mission.

The Department of Justice participates in the development of forensic science standards by sending Subject Matter Experts (SMEs) to work as part of the Organization of Scientific Area Committees (OSAC) for Forensic Science. More information about the OSAC can be obtained at the NIST website at the following link: https://www.nist.gov/forensics/.

The National Institute of Justice (NIJ) continues to operate its NIJ Compliance Testing Program. In CY 2020, approximately 90 models of ballistic-resistant body armor were submitted for testing. In addition to initial testing, follow-up inspection and testing was conducted on approximately 130 models complying with NIJ Standard 0101.06, Ballistic Resistance of Body Armor. NIJ continues to participate in ASTM Committee E54 Homeland Security Applications to develop standardized methods and practices for ballistic and mechanical testing of life safety equipment as well as standards for testing law enforcement public order personal protective equipment. Through ANSI, NIJ also supports ISO/IEC JTC 1/SC 37 Biometrics, which focuses on the standardization of generic biometric technologies pertaining to human beings to support interoperability and data interchange among applications and systems. More about NIJ's standards and conformity assessment activities can be found at: https://nij.gov/standards.

The Department's Office of the Chief Information Officer actively applies the ISO/IEC 20000- 1:2018 and ISO 27001:2013 standards for the delivery of IT and information security services and during 2020 maintained ISO certification via formal audit for continuing compliance with these standards. 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 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 Labor (DOL) Fiscal Year 2020 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 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): 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 2020 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 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): 1

(1) Government Unique Standard
General 2020 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.

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L/EB: CRusin (ok)
OBO/RM: JReba (ok)

Department of Transportation (DOT) Fiscal Year 2020 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, infrastructure, innovation and accountability. We use our safety outreach 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 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, DOT has:
• With the National Science and Technology Council, prepared a Federal-wide report, "Ensuring American Leadership in Automated Vehicle Technologies: Automated Vehicles (AV) 4.0," which sets forth roles for all Executive Branch Departments and Agencies in developing and deploying AV technologies (https://www.transportation.gov/sites/dot.gov/files/2020-02/EnsuringAmericanLeadershipAVTech4.pdf). The role of multiple Federal agencies in working with the private sector to develop voluntary consensus standards is noted. AV 4.0 built upon DOT's "Preparing for the Future of Transportation: Automated Vehicles 3.0 (AV 3.0)," a policy framework which confirmed that the Department "Supports the development of voluntary technical standards and approaches as an effective non-regulatory means to advance the integration of automation technologies into the transportation system." AV 3.0 includes a detailed Appendix identifying automation-related voluntary standards being developed through standards development organizations (SDOs) and associations. (https://www.transportation.gov/av/3)
• Issued revisions to the Federal Pipeline Safety Regulations to improve the safety both of pipelines transporting hazardous liquids, and onshore gas transmission pipelines. These revisions rely upon industry-developed standards and practices.
• Issued a proposed rule to incorporate by reference the current policy and practices for FMCSA employees, State or local government employees, and contractors to obtain and maintain certifications for conducting driver or vehicle inspections, safety audits, or investigations, the Commercial Vehicle Safety Alliance's (CVSA) ''Operational Policy 4: Inspector Training and Certification."
• Issued an Advanced Notice of Proposed Rulemaking (ANPRM) seeking public comment on permitting camera-based rear visibility systems, specifically seeking information on existing industry standards and research underlying those standards, and how they perform when

evaluated according to the ISO 16505/UNECE R46 standards.

• Continued to support the American National Standards Institute (ANSI) Unmanned Aircraft Systems Standardization Collaborative (UASSC), which convened hundreds of members of industry, SDOs, regulatory authorities and others to accelerate UAS adoption, producing the "Standardization Roadmap for Unmanned Aircraft Systems, Version 1.0".

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): 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.

Department of the Treasury (TRES) Fiscal Year 2020 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.

Treasury is not reporting any Government-unique standards and does not have activity in this area.

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

Environmental Protection Agency (EPA) Fiscal Year 2020 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 FY2020 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).
In FY2019 EPA reported on the development of an internal process to approve and manage staff participation in Voluntary Consensus Standards (VCS) and other private sector standards. Consistent with OMB Circular A-119, this internal process helps to ensure that EPA's participation in private sector standards activities is aligned to our mission and strategic priorities, coordinated across the Agency, coordinated with other government agencies, and consistent with related laws and policies. This internal process additionally highlights the importance of Agency participation in standards development, as directed by the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119.

