NIST Interagency Report
NISTIR 8543

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

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This publication is available free of charge from:
https://doi.org/10.6028/NIST.IR.8543

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

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Karen K. Reczek
Standards Coordination Office
Laboratory Programs Laboratory
National Institute of Standards and Technology

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October 2024

U.S. Department of Commerce
Gina M. Raimondo, Secretary

National Institute of Standards and Technology
Laurie E. Locascio, NIST Director and Under Secretary of Commerce for Standards and Technology

NIST IR 8543
October 2024

Publication History
Approved by the NIST Editorial Review Board on 2024-10-16

How to Cite this NIST Technical Series Publication
Reczek, Karen (2024) Twenty-Seventh Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment. (National Institute of Standards and Technology, Gaithersburg, MD), NIST Interagency Report (IR) NIST IR 8543. https://doi.org/10.6028/NIST.IR.8543

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Abstract

In FY 2023, of the 23 federal agencies that reported, only one federal agency, which submitted a report for the first time, added 1 GUS in lieu of VCS. No other agency added or rescinded any GUS in lieu of VCS, leaving a total of 80 previously reported GUS in lieu of VCS still in use. This analysis does not reflect the use of standards by the Department of Defense (DoD) or the National Aeronautics and Space Administration (NASA) as they report their use of GUS on a categorical basis via a different reporting mechanism. Agencies demonstrate the effectiveness of the NTTAA and Circular A-119 by their continuous review of opportunities to rescind GUS in favor of using VCS, and their involvement with the private sector through the VCS process. These activities suggest that federal agencies are cognizant of the benefits of meeting their mission needs by actively seeking to use VCS developed by the private sector.

Keywords

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

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

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

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

This FY 2023 summary, prepared by the National Institute of Standards and Technology (NIST), compiles annual reports provided by the 23 agencies listed in Appendix A. For these reports, agencies were asked to document any new use of GUS in lieu of VCS during FY 2023 and provide a rationale for each new use. Agencies additionally were asked to list any rescinded GUS in lieu of VCS during the past fiscal year, and to briefly describe their activities undertaken to carry out provisions described in Circular A-119. The two questions are listed in Appendix B. Individual agency reports may be found at https://www.nist.gov/standardsgov/nttaa-reports.

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

For FY 2023, only one federal agency reported new GUS used in lieu of VCS, when they submitted a report for the first time. The Federal Energy Regulatory Commission (FERC) reported the use of "Updating Regulations for Engineering and Design Materials for Liquefied Natural Gas Facilities Related to Potential Impacts Caused by Natural Hazards," 185 FERC 61050 (Oct. 23, 2023). The Final Rule does not adopt voluntary consensus standards related to natural hazard evaluation and design criteria for Liquefied Natural Gas (LNG) structures, systems, and components because adopting such standards would be impractical. More detailed information on this rationale is available in their agency report.

For FY 2023, federal agencies did not rescind any GUS used in lieu of VCS.

Summary

In FY 2023, of the 23 federal agencies that reported, only one federal agency, which submitted a report for the first time, added 1 GUS in lieu of VCS. No other agency added or rescinded any GUS in lieu of VCS, leaving a total of 80 previously reported GUS in lieu of VCS still in use. This analysis does not reflect the use of standards by the Department of Defense (DoD) or the National Aeronautics and Space Administration (NASA) as they report their use of GUS on a categorical basis via a different reporting mechanism. Agencies demonstrate the effectiveness of the NTTAA and Circular A-119 by their continuous review of opportunities to rescind GUS in favor of using VCS, and their involvement with the private sector through the VCS process. These activities suggest that federal agencies are cognizant of the benefits of meeting their mission needs by actively seeking to use VCS developed by the private sector.

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

Appendix A: FY 2023 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)

Federal Energy Regulatory Commission (FERC)

General Services Administration (GSA)

Government Publishing Office (GPO)

National Aeronautics and Space Administration (NASA)*

National Archives and Records Administration (NARA)

Nuclear Regulatory Commission (NRC)

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

Appendix B: NTTAA Annual Reporting Survey

Instructions provided to each agency:

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

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

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Process:

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

1. Question 1 is for reporting on your agency's activities in standards and conformity assessment during FY2023. As a reference, we have included the greyed-out response from last year and instructions on completing.
2. Question 2 is for reporting on GUS used in lieu VCS and includes previously reported GUS. Please update by adding any new and removing any rescinded GUS.

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

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

Access Board (ACCESS) Fiscal Year 2022 Agency Report to NIST

Access Board (ACCESS) Fiscal Year 2023 Agency Report

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

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

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

In FY 2023, as in previous reporting years, the Access Board relied heavily on voluntary consensus standards to fulfill its regulatory mission.

We published the Accessibility Guidelines for Pedestrian Facilities in the Public Right-of-Way https://www.federalregister.gov/documents/2023/08/08/2023-16149/accessibility-guidelines-for-pedestrian-facilities-in-the-public-right-of-way on August 8, 2023.

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 2023, 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 (RESNA), Standards Comm. on Cognitive Accessibility;
- TRB Standing Committee on Innovative Public Transportation Services and Technologies;
- RESNA Standards Committee for Assistive Technology for Air Travel; and
- World Wide Web Consortium Web Accessibility Initiative - Accessibility Guidelines Working Group,

Two Access Board members serve as statutory representatives on the Election Assistance Commission (EAC) Board of Advisors and Technical Guidelines Development Committee (TGDC). The TGDC, chaired by the NIST director, is responsible for drafting and recommending versions of the Voluntary Voting System Guidelines (VVSG). The Board of Advisors reviews the VVSG, best practice recommendations, and follows other EAC activities. For FY 2023, the EAC Board of Advisors and TGDC meetings were held virtually and focused on supplemental materials supporting and advancing adoption of VVSG 2.0. In addition to the annual Board of Advisors and TGDC meetings, Access Board members and staff also attend or participate in some other EAC public-facing activities.

Additional information about how the Access Board works with SDO and others to develop accessibility standards and guidelines is available on the can be found on the Access Board website.

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

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

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

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

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

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

Table 1: Current Government Unique Standards FY2022

Consumer Product Safety Commission (CPSC) Fiscal Year 2023 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, 2022 to September 30, 2023, CPSC staff provided technical support or was otherwise engaged in the development of voluntary safety standards for 86 different products, product areas, or hazards. Voluntary standards activities are handled by various standards developing organizations (SDOs) that are accredited by the American National Standards Institute (ANSI). The majority of the standards where staff was involved are developed by either ASTM International (ASTM) or Underwriters Laboratories Inc. (UL). The standards provide safety provisions addressing potential hazards associated with consumer products found in homes, schools, and recreation areas. Twice a year, the CPSC staff issues a Voluntary Standards Tracking and Access Report, otherwise known as the VSTAR Report. This report shows, among other things, the product, product area, or hazard category 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 record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded.**

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

Current total GUS: 2

Table 1: Current Government Unique Standards FY2023

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

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

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

(2) Government Unique Standard
CPSC 16 CFR Parts 1213, 1500, and 1513 for Bunk Beds [Incorporated: 2000]

Voluntary Standard
ASTM F1427-96 Standard Consumer Safety Specification for Bunk Beds

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

Homeland Security

Science and Technology

U.S. Department of Homeland Security
Washington, D.C. 20528

MEMORANDUM FOR: Nathalie M. Rioux
National Institute of Standards and Technology (NIST)
International Standards Policy & Coordination

FROM: Renee Stevens
DHS S&T Senior Standards Advisor

SUBJECT: Annual DHS National Technology Transfer and Advancement Act **(NTTAA)** on Fiscal Year **2023** Standards Activities and Identification of DHS Component Standards Executives

DATE: February 26, 2024

Attached is the annual Department of Homeland Security (DHS) National Technology Transfer and Advancement Act (NTTAA) Report to the National Institute of Standards and Technology (NIST) on Fiscal Year 2023 Standards Activities and the Identification of DHS Component Standards Executives**.** The DHS Science and Technology Directorate (S&T), through the Office of Science and Engineering (OSE), Systems Engineering & Standards (SES), responds to the NTTAA on behalf of DHS regarding the Department's use of voluntary consensus standards and conformity assessment activities. Activities are made public and reported to Congress through the Office of Management and Budget (OMB).

Per the NTTAA and the revised OMB Circular A-119, DHS reports on the following two questions:

> *1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.*
> *2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. 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).*

In addition to facilitating federal participation in the development of voluntary consensus standards and conformity assessment activities, DHS S&T's FY23 standardization activities

included the coordination of activities in response to the National Standards Strategy for Critical and Emerging Technology and the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. DHS S&T Standards coordinated the Department's active involvement in early-stage AI-related standards development with a focus on expanding participation and leadership in AI standards activities where the government serves as the official representative, particularly in areas addressing risk factors (encompassing threats, vulnerabilities, and consequences) and accounting for security considerations.
DHS S&T Standards continues to participate in the Interagency Committee on Standards Policy (ICSP) and co-chairs the AI Standards Coordination Working Group (AISCWG) alongside NIST. DHS S&T facilitated participation of DHS operational components in AI/ML SDO committees/subcommittees by connecting DHS component SMEs with SDOs actively developing AI/ML consensus standards. DHS S&T Standards maintains that standards can be used to support the building of tools, development of methods, and facilitation of community engagement to guide the design of regulatory and enforcement regimes for the mitigation of AI threats. Advancing trustworthy AI technology via standards protects people's rights and safety, making the Nation's progress possible.

All questions or additional requests for information should be communicated to DHS S&T OSE via Standards@hq.dhs.gov and renee.stevens@hq.dhs.gov .

Attachments

1. Attachment 1 FY23 NTTAA DHS Report
2. Attachment 2 DHS Component Standards Executives Update

Attachment 1

Department of Homeland Security (DHS) Fiscal Year 2023 NTTAA Report

DHS's FY2023 NTTAA Agency Annual Report
Component Responses

Department of Homeland Security (DHS) Fiscal Year 2023 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 FY2023 in carrying out the provisions of OMB Circular A-119 includes multiple divisions and components. For more information about DHS, see www.dhs.gov. Summaries of the received responses are presented in the following pages and categorized by Component.

CBP

The U.S. Customs and Border Protection (CBP) Laboratories and Scientific Services **utilizes** consensus standards from the following groups:

- AAFS – American Academy of Forensic Sciences
- AATCC - American Association of Textile Chemists and Colorists
- ABC - American Board of Criminalistics
- ACS – American Chemical Society
- AIC - Arizona Identification Council (AIC)
- ANAB - ANSI National Accreditation Board
- ANSI - American National Standards Institute
- AOAC – Association of Official Agricultural Chemists
- API - American Petroleum Institute
- ASB - Auditing Standards Board (under American Institute of Certified Public Accountants)
- ASCP - American Society for Clinical Pathology

- ASME - American Society of Mechanical Engineers
- ASTM - American Society of Testing and Materials
- ASTM- ASTM International (formerly American Society for Testing and Materials)
- CFSRE – Center for Forensic Science Research & Education
- CFTT - National Institute of Standards (NIST) Computer Forensics Tool Testing Program
- CSAFE – Center for Statistics and Application in Forensic Evidence
- IACIS - International Association of Computer Forensic Examiners
- IAI - International Association for Identification
- ICUMSA - International Commission for Uniform Methods of Sugar Analysis
- ISO – International Organization for Standardization
- IEEE - Institute of Electrical and Electronics Engineers Standards Association
- NAFTZ - National Association of Free Trade Zones
- NFPA - National Fire Protection Association
- OSAC - Organization of Scientific Area Committees for Forensic Science
- SAE - Society of Automotive Engineers
- SAFS - Southern Association of Forensic Scientists
- SANS - SANS Institute Best Practices (SysAdmin, Audit, Network and Security)
- SWAFS - Southwestern Association of Forensic Scientists
- SWGDE - Scientific Working Group on Digital Evidence
- SWGDRUG – Scientific Working Group for the Analysis of Seized Drugs
- TIC Council - Testing, Inspection, and Certification Council (formerly IFIA – International Federation of Inspection Agencies)
- USP – US Pharmacopeia
- Government Standards:
- CISA – Cybersecurity and Infrastructure Security Agency
- EPA – Environmental Protection Agency
- CBP-LSS is directly involved in the development of consensus standards for the following:
    - ASTM – American Society of Testing and Materials
    - D02 Committee – Petroleum Products, Liquid Fuels, and Lubricants
    - E30 Committee - Forensics
    - API – American Petroleum Institute
    - COPM – Committee on Petroleum Measurement Standards Meeting
    - OSAC - NIST Organization of Scientific Area Committees for Forensic Science Dogs and Sensors Subcommittee (affiliate member)
    - AIC - Member, Board of Directors
    - CBP-LSS uses agency-specific standards under the CBP Lab Methods (CBPL Method) that often "incorporate by reference" consensus standards from ASTM, ANSI, and other groups: Technical Documents: Laboratory Methods | U.S. Customs and Border Protection (cbp.gov)

CISA

The Cybersecurity and Infrastructure Security Agency (CISA) partners with standards organizations, consistent with CISA authorities, strategic intent, and DHS International Cybersecurity priorities, to drive policies and create standards to improve interoperability and automate cybersecurity operations, among other outcomes. CISA works with domestic and international partners and engages in standards development at the national and international levels. CISA participates in the following standards bodies:

- 3rd Generation Partnerships Project (3GPP),
- Institute of Electrical and Electronic Engineers (IEEE)
- International Telecommunication Union (ITU)
- Global Systems for Mobile Communication Alliance (GSMA)
- Internet Engineering Task Force (IETF)
- Alliance for Telecommunications Industry Standards (ATIS)
- Wi-Fi Alliance, O-RAN Alliance
- Wireless Broadband Alliance
- OASIS Open

Within those bodies, CISA participates to monitor, support, and influence standards development activities relevant to agency mission objectives.

	CISA Engagement		
Standards Body	Subcommittees/working groups, etc.	What technology/technologies does the subcommittee/group set standards for?	Other relevant activities or information
3rd Generation Partnership Project (3GPP)	3GPP	Cellular telecommunications technologies, including radio access, core network and service capabilities, and system description for mobile telecommunications.	CISA ECD participates to **influence** standards work in support of mission objectives for NS/EP Priority Services for Voice, Video, and Data in 3GPP Systems (e.g., 4G and 5G mobile systems). Also, to ensure NS/EP Priority Services coexistence with other priority services (e.g., Emergency and Mission Critical Services for Group Type Communications).

	3GPP SA1	Services	CISA ECD participates to **influence** stage 1 (service description) specifications for Multimedia Priority Service (MPS) and to ensure MPS support in evolving 3GPP systems (e.g., 5G) and emerging service features.
	3GPP SA2	Architecture	CISA ECD participates to **influence** stage 2 (architecture requirements) specifications in support of priority features for MPS.
	3GPP SA3	Security	CISA ECD participates to **support** 4G and 5G security solutions benefiting MPS.
	3GPP SA5	Management, orchestration, and charging	CISA ECD **actively monitors** work for MPS interests.
	3GPP SA6	Mission critical applications	CISA ECD **actively monitors** work to ensure MPS coexistence with MCS.
	3GPP CT1	User Equipment - Core Network Protocols	CISA ECD participates to **influence** protocol specifications in support of priority features for MPS.
	3GPP CT3	Interworking with External Networks	CISA ECD participates to **influence** CT3 (e.g., policy, interconnection) specifications in support of priority features for MPS.
	3GPP CT4	Core Network Protocols	CISA ECD participates to **influence** CT4 (e.g., HTTP-based APIs) specifications in support of priority features for MPS.
	3GPP RAN1	Radio Layer 1	CISA ECD participates to **influence** RAN1 work in support of priority features for MPS.
	3GPP RAN2	Radio Layer 3 and Radio Layer 3	CISA ECD participates to **influence** RAN2

			work in support of priority features for MPS.
	3GPP RAN3	UTRAN/E-UTRAN architecture and protocols for the Iu, Iur, Iub, S1 and X2 interfaces	CISA ECD participates to **influence** RAN3 work in support of priority features for MPS.
	3GPP RAN4	Performance and protocol aspects	CISA ECD **passively monitors** work for MPS interests.
Institute of Electrical and Electronic Engineers (IEEE)	IEEE 802 LAN/MAN Standards Committee (LMSC)	Local, metropolitan, and other area networks standards	CISA ECD participates to **influence** work to support NS/EP Priority Services in WLAN access networks (a.k.a WiFi networks).
	IEEE 802.11 WG	Wireless Local Area Network (WLAN) Standards	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for ethernet PHY/MAC protocol.
	IEEE 802.11be (TGbe)	Task group for WLAN enhancement	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for ethernet PHY/MAC protocol.
	IEEE 802.11TGm	Task Group for revising and updating the IEEE 802.11 Standards	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for supporting previous generation of WLAN PHY/MAC protocols.
	IEEE 802.11 UHR (Ultra High Reliability)	Study Group for next generation IEEE 802.11 Amendment	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for next generation WLAN PHY/MAC protocol.
International Telecommunication Union (ITU)	ITU Telecommunication Sector (ITU-T)	Telecommunications Standards	CISA ECD **monitors** ITU-T activities for relevance to mission objectives related to NS/EP Priority Services support in global standards.