EPA continued implementation of this internal process in FY2020, including extensive outreach to managers and senior leadership responsible for EPA's 100+ staff currently participating in standards development activities. In FY2020 EPA offices continued to prioritize participation in VCS and other private sector standards development activities as an important means to advance EPA's mission.
We highlight the following as examples:

A. American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Guidelines for Protecting Building Occupants from Smoke During Wildfire and Prescribed Burn Events Committee (GPC44).
Early in 2020, EPA's Office of Air and Radiation (OAR) and Office of Research and Development (ORD) worked with the National Institute of Standards and Technology (NIST) to propose that ASHRAE develop a guideline for protecting building occupants from smoke during wildfire and prescribed burn events.
ASHRAE approved the proposal and a Committee (GP44) was formed in mid-2020. EPA's objectives are to ensure that the developed guideline includes the best technology and science related to monitoring of wildfire smoke and mitigating its health impacts. EPA also wants to ensure that the guideline aligns with current interagency guidance on mitigating the impacts of wildfire smoke. Because of the urgent need to protect building occupants from infiltration of wildfire smoke, a subset of this committee developed interim guidance in the fall of 2020. EPA was an integral part of this group that identified technical information from a range of disciplines (Heating, ventilation, and air conditioning (HVAC) engineers, epidemiologists, public health officials, architects) and synthesized it into an easy to understand process for building managers. The interim guidance emphasizes the importance of a smoke readiness plan, and addresses issues such as upgrading air filters, use of portable air cleaners, and HVAC system management during the SARS-CoV-2 pandemic. This interim guidance was approved

by the full ASHRAE committee ahead of the 2021 wildfire season.

B. ASTM International committee E35 (Pesticides, Antimicrobials, and Alternative Control Agents), subcommittee E35.15 (Antimicrobial Agents)

EPA's Office of Pesticide Programs (OPP) within the Office of Chemical Safety and Pollution Prevention (OCSPP) actively participates with ASTM International Committee E35 and Subcommittee E35.15 to develop new and revise existing standard methods for disinfectant efficacy testing (e.g., towelette testing, laundry sanitizers, virology testing) and to advance relevant research in these areas. As of FY2020 there are twelve ASTM standards that pertain to OPP's regulatory guidance, including to the Series 810 - Product Performance Test Guidelines, which are generally intended to meet testing requirements for the

effectiveness of pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA staff serve as the technical contacts for five of these ASTM standards. Within the ASTM standards development process, technical contacts play an important role that may include serving as the primary author of a new or revised standard, addressing technical questions about the standard from the public, etc.

C. American National Standards Institute (ANSI) development of the Standardization Roadmap for Unmanned Aircraft Systems (Version 2.0)

EPA's Office of Pesticide Programs (OPP) within the Office of Chemical Safety and Pollution Prevention (OCSPP) provided guidance and comment on the American National Standards Institute (ANSI) development of the Standardization Roadmap for Unmanned Aircraft Systems (Version 2.0). This roadmap was published by the ANSI Unmanned Aircraft System Standardization Collaborative (UASSC). The UASSC's mission is to coordinate and accelerate the development of the standards and conformity assessment programs needed to facilitate the safe integration of unmanned aircraft systems (UAS) – commonly known as drones – into the national airspace system (NAS) of the United States. The UASSC is also focused on international coordination and adaptability. The Roadmap identifies existing standards and standards in development, defines where gaps exist, and makes recommendations for priority areas where there is a perceived need for additional standardization. EPA's review and comment toward the roadmap provided related to the development of section 8.3.2 of the Roadmap, Pesticide Application.