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

			objectives for NS/EP Priority Services over IP transport networks.
	Automated Certificate Management Environment (acme)	ACME protocols and API	CISA ECD **actively monitors** work relevant to mission objectives for NS/EP Priority Services over IP transport networks.
	Transport Area Working Group (tsvwg)	IP transport and routing protocols	CISA ECD **influence** work relevant to mission objectives for NS/EP Priority Services over IP transport networks.
	Adaptive DNS Discovery (add)	DNS protocols	CISA ECD **actively monitors** work relevant to mission objectives for NS/EP Priority Services over IP transport networks.
	Traffic Engineering (TE) Architecture and Signaling (teas)	Network Slicing	CISA ECD **actively monitors** work relevant to mission objectives for NS/EP Priority Services over IP transport networks.
	Transport Layer Security (tls)	Transport Security	CISA ECD **actively monitors** work relevant to mission objectives for NS/EP Priority Services security and Privacy
	Messaging Layer Security (mls)	Message security for Groups	CISA ECD **actively monitors** work relevant to mission objectives for NS/EP Priority Services security and Privacy
	Remote Attestation Procedures (rats)	Remote Attestation	CISA ECD **actively monitors** work relevant to mission objectives for NS/EP Priority Services security and Privacy
Alliance for Telecommunications Industry Standards (ATIS)		National Telecommunications Standards	CISA ECD participates to **influence** work to define national specific aspects for NS/EP Priority Services using global standards features (e.g., 3GPP, IETF).

	Packet Technologies and Systems Committee	Services, architectures, and signaling,	CISA ECD participates to **influence** work to define national standards for NS/EP Priority Services for Voice, Video, and Data.
	ATIS/SIP Forum IP-NNI Task Force	IP Network-to-Network Interconnections	CISA ECD participates to **influence** work to allow interconnection and interoperability of NS/EP Priority Services for Voice, Video, and Data.
	Wireless Technologies and Systems Committee	Wireless/mobile telecommunications networks in the U.S.	CISA ECD participates to **influence** work relevant to support of NS/EP Priority Services for Voice, Video, and Data.
	5G North American Needs Focus Group	Coordinate North American Needs in 3GPP	CISA ECD participates to **influence** need for NS/EP Priority Services.
	5G Supply Chain Working Group	Development of ATIS standards on supply chain	CISA ECD participates to **passively monitor** work relevant to ECD mission objectives for NS/EP Priority Services.
	Next G Alliance	Development of the National Roadmap for 6G and Beyond.	CISA ECD participates to **passively monitor** work relevant to ECD mission objectives for NS/EP Priority Services.
WiFi Alliance		Development of requirements and test programs for Wi-Fi interoperability	CISA ECD participates to **influence** work to define a NSEP Priority Access features for WLAN PHY/MAC protocol interoperability.
	Wi-Fi 7 Marketing Task Group (MTG)	Development of use cases, requirements and features for Wi-Fi interoperability	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for WLAN PHY/MAC protocol interoperability.

	Wi-Fi 7 Technical Task Group (MTG)	Development of test-cases, Test and Validation for Wi-Fi interoperability	CISA ECD participates to **influence** work to define a NSEP Priority Access feature for WLAN PHY/MAC protocol interoperability.
	Wi-Fi Optimized Connectivity Experience (OCE) Task Group (Marketing and Technical)	Development of requirements, features and use cases for Wi-Fi QoS interoperability	CISA ECD participates to **influence** WLAN QoS work relevant to ECD mission objectives for NS/EP Priority Services.
O-RAN Alliance		Defining architecture and solution for intelligent, open, virtualized and fully interoperable Radio Access Networks	CISA ECD participates to actively monitor work relevant to mission objectives for NS/EP Priority Services
Wireless Broadband Alliance		Standards and guidelines for NextGen Wi-Fi, OpenRoaming, 5G and IoT.	CISA ECD **monitors** to determine relevance to mission objectives for NS/EP Priority Services support in Wi-Fi access networks and OpenRoaming solution
OASIS Open	Automated Course of Action Operations (CACAO) for Cyber Security TC	Defining the standard for implementing course of action playbooks for cybersecurity operations.	CISA CSD participants to **influence** work relevant to CSD mission objectives.
	Common Security Advisory Framework (CSAF) TC	Standardizing automated disclosure of cybersecurity vulnerability issues	CISA CSD participants to **influence** work relevant to CSD mission objectives.
	Cyber Threat Intelligence (CTI) TC	Supporting automated information sharing for cybersecurity situational awareness, real-time network defense, and sophisticated threat analysis	CISA CSD participants to **influence** work relevant to CSD mission objectives as a co-chair of the Interoperability subcommittee.

CWMD

In 2023, Countering Weapons of Mass Destruction Office (CWMD) continued activities in accordance with OMB Circular A-119 which directs that "agencies must consult with voluntary consensus standards bodies in the development of standards when consultation and participation is in the public interest and is compatible with their missions, authorities, priorities, and budgetary resources." To this end, CWMD continued to sponsor and participate in the development and maintenance of the Institute of Electrical and Electronics Engineers (IEEE) and

American National Standards Institute (ANSI) voluntary consensus standards for radiation and nuclear threat detection systems used in homeland security and American Society for Testing and Materials (ASTM) International voluntary consensus standards for biological threat detection systems. The CWMD Standards Program participated in the development and publication of IEEE N42.62: Standard for Passive Imaging Radiation Devices (PIRDs) for the Localization and Identification of Radioactive and Nuclear Materials. The Program also held initial planning meetings and published an IEEE Project Authorization Request (PAR) to commence the revision of the IEEE N42.35 standard for Radiation Portal Monitors in 2024. CWMD supported the development and publication of a new ASTM Standard developed by a CWMD sponsored ASTM Standards Working Group, the "Standard Specification for Field Screening Devices Used for Identification of Biological Agents" (ASTM E3394-23) and the associated Test Method (ASTM E3395-23). CWMD also supported the establishment of an ASTM Task Group, WK83732, to develop a Data Format Standard for Biodetection Instruments. CWMD participated with the U.S. Committee for International Electrotechnical Commission (IEC) international standards for radiation detection systems. In 2023 the IEC initiated the formation of a Standards Working Group for the development of a standard for radiation detection equipment replay tools. CWMD continued to sponsor free access to IEEE Series N42 standards for radiation detection for homeland security that are available at: https://ieeexplore.ieee.org/browse/standards/get-program/page.

The government-unique standards that are currently in use by CWMD are as follows:

Document Number	*Document Title/Designation*	*Publication Date*	*New in 2023? (Yes or No)*	*Notes*
500-DNDO-117250v2.0	Technical Capability Standard for Handheld Instruments Used for the Detection and Identification of Radionuclides	November 2019	No	These Technical Capability Standards were developed in collaboration with NIST in accordance with Congressional direction in the Safe Port Act of 2006. They were specifically developed to supplement existing voluntary consensus standards and do not duplicate or contradict them.
500-DNDO-119420v0.00	Technical Capability Standard for Backpack Based Radiation Detection Systems	August 2013	No	Same as above
500-DNDO-119430v0.00	Technical Capability Standard for Vehicle Mounted Mobile Systems	August 2013	No	Same as above

500-DNDO-119430v0.00	Technical Capability Standard for Aerial Mounted Radiation Detection Systems	February 2017	No	Same as above
500-CWMD-130170v0.00	Technical Capability Standard for Radiation Portal Monitor Systems with Energy Analysis Capability	November 2019	No	Same as above

FEMA

The Federal Emergency Management Agency (FEMA)/Resilience/Floodplain Management Division staff participate as members of a committee involved in updating ASCE 24-24 Flood Resistant Design and Construction to ensure the consensus standards comply with the minimum standards set forth in Code of Federal Regulations, Part 60 – Criteria For Land Management and Use, Subpart A-Requirements for Flood Plain Management Regulations which sets forth participation requirements for communities for the National Flood Insurance Program, specifically 60.3 (https://www.ecfr.gov/current/title-44/chapter-I/subchapter-B/part-60). Additional information can be obtained at FEMA, Floodplain Management, https://www.fema.gov/floodplain-management. FEMA provides subject matter experts to participate on design standards committees and the update cycles of the ICodes. These standards include:

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

FLETC

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

standards. FLETC will continue to examine its programs to ensure compliance with DHS Directive 078-04.