D. NSF/ANSI/CAN 61: Drinking Water System Components

EPA's Office of Research and Development (ORD) participates in the NSF International committees responsible for developing NSF/ANSI/CAN 61. In FY 2020, the Office of Ground Water and Drinking Water (OGWDW) within EPA's Office of Water undertook rulemaking under the Reduction of Lead in Drinking Water Act (RLDWA). ORD and OGWDW worked closely to ensure that, as much as possible, modifications to NSF/ANSI/CAN 61 could be made to keep it consistent with RLDWA so that use of NSF/ANSI/CAN 61 could fulfil EPA's needs specified in the final rule "Use of Lead Free Pipes, Fittings, Fixtures, Solder, and Flux for Drinking Water." The revised NSF/ANSI/CAN 61 contains aspects that fulfill the RLDWA - as well as other aspects that go beyond the RLDWA – without imposing additional testing burden on the plumbing and plumbing products industry. This modification helped increase industry

acceptance of the final rule since many plumbing manufacturers have a history of reliance on NSF/ANSI/CAN 61.

EPA has also been working within NSF/ANSI/CAN 61 to get the acceptance criterion for lead release certification under NSF/ANSI/CAN 61 Section 9 lowered, to provide better health protection against lead contamination for products used in schools and day care centers, as well as residences and commercial buildings. This revision to the NSF/ANSI/CAN 61 standard was done through the NSF standard Task Group process. With the 2020 edition of NSF/ANSI/CAN 61 the lower lead acceptance criterion became a voluntary test with new product labeling requirements to help consumers identify the lowest lead-leaching products. There is also a multi-year phase in to make the lower lead acceptance criterion a mandatory component of NSF/ANSI/CAN 61 in the future.

In addition, we highlight additional examples from FY 2019 that were not included in EPA's FY 2019 reporting:

A. NSF/ANSI 426-2018: Environmental Leadership and Corporate Social Responsibility Assessment of Servers

Rare earths are a key material used in hard disk drives used in servers. Mining of rare earths has significant impacts on water and soil quality, generates waste, and requires energy use. Reusing rare earths can help reduce the impacts of mining as well as increase the resiliency and security of the United States by ensuring access to these materials for new products. The U.S. government has indicated its interest in increasing recycling of rare earths and other critical minerals in EO13817 – A Federal Strategy to Ensure Secure and Reliable Supplies of Critical Minerals.

EPA initiated development of criteria to include in NSF/ANSI 426 addressing these issues. EPA conducted outreach to and collaborated with the U.S. Department of Energy's (DOE's) Critical Materials Institute, Seagate (a major disk drive manufacturer), the Green Electronics Council (GEC), and other experts, encouraging them to participate in an NSF task group that would explore options and develop criterion for possible inclusion in NSF/ANSI 426. In FY2020 NSF/ANSI 426 incorporated criterion that:
• incentivize use of recycled rare earths in hard disk drives (criterion 7.1.4) and
• enable easier location of the hard disk drives for recyclers (criterion 9.2.4).
NSF/ANSI 426 is the first known standard built to help purchasers identify and procure more sustainable servers, and the first one in any sector known to incentivize use of recycled rare earths. At the time of the publication of this standard, there were no known instances of successful use of recycled rare earths in products. The criterion that incentivized use of recycled rare earths was included in the standard as an aspirational goal in the hopes of sparking some movement toward meeting this objective.

Spurred by the criterion in the NSF/ANSI 426, Dell decided to take on this challenge. Through the creation of innovative partnerships with suppliers, Dell was able to develop a new closed-loop process to recover the rare earth magnets from recovered enterprise equipment. The magnets are reformed for reuse in new hard-disk drives (HDDs) in Dell Latitude 5400 and 5500 notebooks.

During the pilot alone, Dell diverted 660 pounds of magnet material from landfills to create 25,000 HDDs. The process is scalable to use over 8,000 pounds of magnet material to create over 300,000 closed-loop HDDs annually. The same process can be adapted to build drives for other drive models by reshaping the magnets or even in other magnet industries such as magnetic resonance imaging (MRI) machines or electric vehicle motors. EPA awarded Dell a 2019 EPA Sustainable Materials Management Electronics Challenge Gold Award Winner for this work.

B. The NELAC (National Environmental Laboratory Accreditation Council) Institute (TNI)
Throughout FY2019, EPA's Office of Water collaborated with The NELAC (National Environmental
Laboratory Accreditation Council) Institute (TNI) on updating and implementing TNI standards that focus
on laboratory accreditation as it relates to the Clean Water Act (CWA). This collaboration helps to improve consistency of the various state wastewater laboratory certification programs, as essential components of each state's National Pollutant Discharge Elimination System (NPDES) permit program.

C. Standard Methods
EPA's Office of Water completed a collaborative effort with the Standard Methods Committee (which is responsible for developing Standard Methods for the Examination of Water and Wastewater) that began in FY2018 to develop a method for the analysis of peracetic acid (PAA) in wastewater. EPA supported the design of the method and a unique interlaboratory method validation study that brought together multiple analysts in a single location in order to validate the method for an analyte with a very short holding time (e.g., minutes). A proposed version of Standard Method 4500-PAA PERACETIC ACID (RESIDUAL) was published in October of 2019. EPA expects to propose the method for inclusion at 40 CFR 136 in a future rulemaking effort.

D. Standard Methods and ASTM International D19 Committee on Water
EPA's Office of Water is finalizing a Methods Update Rule (MUR) to allow the use of additional Voluntary Consensus Standards (VCSs) for determinations of microbial and chemical pollutants in wastewater. EPA proposed to revise 40 CFR 136 (October 22, 2019, 84 FR 56590), which lists analytical testing procedures (methods) required to be used by industries and municipalities when analyzing the chemical, physical, and biological properties of wastewater and other environmental samples for reporting under the EPA's National Pollutant Discharge Elimination System (NPDES) permit program.
(https://www.federalregister.gov/documents/2019/10/22/2019-22437/clean-water-act-methods-update- rule-for-the-analysis-of-effluent)

EPA worked directly with the Standard Methods Committee and the ASTM D19 Committee to include, enhance, or clarify the quality control requirements associated these methods, where feasible. EPA then requested that these organizations submit to EPA new VCSs and revised versions of older VCSs to be considered for inclusion in a proposed Methods Update Rule (MUR) related to the NPDES permit program. Standard Methods and ASTM International submitted these revised VCSs with changes clearly identified and new VCSs with supporting performance data. EPA reviewed all information to ensure the methods were appropriate for use as alternatives to the existing EPA-approved methods for NPDES compliance monitoring. EPA

published the proposed rule on October 22, 2019 and took public comments on the incorporation of these VCSs into the regulations at 40 CFR 136.3. All of these VCSs were favorably received by the public. EPA plans to finalize these methods into the 40 CFR 136.3 regulations in Spring 2021.

The MUR contained four revised microbiological and 27 revised chemical methods from Standard Methods, and 46 revised chemical methods and minor editorial changes from ASTM.

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): 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

a. ASTM D3154-00 (2014) Standard Method for Average Velocity in a Duct (Pitot Tube Method)

b. ASME B133.9-1994 (2001) - Measurement of Exhaust Emissions from Stationary Gas Turbine Engines

Rationale

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

b. Not a quantitative method, per se, although a good primer for this source category that includes technical descriptions of manual and instrumental sampling procedures, as well as performance specifications for instrumental methods. This standard has many good references, including the EPA Methods and Performance Specifications. Only use for engines and turbines. Not a method. (not for EPA Methods 2, 3A, 4, 5).

(26) Government Unique Standard
EPA Method 5 [Incorporated: 2015]
Voluntary Standard
ASME B133.9-1994 (2001)
ISO 9096:1992 (2003)
ANSI/ASME PTC-38-1980 (1985)
ASTM D3685/D3685M-98 (2005) CAN/CSA Z223.1-M1977
Rationale

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

(27) Government Unique Standard
EPA Method 515.4 – Chlorinated Acids in DW by LL Fast CG/ECD [Incorporated: 2003]
Voluntary Standard
ASTM D5317-98 -- Standard Test Method For Determination of Chlorinated Organic Acid Compounds in Water by Gas Chromatography With an Electron Capture Detector
Rationale
ASTM D5317-98 specifies acceptance windows for the initial demonstration of proficiency for laboratory fortified blank samples that are as small as 0 percent to as large as 223 percent recovery for picloram, with tighter criteria for other regulated contaminants. Therefore, this method permits unacceptably large control limits, which include 0 percent recovery.