ICE

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

OHSS

Created in 2023, the Office of Homeland Security Statistics (OHSS) provides reports and statistical data covering a range of topics and domains. OHSS is led by the DHS Statistical Official and supported by the DHS Statistical Official Council (SOC), which consists of senior career officials appointed as Statistical Officials for each operational Component that provides data to OHSS. Through consensus of the DHS SOC, common homeland security statistical standards are adopted and applied. Standards are maintained and managed through a digital platform (Matrix by Collibra). OHSS is currently working to expand DHS statistical standards beyond the immigration domain, to include all homeland security domains.

PARM

Program Accountability and Risk Management (PARM) develops and maintains acquisition program management policy, procedures and guidance processes that provide for the use of voluntary consensus standards for engineering, logistics, and sustainment throughout the entire life cycle spectrum.

S&T Standards

S&T Standards (STN) serves to integrate and coordinate standards across DHS via R&D, acquisition, strategic sourcing, grants, regulation and rulemaking for implementation into DHS operational technology and procedures. STN does this in multiple ways:

- Direct consensus standards committee participation (INCITS, ASTM, NFPA, AIA, OASIS),
- Sponsoring foundational research for consensus standards development (IEEE, ASTM, OASIS, IEC)
- Providing standards access subscription services to DHS, and
- Administration of the DHS Standards Council, an intra-agency group chartered to (1) support the responsibility of the U/S of S&T to coordinate standards activities in the Department and (2) support the responsibilities of the agency Standards Executive as identified in OMB Circular A-119.

S&T TCD

S&T Technology Centers Division (TCD) operates and maintains the Project 25 Compliance Assessment Program (P25 CAP). P25 CAP is a voluntary program, which allows P25 radio manufacturers to publicly attest to their products' compliance to the P25 standard through P25 CAP testing at DHS-recognized laboratories. P25 CAP testing includes performance, interoperability and conformance testing. As proof, suppliers are required to submit Summary Test Report (STR) and Supplier's Declaration of Compliance (SDOC) documents. These documents are available on S&T's Approved (Grant-Eligible) Equipment web page. S&T does not develop P25 standards, rather they are developed by the Telecommunications Industry Association. S&T does participate in TIA meetings to promote standards development activities critical to public safety end users. Further, S&T works with stakeholders to develop test cases that are adopted as part of the P25 CAP. For more information on P25 CAP: https://www.dhs.gov/science-and-technology/p25-cap

- S&T TCD proactively promotes Standards for Resilient Positioning, Navigation and Timing (PNT) User Equipment through its involvement in IEEE 1952. This standard specifies technical requirements and expected behaviors for resilient Positioning, Navigation, and Timing (PNT) User Equipment (UE). The scope is limited to the reception, ingestion, processing, handling, and output of PNT data, information, and signals. Based on technical requirements, the standard defines different levels of resilience to enable users to select a level that is appropriate based on their risk tolerance, budget, and application criticality. This standard applies to UE that outputs PNT solutions, including PNT systems of systems, integrated PNT receivers, and PNT source components (such as Global Navigation Satellite System (GNSS) chipsets). S&T partially sponsors this working groups activities and is a voting member. Further information can be found here: https://sagroups.ieee.org/p1952/

- S&T TCD is committed to the continued development of wireless cellular communications standards including 5G/6G and beyond. S&T actively participates in 3GPP meetings, in coordination with DHS CISA and other U.S. Federal Government agencies. S&T has submitted work items to 3GPP working groups to ensure DHS

component equities are considered in new standards development. Further information can be found here: https://www.3gpp.org/

- DHS S&T TCD participates in the INCITS/Biometrics Technical Committee. This committee develops standards to support interoperability and data interchange among biometric applications, systems, and common file frameworks. Areas of focus are Biometric Vocabulary Harmonization, Biometric Technical Interfaces, Biometric Data Interchange Formats, Technical Implementation of Biometric Systems, Biometric Performance Testing, and Cross -Jurisdictional/Societal Aspects of Biometrics. Standardization efforts encompass Governmental and Commercial applications, both domestic and international. Specific activity includes:
- S&T TCD serves as editor for ISO/IEC 19795-10: Biometric Performance Testing and Reporting – Part 10: Quantifying Biometric System Performance Variation Across Demographic Groups. This standard will help establish the appropriate guidance to help government and industry organizations that deploy biometric technology to perform appropriate testing and report results. Most recently, on January 8, 2024, S&T completed a successful adjudication of national body comments received on Draft International Standard (DIS) 19795-10 within SC37 WG5. The accepted disposition of comments has been shared with ISO. Experts from USA, France, Australia, Germany, Japan, and FIDO Liaison contributed to the discussion. The next step is to prepare the Final Draft International Standard (FDIS) document by April which will be discussed at the next ISO meeting in June leading to a published standard by August 2024. https://www.iso.org/standard/81223.html

- DHS S&T TCD participates in ISO/IEC JTC 1/SC 37. The scope of ISO/IEC JTC 1/SC 37 is the "Standardization of generic biometric technologies pertaining to human beings to support interoperability and data interchange among applications and systems." ISO/IEC JTC 1/SC 37 is made up of six working groups (WGs), each of which carries out specific tasks in standards development within the field of biometrics. More specifically, DHS S&T participates in SC37/WG 5, "Biometric Testing and Reporting". Specific activity include:
    - ISO/IEC 30107, Information Technology – Biometric Presentation Attack Detection. This standard established terms and definitions that are useful in the specification, characterization, and evaluation of presentation attack detection methods. https://www.iso.org/standard/83828.html

- DHS S&T TCD participates in ISO/IEC JTC 1/SC17. The scope of ISO/IEC JTC/SC17 is "Cards and security devices for personal identification". DHS S&T actively participates in WG10, "Motor Vehicle Driver License and Related Documents (mDL). Specific projects include:
    - S&T TCD participates in ISO/IEC 23220 Issuance and Provisioning – binding the ID record to mobile devices. This standard specifies generic system architectures

and generic life-cycle phases of mobile eID systems in terms of building blocks for mobile eID system infrastructures. It standardizes interfaces and services for mdoc apps and mobile verification applications. https://www.iso.org/obp/ui/en/#iso:std:iso-iec:23220:-1:ed-1:v1:en.

- Specific activity includes: S&T TCD sponsored NIST development of a reference reader implementation for interoperability testing based on the international standard ISO/IEC 18013-5, which describes the interface, data structure and security protocols for interoperable mDL solutions. The standard established 1) interface specifications between mDL and mDL reader and 2) interface specification between mDL reader and issuing authority infrastructure. https://www.iso.org/standard/69084.html

- S&T TCD sponsored NIST development of a reference reader implementation for interoperability testing based on the international specification ISO/IEC 18013-7, which describes mDL add-on functions including the use online which is expected to the majority of interactions. S&T is partnering with the NIST National Cybersecurity Center of Excellence to accelerate adoption of identities on mobile devices by demonstrating cross-sector use cases cooperatively. Details can be found https://www.nccoe.nist.gov/projects/digital-identities-mdl. This specification can be found at https://www.iso.org/standard/82772.html

- S&T TCD participates in ISO/IEC 30107, Information Technology – Biometric Presentation Attack Detection. This standard established terms and definitions that are useful in the specification, characterization and evaluation of presentation attack detection methods. https://www.iso.org/standard/83828.html

- S&T TCD participates in the ANSI NIST ITL Standards Update, focused on the data format for the interchange of fingerprint, facial and other biometric information. https://www.nist.gov/programs-projects/ansinist-itl-standard