Voluntary Standard
Standard Method 6640 B for the chlorinated acids
Rationale
The use of this voluntary consensus standard would have been impractical due to significant shortcomings in the sample preparation and quality control sections of the method instructions. Section 1b of Method SM 6640 B states that the alkaline wash detailed in section 4b2 is optional. The hydrolysis that occurs during this step is essential to the analysis of the esters of many of the analytes. Therefore, this step is necessary and cannot be optional. In addition, the method specifies that the quality control limits for laboratory-fortified blanks are to be based upon plus or minus three times the standard deviation of the mean recovery of the analytes, as determined in each laboratory. Therefore, this method permits unacceptably large control limits, which may include 0 percent recovery.

(28) Government Unique Standard
EPA Method 531.2 – N-Methylcarbamoylozimes/ates, Aqueous In/HPLC [Incorporated: 2003]
Voluntary Standard
Standard Method 6610, 20th Edition
Rationale
Standard Method 6610, 20th Edition has recently been approved for compliance monitoring. Standard Method 6610, 20th Supplemental Edition permits the use of a strong acid, hydrochloric acid (HCL), as a preservative. The preservatives in all of the other approved EPA and Standard Methods procedures for these analytes are weak acids that adjust the pH to a specific value based upon the pKa of the preservative. The use of HCL would require accurate determinations of the pH of the sample in the field and could be subject to considerable error and possible changes in pH upon storage. Although not specifically observed for oxamyl or carbofuran during the development of similar methods, structurally similar pesticides have been shown to degrade over time when kept at pH 3. Therefore, approval of this method is impractical because it specifies the use of a strong acid (HCL) when positive control of the pH is critical.

Voluntary Standard
Standard Method 6610, 20th Supplemental Edition
Rationale

Standard Method 6610, 20th Edition has recently been approved for compliance monitoring. Standard Method 6610, 20th Supplemental Edition permits the use of a strong acid, hydrochloric acid (HCL), as a preservative. The preservatives in all of the other approved EPA and Standard Methods procedures for these analytes are weak acids that adjust the pH to a specific value based upon the pKa of the preservative. The use of HCL would require accurate determinations of the pH of the sample in the field and could be subject to considerable error and possible changes in pH upon storage. Although not specifically observed for oxamyl or carbofuran during the development of similar methods, structurally similar pesticides have been shown to degrade over time when kept at pH 3. Therefore, approval of this method is impractical because it specifies the use of a strong acid (HCL) when positive control of the pH is critical.

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

(30) Government Unique Standard
EPA Method 6 - Determination of Sulfur Dioxide Emissions from Stationary Sources [Incorporated: 2018]
Voluntary Standard

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

b. ISO 11632:1998 (2016) - Stationary Source Emissions Determination of the Mass Concentration of Sulfur Dioxide Ion Chromatography

Rationale

a. This standard is only applicable to sources with 30 mg/m3 SO2 or more. Also, this standard does not separate SO3 from SO2 as does the EPA methods; therefore, ISO 7934:1998 is not valid if more than a negligible amount of SO3 is present. Also, it does not address ammonia interferences.

b. Sampling procedures are similar to EPA Method 6, but lacks in detail and quality control procedures, such as calibration checks and leaks tests.

(31) Government Unique Standard
EPA Method 7E [Incorporated: 2015]
Voluntary Standard
ANSI/ASME PTC 19-10-1981-Part 10 ISO 10396:1993 (2007)
ASTM D5835-95 (2007)
CAN/CSA Z223.2-M86 (1999)
Rationale
The use of these voluntary consensus standards would not be practical with applicable law due to a lack of equivalency, documentation, validation data and other important technical and

policy considerations.

(32) Government Unique Standard
EPA Method 9 [Incorporated: 2016]
Voluntary Standard
ASTM D7520-09 “Standard Test Method for Determining Opacity of a Plume in the Outdoor Ambient Atmosphere”
Rationale
The use of this voluntary consensus standard would not be practical due to a lack of equivalency, documentation, validation data and other important technical and policy considerations. The EPA did not receive comments during the notice and comment period that caused us to alter the standards and methods in the final permits.

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

Voluntary Standard
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations
Rationale
Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

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

Voluntary Standard
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations
Rationale
Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

(35) Government Unique Standard
EPA Performance Specification 2 (nitrogen oxide portion only) [Incorporated: 2001]
Voluntary Standard

ISO 10849:1996, Determination of the Mass Concentration of Nitrogen Oxides--Performance

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

(36) Government Unique Standard
EPA Performance Specification 2 (sulfur dioxide portion only) [Incorporated: 2001]
Voluntary Standard
ISO 7935:1992, Stationary Source Emissions--Determination of the Mass Concentration of Sulfur Dioxide--Performance Characteristics of Automated Measuring Methods"
Rationale
Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

(37) Government Unique Standard
SW846-6010b [Incorporated: 2002]
Voluntary Standard
ASTM C1111-98 (1998) - Standard Test Method for Determining Elements in Waste Streams by Inductively Coupled Plasma-Atomic Emission Spectrometers
Rationale
This standard lacks details for instrument operation QA/QC, such as optimizing plasma operating conditions; upper limit of linear dynamic range; spectral interference correction; and calibration procedures, which include initial and continuous calibration verifications. Also lacks internal standard and method of standard addition options for samples with interferences.

Voluntary Standard
ASTM D6349-99 (1999) - Standard Test Method for Determining Major and Minor Elements in Coal, Coke, and Solid Residues from Combustion of Coal and Coke by Inductively Coupled Plasma-Atomic Emission Spectrometers
Rationale
This standard lacks details for instrument operation QA/QC, such as optimizing plasma operating conditions, upper limit of linear dynamic range, spectral interference correction, and calibration procedures, that include initial and continuous calibration verifications. Also lacks details for standard preparation, and internal standard and method of standard addition options for samples with interferences.

(38) Government Unique Standard
Validated Method 8327: Per-and Polyfluoroalkyl Substances (PFAS) Using External Standard Calibration and Multiple Reaction Monitoring (MRM) Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) [Incorporated: 2019]
Voluntary Standard
ASTM D7979-19: Standard Test Method for Determination of Perfluorinated Compounds in

Water, Sludge, Influent, Effluent and Wastewater by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS)
Rationale
For the reasons set forth below, EPA determined that PFAS analytical methods should be

validated by multiple laboratories, rather than by a single lab, for use under the Resource Conservation and Recovery Act (RCRA) and other EPA programs, e.g., the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The ASTM D7979 standard is not multi-lab validated for the matrices of concern for RCRA and CERCLA.

Multi-lab validation accomplishes several purposes: First, it is a means to assess accuracy and reproducibility of data independent of the organization that developed the method. Second, it reduces uncertainty regarding the method used to produce the data to support decision making. By assuring accuracy and reproducibility of the data and confidence in the method, methods that are multi-lab validated provide additional assurance to EPA decision-makers and the public that resulting data used to protect human health and the environment are robust, reliable and of known quality.

EPA test methods that support RCRA and are used by other Federal programs can be found in the EPA publication, Test Methods for Evaluating Solid Waste: Physical/Chemical Methods, also known as SW-846. Under RCRA's SW-846 methods program, the methods development and validation process for Validated Method 8327 and other methods contained in SW-846 includes posting a method on EPA's public website for public comment, comment adjudication and relevant method revisions

(39) Government Unique Standard
WaterSense Specification for Spray Sprinkler Bodies Appendix B: Spray Sprinkler Body Performance test method [Incorporated: 2017]
Voluntary Standard
ASABE/ICC 802-2014, "Landscape Irrigation Sprinkler and Emitter Standard"
Rationale
WaterSense used ASABE/ICC 802-2014 (section 303.5.2) as the basis for its sprinkler performance test. However, no product testing was done by the ASABE/ICC standard development committee prior to publishing the standard. When WaterSense did this testing many changes had to be made to eliminate redundant steps, correct deficiencies in the method and provide sufficient detail to run the test consistently at any laboratory. WaterSense has submitted the revised method to the ASABE/ICC 802 committee for consideration in the revision of the standard

Federal Communications Commission (FCC) Fiscal Year 2020 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.

Another example is the successful use of the Telecommunications Industry Association Telecommunications System Bulletin 10-F, "Interference Criteria for Microwave Systems." This standard, referenced within several Commission rule parts has become the cornerstone for applicants and licensees to successfully coordinate the use of microwave communications systems.

Also, on October 2, 2017 the European standard for wireless microphones ETSI EN 300 422-1 V1.4.2 (2011-08): "Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wireless Microphones in the 25 MHz to 3 GHz frequency range; Part 1: Technical characteristics and methods of measurement, was incorporated by reference in Section 15.38 of the FCC rules. This standard is used for the evaluation of the out-of-band emissions of wireless microphones.
When making measurements to demonstrate compliance with the FCC rules it is required to use the appropriate measurement methods as specified in the applicable section of the FCC rules. For example, for Part 15 devices see Section 15.31 for a list of required measurement standards.