TSA

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

USCG

The Coast Guard (USCG) supports the provisions of OMB Circular A-119 and maintains one of the most robust standards programs in the Federal Government to meet our regulatory and research and development objectives. The Coast Guard remains committed to developing and adopting nationally and internationally recognized standards as a means to improve maritime safety, security, and marine environmental protection, and to promote the competitiveness of U.S. businesses in the global marketplace. Incorporating voluntary consensus standards helps the Coast Guard fulfill its regulatory functions more efficiently, develop the Government/industry partnerships crucial to stewardship, and gain valuable public feedback necessary for effective policy development. The Coast Guard aggressively supports a broad range of standards development organizations through funding, active engagement, and membership on numerous committees. This vigorous participation helps us raise and resolve genuine issues related to public safety, national security, and preservation of the marine environment with our industry partners.
The Coast Guard participates in the DHS Standards Council and the Interagency Council on Standards Policy. We also regularly collaborate with the National Institute for Standards and Technology Standards Directorate on training and conformity assessment issues. For additional information, access the link to the Director of Commercial Regulations & Standards, the agency's standards-specific website(s) where information about agency standards and conformity assessment related activities are available: http://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Commercial-Regulations-standards-CG-5PS)

The government-unique standards that are currently in use by USCG are as follows:

Document Number	*Document Title/Designation*	*Publication Date*	*New in 2023? (Yes or No)*	*Notes*
NA	Standard Alphabets for Highways Signs	1966	No	Federal Highway Administration (FHWA)
NA	The Ship's Medicine Chest and Medical Aid at Sea	1984	No	Dept. of Health and Human Services
55DC	Guideline: Codes For Named Populated Places, Primary County Divisions, And Other Locational Entities of the United States and Outlying Areas	1987	No	U.S. Department of Commerce
ZZ-H-451f	Hose, Fire, Woven-jacketed Rubber - or Latex or Rubber-Coated Fabric-lined, with couplings	1984	No	General Services Administration

MIL-C-24640A	Cables, Light Weight, Electric, Low Smoke, for Shipboard Use, General Specification for Supplement 1	1995	No	Department of Defense
MIL-C-24643A	Cables and Cords, Electric, Low Smoke, for Shipboard Use, General Specification for, Amendment 2	1996	No	Department of Defense
MIL-DTL-24640C	Cables, Lightweight, Low Smoke, Electric, for Shipboard Use	2011	No	Department of Defense
MIL-DTL-24643C	Cables, Electric, Low Smoke Halogen-Free, for Shipboard Use, General Specification for	2011	No	Department of Defense
MIL-W-76D	Wire and Cable, Hook-Up, Electrical, Insulated, General Specification for Amendment 1	2003	No	Department of Defense
MIL-HDBK-299(SH)	Cable Comparison Handbook Data Pertaining to Electric Shipboard Cable	1991	No	Naval Sea Systems Command (NAVSEA)
MIL-DTL-24643C	Detail Specification Cables, Electric, Low Smoke Halogen-Free, for Shipboard Use, General Specification for	2011	No	Department of Defense
MIL-C-24640A	Cables, Light Weight, Electric, Low Smoke, for Shipboard Use, General Specification for Supplement 1	1995	No	Department of Defense
MIL-C-24643A	Cables and Cords, Electric, Low Smoke, for Shipboard Use, General Specification for, Amendment 2	1996	No	Department of Defense
MIL-W-76D	Wire and Cable, Hook-Up, Electrical, Insulated, General Specification for Amendment 1	2003	No	Department of Defense

MIL-C-24640A	Cables, Light Weight, Electric, Low Smoke, for Shipboard Use, General Specification for Supplement 2	1995	No	Department of Defense
MIL-C-24643A	Cables and Cords, Electric, Low Smoke, for Shipboard Use, General Specification for, Amendment 3	1996	No	Department of Defense
MIL-HDBK-299(SH)	Military Handbook Cable Comparison Handbook Data Pertaining to Electric Shipboard Cable Notice 1	1991	No	Naval Sea Systems Command (NAVSEA)
FF 4-72.16	Standard for Mattress Flammability	2010	No	U.S. Department of Commerce
None	FCC Type Accepted Category 1, 406 MHz EPIRB	None	No	Federal Communications Commission (FCC)
304-2	Electrical Cable, Ratings and Characteristics	1987	No	Naval Sea Systems Command (NAVSEA)
PHS 84-2024	The Ship's Medicine Chest and Medical Aid at Sea	1984	No	Public Health Service
Federal Test Method Standard No. 191a, Method 5304.1	Abrasion Resistance of Cloth, Oscillatory Cylinder (Wyzenbeek) Method	1971	No	Department of Defense
595C	Colors Used in Government Procurement.	2008	No	General Services Administration
MIL-C-17415F	Military Specification, Cloth, Coated, and Webbing, Inflatable Boat and Miscellaneous Use	1989	No	Department of Defense
MIL-P-17549D(SH)	Military Specification, Plastic Laminates, Fibrous Glass Reinforced, Marine Structural	1981	No	Department of Defense
MIL-R-21607E(SH)	Military Specification, Resins, Polyester, Low Pressure Laminating, Fire-Retardant	1990	No	Department of Defense
MIL-C-19663D	Military Specification, Cloth, Woven Roving, For Plastic Laminate	1988	No	Department of Defense
MIL-R-21607E(SH)	Military Specification, Resins, Polyester, Low Pressure Laminating, Fire-Retardant	1990	No	Department of Defense

Special Publication 440	Color, Universal Language and Dictionary of Names	None	No	National Bureau of Standards (NIST)
751a	Stitches, Seams, and Stitchings	1965	No	Department of Defense
Federal Test Method Standard No. 191A	Textile Test Methods	1978	No	Department of Defense
Federal Test Method Standard No. 191A, Method 5100	Strength and Elongation, Breaking of Woven Cloth; Grab Method	1978	No	Department of Defense
Federal Test Method Standard No. 191A, Method 5132	Strength of Cloth, Tearing; Falling-Pendulum Method	1978	No	Department of Defense
Federal Test Method Standard No. 191A, Method 5134	Strength of Cloth, Tearing; Tongue Method	1978	No	Department of Defense
TSO-C13d	Federal Aviation Administration Standard for Life Preservers	1983	No	Federal Aviation Administration
Federal Test Method Standard No. 191A, Method 5804.1	Weathering Resistance of Cloth; Accelerated Weathering Method	1978	No	Department of Defense
Federal Test Method Standard No. 191A, Method 5762	Method 5762, Mildew Resistance of Textile Materials; Soil Burial Method	1978	No	Department of Defense
MIL-L-24611	Life Preserver Support Package For Life Preserver, MK 4	1982	No	Department of Defense
42S5	Screws, machine, cap and set, and nuts	1999	No	Navy Department Specifications
43B11	Bolts, nuts, studs, and tap-rivets (and materials for same)	None	No	Navy Department Specifications

EPA/600/R-10/146	Generic Protocol for the Verification of Ballast Water Treatment Technologies	2010	No	US Environmental Protection Agency.
L-S-300 B	Sheeting and Tape, Reflective: Nonexposed Lens, Adhesive Backing	1974	No	General Services Administration
Federal Test Method Standard 141a	Paint, Varnish, Lacquer and Related Materials; Methods of Inspection, Sampling and Testing	1979	No	General Services Administration
Federal Test Method Standard 141a, Method 6141	Paint, Varnish, Lacquer and Related Materials; Methods of Inspection, Sampling and Testing	1980	No	General Services Administration
Federal Test Method Standard 141a, Method 6142	Paint, Varnish, Lacquer and Related Materials; Methods of Inspection, Sampling and Testing	1980	No	General Services Administration
Federal Test Method Standard 370	Instrumental Photometric Measurements of Retroreflective Materials and Retroreflective Devices	1977	No	General Services Administration
MIL-R-21607 D	Resins, Polyester, Low Pressure Laminating, Fire-retardant	1979	No	Department of Defense
CCC-C-426 D	Cloth, Drill, Cotton	1979	No	General Services Administration
CCC-C-443 E	Cloth, Duck, Cotton (Single and Plied Filling Yarns, Flat)	1979	No	General Services Administration
MIL-C-43006 E	Cloth and Strip Laminated, Vinyl Nylon High Strength, Flexible	1979	No	Department of Defense
L-P-375 C	Plastic Film, Flexible, Vinyl Chloride	1979	No	Department of Defense
MIL-C-17415 E	Cloth, Coated, and Webbing, Inflatable Boat and Miscellaneous Use	1979	No	Department of Defense
MIL-C-17415 E	Cloth, Coated, and Webbing, Inflatable Boat and Miscellaneous Use	1979	No	Department of Defense
Federal Test Method Standard 370	Instrumental Photometric Measurements of Retroreflective Materials and Retroreflective Device	1979	No	General Services Administration