Other measurement procedures that have been found acceptable by the Commission, in

accordance with Section 2.947, may also be used. See Measurement Procedures and 47 CFR Section 2.947.

Conformity Assessment.
Radio Frequency (RF) devices are required to be properly authorized under 47 CFR Part 2 prior to being marketed or imported into the United States. The Office of Engineering and Technology (OET) administers the equipment authorization program under the authority delegated to it by the Commission. This program is one of the principal ways the Commission ensures that RF devices used in the United States operate effectively without causing harmful interference and otherwise comply with the Commission's rules. All RF devices subject to equipment authorization must comply with the Commission's technical requirements prior to importation or marketing. See Equipment Authorization Approval Guide

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 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

Federal Trade Commission (FTC) Fiscal Year 2020 Agency Report

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

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

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

2. Please list the government-unique standards (GUS) your agency 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

Government Publishing Office (GPO) Fiscal Year 2020 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).
Standards referenced on GPO's web-pages:
CS https://gpo.gov/pdfs/vendors/sfas/ppr.pdf
CS https://www.gpo.gov/pdfs/vendors/sfas/qatap.pdf
CS https://www.gpo.gov/pdfs/vendors/sfas/terms.pdf
CS https://www.gpo.gov/vendors/microforms.htm
CS https://www.gpo.gov/pdfs/customers/sfas/ jcpregs.pdf
CS http://www.gpo.gov/pdfs/vendors/sfas/071jcp.pdf
CS https://www.gpo.gov/pdfs/vendors/sfas/O-90film.pdf
CS https://www.gpo.gov/pdfs/vendors/sfas/O-91paper.pdf
CS http://www.gpo.gov/pdfs/customers/sfas/vol12/vol_12.pdf
CS https://www.gpo.gov/pdfs/customers/Guidelines_Attending_PressSheetInspections.pdf
CS https://www.gpo.gov/pdfs/vendors/sfas/contractors_holding_psi.pdf
LSCM/PST https://www.fdlp.gov/cataloging-guidelines
FIN http://www.main.gpo.gov/FA/Accounting_Policies_Manual_Q1_FY2019.pdf
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 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

General Services Administration (GSA) Fiscal Year 2020 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 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): 5

(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-DTL-22520G, Crimping Tools, Wire Termination, General Specification for [Incorporated: 2019] Voluntary Standard
SAE AS22520, Crimping Tools, Wire Termination, General Specification for Rationale
Temporary use of GUS continued in FY2019 to allow transition to VCS.

(4) 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.

(5) Government Unique Standard
MIL-I-81969B, Installing and Removal Tools, Connector Electrical Contact, General Specification for [Incorporated: 2019]
Voluntary Standard
SAE AS81969, Installing and Removal Tools, Connector Electrical Contact, General Specification for Rationale
Temporary use of GUS continued in FY2019 to allow transition to VCS.

National Archives and Records Administration (NARA) Fiscal Year 2020 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 2020 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 2020 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

3. **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

National Aeronautics and Space Administration (NASA) Fiscal Year 2020 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 facilitates selection and use of voluntary consensus standards (VCS) in lieu of NASA technical standards or other government agency standards. 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 adapted 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 directly cites Office of Management and Budget (OMB) Circular No. A-119 and the preference for use of VCS and participation in VCS bodies' activities in NASA directives (NASA Policy Directive (NPD) 7120.4, NASA Engineering and Program/Project Management Policy, and NASA Procedural Requirements (NPR) 7120.10, Technical Standards for NASA Programs and Projects). NASA 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.

NASA encourages participation in VCS developing bodies and collects data on participation in development and revision of VCS. During this reporting period, 81 NASA representatives participated in 254 VCS development/revision activities in 33 VCS bodies. NASA's participation in VCS development/revision increased from 70 participants in FY2019 to 81 in FY2020, an increase of over 15 percent. NASA representatives participated in 179 VCS bodies' development/revision activities in FY2019 and in 254 development/revision activities in FY2020, an increase of over 40 percent.

NASA expertise and experience will or is expected to be used in the assessment of national and international commercial human spaceflight standards, though the maturity of these standards is still in early stages of development. Current NASA documentation exists as commercial crew and cargo program requirements documents.

An example of NASA's use of VCS is that NASA participates in the revision of ISO 14624-1, Space systems— Safety and compatibility of materials — Part 1: Determination of upward flammability of materials; ISO 14624-2, Space systems — Safety and compatibility of materials — Part 2: Determination of flammability of electrical-wire insulation and accessory materials; and ISO 14624-3, Space systems — Safety and compatibility of materials — Part 3: Determination of offgassed products from materials and assembled articles and tailors those test procedures to meet NASA's needs in NASA-STD-6001, Flammability, Offgassing, and Compatibility Requirements and Test Procedures. The following VCS are also cited in NASA-STD-6001 as requirements, with exceptions, for test methods: ASTM D240, Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter; ASTM D2863, Standard Test Method for Measuring the Minimum Oxygen Concentration to Support Candle-Like Combustion of Plastics (Oxygen Index); ASTM D3294, Standard Specification for

Polytetrafluoroethylene

(PTFE) Resin Molded Sheet and Molded Basic Shapes; ASTM D4809, Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter (Precision Method); ASTM E502, Standard Test Method for Selection and Use of ASTM Standards for the Determination of Flash Point of Chemicals by Closed Cup Methods; ASTM E1354, Standard Test Method for Heat and Visible Smoke Release Rates for Materials and Products Using an Oxygen Consumption Calorimeter; ASTM G72, Standard Test Method for Autogenous Ignition Temperature of Liquids and Solids in a High-Pressure Oxygen-Enriched Environment; ASTM G74, Standard Test Method for Ignition Sensitivity of Nonmetallic Materials and Components by Gaseous Fluid Impact; ASTM G86, Standard Test Method for Determining Ignition Sensitivity of Materials to Mechanical Impact in Ambient Liquid Oxygen and Pressurized Liquid and Gaseous Oxygen Environments; ASTM G124-10, Standard Test Method for Determining the Combustion Behavior of Metallic Materials in Oxygen-Enriched Atmospheres; ASTM G125, Standard Test Method for Measuring Liquid and Solid Material Fire Limits in Gaseous Oxidants; and SAE AS4373, Test Methods for Insulated Electric Wire (Method 508, Dry Arc Propagation Resistance only). As new revisions are developed, more VCS are incorporated where appropriate.

NASA subject matter experts also support IPC—Association Connecting Electronics Industries to ensure that the technical and training requirements in the Space Addendums to IPC documents (e.g., IPC- 6012xS, J-STD-001xS, and IPC/WHMA-A-620xS) continue to meet or exceed the baseline requirements of equivalent NASA specifications. NASA continues to participate in re-registration audits for ISO 9001 Quality Management System, in ISO 14001 Environmental Management System inspections and compliance activities, and in OSHA's Voluntary Protection Program (VPP) assessments. Various other audits and follow-ups included internal quality, safety, environmental, and health inspections, including those for explosives, propellants, pyrotechnics, environmental compliance, and occupational health.

Standards are critical in defining engineering, safety and mission assurance, and health and medical requirements for NASA missions. These technical standards include VCS, 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 167 VCS Standards Developing Bodies.

NASA is currently leading the revision of AWS D17.1/D17.1M, Specification for Fusion Welding for Aerospace Applications.

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):
This agency reports voluntary consensus standards usage on a category basis

Nuclear Regulatory Commission (NRC) Fiscal Year 2020 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 http://www.nrc.gov/reading- rm/doc-collections/cfr/. 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: http://www.nrc.gov/reading-rm/doc-collections/#reg.

The NRC implements 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 October 2020, the NRC hosted the fourth NRC Standards Forum. The goals of the NRC Standards Forum are to identify and prioritize standards for development or revision and to initiate or support collaboration 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 nominally held once a year. A summary and related documents for the October 2020 Standards Forum can be found at https://www.nrc.gov/about-nrc/regulatory/standards- dev/standards-forum/2020.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 that 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: http://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 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): 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, which 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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NUREG-1736, “Consolidated Guidance: 10 CFR Part 20—Standards for Protection against Radiation.”