Federal Test Method Standard 141a, method 4010	Federal Standards and Test Methods Length-Weight Relation; Thread; Yards Per Pound (m/kg)	1978	No	General Services Administration
Federal Test Method Standard 141a, method 4100	Strength and Elongation, Breaking; and Tenacity; of Thread and Yarn; Single Strand	1978	No	General Services Administration
Federal Test Method Standard 141a, method 5804	Weathering Resistance of Cloth; Accelerated Weathering Method	1978	No	General Services Administration
V-T-295E	Thread, Nylon	1986	No	General Services Administration
MIL-T-43548C	Thread, Polyester Core: Cotton-, Rayon-, or Polyester-Covered	1986	No	Department of Defense
MIL-T-43624A	Thread, Polyester, Spun.	1982	No	Department of Defense
MIL-R-7575C	Military Specification, Resin, Polyester, Low-Pressure Laminating	1966	No	Department of Defense
MIL-R-24719(SH)	Military Specification, Resins, Vinyl Ester, Low Pressure Laminating	1989	No	Department of Defense
ZZ-H-451f	Hose, Fire, Woven-Jacketed Rubber or Cambric-Lined, with Couplings, F	1984	No	Department of Defense
MIL-P-21929B	Plastic Material, Cellular Polyurethane, Foam-in-Place, Rigid (2 Pounds per Cubic Foot)	1991	No	Department of Defense
MIL-P-21929C	Plastic Material, Cellular Polyurethane, Foam-in-Place, Rigid (2 and 4 pounds per cubic foot)	1991	No	Department of Defense
MIL-R-21607E(SH)	Resins, Polyester, Low Pressure Laminating, Fire Retardant	1990	No	Department of Defense

USCIS

In FY22, the United States Citizenship and Immigration Services (USCIS) Chief Data Office and USCIS Chief Information Officer signed a memorandum to implement data standards across the USCIS Enterprise. Standards implementation will occur as part of a multi-step process and commenced with an information exchange inventory to define what data moves among systems at USCIS. USCIS has developed and is implementing data standards in its technology systems, which are used to perform the mission. USCIS has 117 approved data standards, 28 of which are DHS-approved data standards. USCIS participates in the Office of Homeland Security Statistics (OHSS) Immigration's Data Integration Initiative (IDII) to help promote consistent data standards across the department. USCIS standards are maintained locally and made available via the Reference Data as a Service (RefDaaS) platform, USCIS SharePoint site and a DHS-hosted instance of Collibra.

USSS

The United States Secret Service (USSS) uses several Voluntary Consensus Standards (ISO, ASTM, MIL SPEC, IBC Building Codes, etc.) to conduct the development, testing and procurement of equipment and technology and facilities. The USSS has participated in the development of Voluntary Consensus Standards. USSS does not maintain a standards-specific website. The USSS does not utilize Government Unique Standards.

2. ***Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. 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):***

   NOTE: Please list ALL government-unique standards you are using currently, and also indicate on your list which of the standards are new in FY2023:

There are **no** government-unique standards that are **new** in FY2023.

The following Components responded with no inputs for the FY2023 reporting timeframe:

- OCIO
- OGC
- OCFO
- CPO
- OCSO
- S&T Chief Scientist

Attachment 2

Component Standards Executive Updated for FY24

Component	Title	Name	Email	Phone
CISA	Associate Chief for Strategic Technology	Dr. Garfield Jones	Garfield.Jones@cisa.dhs.gov	202-941-7957
CBP	Chief Technology Officer	Sunil Madhugiri	sunil.madhugiri@cbp.dhs.gov	571-242-1810
CWMD	Chief Data Officer	Lon Gowen, Ph.D.	lon.gowen@hq.dhs.gov	202-731-7316
FEMA	Program Analyst	Charles Baker	charles.baker@fema.dhs.gov	202-600-1885
FLETC	Deputy Assistant Director/Acting Chief Financial Officer	Ms. Brandi Crusan	Brandi.Crusan@fletc.dhs.gov	912-554-4479
ICE	Chief Technology Officer	Richard J. Clark	richard.j.clark@ice.dhs.gov	202-732-7124
PARM	Systems Engineer	Everett Rhoades	Everett.Rhoades@hq.dhs.gov	202-343-4518
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Department of Commerce (DOC) Fiscal Year 2023 Agency Report

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

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

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

Together with other branches of DOC, the five branches listed in this report support the strategic goals of enhancing U.S. leadership, accelerating job creation, strengthening U.S. economic and national security, fulfilling constitutional requirements, and delivering excellent customer service. The following report compiles information about how these organizations used their engagement in voluntary consensus standards and conformity assessment activities during FY2023 to support these critical mission areas in fulfillment of the Office of Management and Budget (OMB) and the National Technology Transfer and Advancement Act (NTTAA) reporting requirements.

<u>The U.S. Census Bureau (Census Bureau)</u>

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

The 2023 Census Bureau geographic products include TIGER/Line shapefiles for the most current legal, statistical, and administrative boundaries and names, as collected by the Census Bureau. These include boundaries for urban areas, congressional districts, state legislative districts, and other geographic areas. Harvesting the metadata to the GeoPlatform.gov and

Data.gov using ISO metadata standards is a requirement of the Geospatial Data Act (GDA) of 2018 for the Census Bureau's National Geospatial Data Asset (NGDA) datasets.

The Census Bureau led the development of ISO 19160-3:2020, Addressing – Part 3: Address data quality and was actively involved in the development of ISO 19160-2, Addressing - Part 2: Assigning and maintaining addresses for objects in the physical world (see item 9 below). These standards and programs, in addition to ongoing research and innovation activities, were designed to improve public access, discoverability, integration, data sharing, and to support the open government initiative and the provisions of OMB Circular A-119.

Standards Development and Policies: In 2023, the following activities exemplified the Census Bureau's direct application of standards policies, membership in standards bodies, ISO standards licensing, and continued development of voluntary consensus standards to implement within the GSP and its geospatial data products.

1. Commerce continues to provide leadership to the United Nations Committee of Experts on Global Geospatial Information Management (UN-GGIM), helping to promote innovation, leadership, frameworks, and partnerships to enhance geospatial information management globally. The Census Bureau is the appointed head of the U.S. Delegation to the UN-GGIM and Co-Chair for the High-level Group on the Integrated Geospatial Information Framework (IGIF). The IGIF guides country-specific action plans for policies, development, endorsement, adoption, implementation, and/or use of standards to facilitate the interoperability of geospatial information. The IGIF published the *UN-IGIF Part 2 Implementation Guide* with specific guidance, options, and actions for each of the nine strategic pathways, including standards. In addition, *A Guide to the Role of Standards in Geospatial Information Management* is available online to increase awareness of the benefits of a standards-based approach to geospatial data management to contribute to innovation, new technologies, and data sources to support the Sustainable Development Goals (SDGs).
2. The Commerce Geospatial Working Group (CGWG) published the Commerce Geospatial Strategy (2021-2024) and the associated Commerce Geospatial Strategic Action Plan. In 2023, DOC continued progress in meeting the GDA requirements, including monthly reporting to DOC's Chief Data Officer and DOC's Data Governance Board on key Commerce Geospatial Strategic Action Plan milestones and accomplishments. These documents refer to open international standards, standards initiatives, metadata standards implementation, and standards development to support enhanced interoperability and equitable access to all DOC geospatial data users.
3. The Commerce Geospatial Standards Users' Group (CGSUG) includes members from the Census Bureau, the National Oceanic and Atmospheric Administration (NOAA), and the National Institute of Standards and Technology (NIST) and continues to leverage geospatial expertise and innovation in standards in FY23. This group met quarterly to raise awareness on critical geospatial topics and activities pertaining to

standards. The CGSUG has developed an agency repository to hold supporting metadata and standards research and meeting documentation, participated in voluntary consensus standards development, collaborated with the OGC, and participated in discussions on best practices for metadata standards and compliance.

4. Census Bureau staff participate in geospatial standards development through the International Committee for Information Technology Standards (INCITS) Technical Committee GIS - Geographic Information Systems (INCITS-GIS) and the U.S. Technical Advisory Group to the ISO Technical Committee 211 Geographic information/Geomatics (TC 211).
5. The Census Bureau's NGDA datasets represent a portfolio of geospatial datasets derived from the MAF/TIGER System. The Census Bureau's TIGER/Line shapefiles for these NGDA datasets are accessible by the public and discoverable on Census.gov, GeoPlatform.gov, and Data.gov. Each year, over 33,000 metadata files representing the Census Bureau's NGDA datasets are harvested to these open data portals, adhere to FAIR principles (Findable, Accessible, Interoperable, Reusable), and utilize ISO metadata standards (listed below in item 7).
6. In FY23, members of the Census Bureau Geospatial Standards Working Group (CBGSWG) provided oversight for implementing geospatial standards for Census Bureau products and services.
7. The Census Bureau submitted responses to the FGDC for the upcoming 2024 update to the NGDA Baseline Standards Inventory Survey (NBSI) and identified fourteen (14) critical ISO standards that are applied to the NGDA datasets in the FGDC's Governmental Units, and Administrative and Statistical Boundaries Theme portfolio. The Census Bureau maintains annual subscriptions to these and multiple standards from the ANSI. The Census Bureau staff accesses all licensed ISO standards from the Standards Connect portal provided by ANSI. The following ISO standards and amendments were documented in FY23 for the NBSI update and added to Governmental Units Geospatial Standards page on the Governmental Units Theme community hub site on the GeoPlatform:

- 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 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.
- ISO 19103:2015 (R2002) Geographic information – Conceptual schema language.
- ISO 19107:2019 (2023) Geographic information - Spatial schema.

- ISO 19108:2002 (R2018) Geographic information - Temporal schema.
    - ISO 19108/Cor1:2006 (R2020) Geographic information - Technical Corrigendum 1.
- INCITS/ISO 19110:2016 [R2018] Geographic information - Methodology for feature cataloging.
- INCITS/ISO 19111:2019/AM1:2021 (2022) Geographic information - Referencing by Coordinates - Amendment 1.
- INCITS/ISO 19115-2:2019/AM1:2022 (2022) Geographic information – Metadata – Part 2: Extensions for acquisition and processing - Amendment 1.
- ISO 19136-1:2020 Geographic information – Geography Markup Language (GML) - Part 1: Fundamentals.
- INCITS/ISO/TS 19139-2:2012 (2017) Geographic information - Metadata XML schema implementation - Part 2: Extensions for imagery and gridded data.
- INCITS/ISO 19157:2013/AM1:2018 (2020) Geographic information – Data quality - Amendment 1: Describing data quality using coverages.

8. The following FGDC Standards have been established for the thirty-one (31) Census Bureau NGDA Datasets within the Transportation Theme and Governmental Units, and Administrative, and Statistical Boundaries Theme portfolios in accordance with the Geographic Information Framework Data Standard established by the FGDC for seven data themes within the National Spatial Data Infrastructure (NSDI). These standards were initially developed through the Geospatial One-Stop e-Government initiative.

    - Geographic Information Framework Data Content Standard, Part 5: Governmental unit and other geographic area boundaries, FGDC-STD-014.5-2008, https://www.fgdc.gov/standards/projects/framework-data-standard/GI-framework-data-standard-Part5.
    - Geospatial Positioning Accuracy Standards Part 3: National Standard for Spatial Data Accuracy FGDC-STD-007.3-1998, https://www.fgdc.gov/standards/projects/FGDC-standards-projects/accuracy/part3/chapter3.
    - United States Thoroughfare, Landmark, and Postal Address Data Standard, FGDC-STD-016-2011, https://www.fgdc.gov/standards/projects/address-data.

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

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

International Trade Administration (ITA):

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

10. In FY2023, ITA participated in a variety of trade-related international standards activities, including standards development, policy dialogues, and capacity building efforts. ITA experts participated in the International Electrotechnical Commission (IEC) Systems Committee for Smart Manufacturing, International Organization for Standardization (ISO)/ Technical Committee (TC) 199 on Safety and Machinery, TC 313 on Packaging Machinery, and TC 347 on Data-driven agrifood systems through ITA's Market Development Cooperator Program (MDCP). ITA regularly notifies relevant U.S. stakeholders about opportunities to participate in new standards development activities that might have trade implications with the aim of preventing future market access issues for U.S. exporters. In FY2023 ITA worked with NIST, the National Telecommunications and Information Administration (NTIA), and the Department of State to publish a monthly newsletter highlighting international standards development activities in critical and emerging areas where U.S. engagement could support U.S. industry.
11. In FY2023 ITA was part of interagency teams addressing standards policy and development in the 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, greenhouse gas emissions, cybersecurity, autonomous and electric vehicles, and conformity assessment. ITA engaged on standards issues with the ASEAN Consultative Committee on Standards and Quality (ACCSQ), including organizing workshops and discussions on advanced manufacturing and digital trade standards – particularly those related to

cybersecurity and promoting digital trust - and participated in work on standards for critical and emerging technologies through the Quad (Australia, India, Japan, and U.S.) including on Artificial Intelligence (AI) and advanced communications.

12. ITA participated in ongoing bilateral engagement on standards issues with various trading partners including through the U.S.-Brazil Commercial Dialogue, the U.S.-Singapore Partnership for Growth and Innovation (PGI), and the U.S.- European Union (EU) Trade and Technology Council (TTC), among others. ITA maintained Standards Attaché postings in Beijing, Brussels, Johannesburg, Mexico City, Riyadh, and Sao Paulo.
13. ITA staff serve as part of the U.S. delegation headed by the Office of the U.S. Trade Representative (USTR) to the World Trade Organization's (WTO's) Committee on Technical Barriers to Trade (TBT) that addresses specific standards-related trade concerns. ITA supported USTR in pursuing standards and conformity assessment-related trade concerns on the floor of the WTO TBT Committee against a number of countries in FY2023, including but not limited to China, India, Indonesia, and the European Union. During FY2023, ITA participated as part of the U.S. delegations for Trade and Investment Framework Agreements (TIFA) with Saudi Arabia, Egypt, and Taiwan, and in collaborative discussions with Kenya on standards as part of the Strategic Trade and Investment Partnership (STIP). ITA regularly works with U.S. industry to raise concerns regarding compliance by our trading partners with trade agreement commitments found in the WTO TBT Agreement and applicable Free Trade Agreement (FTA) TBT chapters.
14. Finally, ITA co-manages the Industry Trade Advisory Committee on Standards and Technical Trade Barriers (ITAC 15) with USTR which provides input to the Secretary of Commerce and USTR on standards-related policy matters.
15.

National Institute of Standards and Technology (NIST)

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

As specified in the NTTAA, in authorizing legislation, and in OMB Circular A-119, NIST, through its Standards Coordination Office (SCO), assists and guides federal agencies in leveraging voluntary consensus standards and private sector conformity assessment mechanisms in their programs, procurement, and regulatory activities. SCO chairs the Interagency Committee on Standards Policy (ICSP) and works closely with federal agencies to reduce unnecessary duplication and complexity in standards and conformity assessment practices. SCO provides consultation and advice to other Federal agencies in implementing conformity assessment

programs, and holds leadership roles in ANSI governance, policy, and program oversight committees. SCO also hosts www.Standards.gov to serve as a standards and conformity assessment related resource for Federal agencies, industry, and the public.

On May 4, 2023 the Biden-Harris Administration Released the United States Government's National Standards Strategy for Critical and Emerging Technology (USG NSSCET) to strengthen U.S. leadership and competitiveness in standards for advanced technologies that are critical to the nation's economy and national security. This strategy will help accelerate private sector-led standards efforts for CETs, contributing to interoperability, facilitating access to global markets, and ensuring U.S. competitiveness and innovation. NIST is leading implementation of the strategy across U.S. Government to implement objectives focused on investment, participation, workforce, and integrity, and inclusivity.

5G Network Security

NIST contributes to 5G standards development organizations to improve the security and resilience of 5G mobile networks. NIST participates in the 3GPP's SA3 working group to modernize the cryptographic protocols used in 5G networks. Through participation in these 5G security-focused standards setting groups, NIST provides contributions and impact specifications relevant to our various areas of cybersecurity expertise. Some of these areas include cybersecurity risk management, identity and access management, and cryptography, including quantum safe cryptography.

Artificial Intelligence

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

Automotive Industry

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

NIST is a member of the U.S. EU Trade and Technology Council WG 1 Subgroup Megawatt Charging Systems for Heavy-duty Recharging Points. Both the U.S. and EU industry stakeholders have been a part of creating the Megawatt Charging System (MCS) white paper concept for the charging of electric heavy-duty vehicles. The same stakeholders are working within SAE, IEC and ISO committees who are critical for the rollout of dedicated e-mobility infrastructure. The ISO 15118 standard for vehicle-to-grid communication has been identified as a minimum requirement for vehicle charging in the EU and U.S., recognizing that solutions may be also possible among private sector operators.

These efforts will ensure that stakeholders will benefit from fully compatible technical specifications, reducing both manufacturing and deployment costs and thus facilitating transatlantic cooperation for e-mobility to become mainstream.

Biotechnology

NIST has participated in ISO TC276 Biotechnology since its inception in 2013. NIST served as the convenor of WG3 on analytical methods until it became a sub-committee (SC1) under TC276 in January 2024. NIST staff now serve as the Chair and Secretariat of TC276/SC1. NIST has several staff in leadership roles throughout the committee to include convenors, secretaries, and project leaders. ISO TC 276 develops standards and reports addressing biobanks and bioresources, analytical methods, bioprocessing, data processing, and metrology related to biotechnology. NIST also manages and chairs the U.S. TAG to ISO TC 276 on Biotechnology and the U.S. TAG to ISO TC276/SC1 on analytical methods.

Blockchain

NIST actively participates and holds leadership positions in ISO TC 307 on Blockchain and Distributed Ledger Technologies and its US mirror committee. NIST has contributed to ISO 22739 - Blockchain and distributed ledger technologies — Vocabulary. NIST staff has been instrumental in the launch of a US led project on Physical Assets disposition: ISO/AWI 20435 Representing Physical Assets using Non-Fungible Tokens. NIST is very active in and several other projects on identity, security, and interoperability, including a collaboration on digital currencies that is synchronized with interagency colleagues active in ISO TC 68 on Financial Services.

Cyber Infrastructure

NIST played key leadership roles in support of cyber infrastructure standardization. A NIST representative served as the INCITS Subcommittee Vice Chair for ISO/IEC JTC 1 SC 38, the WG 3 Ad-Hoc Chair within SC 38, and the SC 38 Advisory Group Stakeholder Engagement Chair. A NIST representative also served as Head of Delegation for the Spring 2023 SC 38 plenary meetings. NIST served as Chair of the Industry Internet of Things (IoT) (II) Consortium Architecture and Patterns Task Group and various draft standards within the II Consortium. In addition, NIST actively participated in ISO/IEC JTC 1 SC 41 (IoT and Digital Twins) WG 3 activities, served as lead architect on ISO/IEC 30141 Internet of Things Reference Architecture ed2,

participated in SC 7 (Software and Systems) WG 42 (Architecture) and served on Advisory Group 8, also within ISO JTC 1, on Meta Reference Architecture and Reference Architecture for Systems Integration. NIST also participates in the development of ISA/IEC 62443 which covers cybersecurity for industrial systems. NIST sits on the ISA99 committee which authors the standards and leads the joint team which is looking at industrial internet of things and industrial cloud services.

Cybersecurity Risk Management

NIST contributes to various international standards development efforts related to cybersecurity risk management. The latest revision of ISO/IEC 27002 information security controls was published in February 2022 and contains attributes and concepts that align with the functions of the NIST Cybersecurity Framework. NIST serves as editor for a project (ISO/IEC 27028) developing guidance on using the attributes in ISO/IEC 27002 and will remain active within ISO/IEC JTC 1 SC 27 to help promote alignment between ISO standards and NIST resources, including the transition to the NIST Cybersecurity Framework Version 2.0. NIST also served as co-editor of recently published ISO/IEC 27070 - *Security techniques — Requirements for establishing virtualized roots of trust*. NIST participated in revisions to ISO/IEC 27017 - *Security techniques — Code of practice for information security controls based on ISO/IEC 27002 for cloud services* and ISO/IEC 27008 - *Security techniques — Guidelines for the assessment of information security controls*.

Cryptography and Post-Quantum Cryptography

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

Cryptographic Module Validation

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

Digital Evidence and Forensic Science

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

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

Forensic Science

NIST served as a member-at-large on the Forensic Standards Science Board of the Organization of Scientific Area Committees (OSAC), as Vice Chair for the OSAC Digital Evidence Subcommittee, as the statistician on the OSAC Seized Drug Subcommittee, as the statistician on the OSAC Speaker Recognition Subcommittee, as the statistician on the OSAC Toxicology Subcommittee, and as the statistician on the OSAC Crime Scene Investigation and Reconstruction Subcommittee. NIST also served as the Liaison to the OSAC Statistics Task Group and on numerous OSAC Task Groups responsible for drafting individual standards, maintaining terminology, and improving OSAC operations. NIST served as Liaison to the Scientific Working Group on Digital Evidence (SWGDE) Executive Committee and as Project Lead on Quality Management for SWGDE. NIST participated in the ASTM E30 committee on Forensic Sciences.

Identity Management and Authentication

NIST participates in several committees and standardization initiatives related to identity management and authentication, including ISO/IEC 24760 series - A framework for identity management, ISO/IEC 23220 - Building blocks for identity management via mobile devices series, ISO/IEC 18013 Part 5 - Mobile driving license (mDL) application and Part 7 - Mobile driving license (mDL) add-on functions and Web Incubator Community Group where web interface is being defined for digital identities. NIST is also engaged in the World Wide Web Consortium's (W3C) Federated Credential Management Community Group and participates across multiple working groups within the Open ID Foundation and the FIDO Alliance.

Interoperable Health Information

NIST held leadership positions within Health Level Seven (HL7) as Conformance Work Group Co-chair, Healthcare Device Work Group Co-chair, Version 2 Management Board Member, Terminology Services Management Work Group, and HL7 Unified Terminology Governance Subcommittee and Terminology Infrastructure Work Group. A NIST representative held a leadership position as the SDO IEEE-Standards Association Vice-Chair for the ISO/IEEE 11073 Point-of-Care Device Work Group. A NIST representative served as the test lead for Integrating Healthcare Enterprise (IHE) devices and participated in IHE-DEV technical and planning committees and International "Connectathon" events as a lead test monitor. NIST Representatives held testing advisory positions and developed and supported the Department of Health and Human Services (HHS) Centers and Disease Control and Prevention (CDC), American Immunization Registry Associations (AIRA) Measurement for Assessment & Certification Advisory Workgroup (MACAW), Association of Public Health Laboratories (APHL) and the HHS Office of the National Coordinator (ONC).

Internet Protocols

NIST continues to advance protocols for secure Internet routing in the Internet Engineering Task Force (IETF). NIST has provided standards contributions on core protocols as well as being active in operational focused groups in the IETF. NIST also participates in IETF working groups focused on the Domain Name System (DNS) and authentication and authorization protocols used to support zero trust.

Internet of Things (IoT)

NIST participates within ISO/IEC JTC 1/SC 41 Internet of things and digital twin to contribute on a variety of IoT related standards. NIST is actively engaged within JTC 1 SC 27 WG 4 on IoT Security activities, including significant contributions to ISO/IEC 27404 - Cybersecurity labelling framework for consumer IoT and ISO/IEC 27402 - IoT security and privacy - Device baseline requirements. Within IETF, NIST co-chairs the Software Updates for Internet of Things (SUIT) working group focused on designing a firmware update solution suitable for tiny IoT devices.

Privacy

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

Quantum technologies

NIST has contributed to the establishment of IEC/ISO/Joint Technical Committee (JTC) 3 Quantum technologies and has also been selected as the administrator of the US Technical Advisory Group (TAG), whose job it is to facilitate US consensus positions for all international developing standards and ballots. The US is among 26 participating countries, that are supplying active experts, and 9 observing countries. The first Plenary meeting was held on 28-30 May 2024 in Seoul, Korea. The result of this meeting was the establishment of 6 Adhoc Groups (AHG) to explore approaches to quantum standards development in quantum terminology and metrics, quantum computing and simulation, quantum secure communication, quantum sensors, quantum enabling technologies, and quantum random number generation, as well as an advisory group on Strategic planning. The United States is convening AHG 2

Quantum terminology and metrics. All AHGs are submitting recommendations to be further discussed during the 2nd Plenary meeting in October in Edinburgh, UK.

Usability

NIST contributed to standards on the testing of usability-related information. As experts in Joint Working Group 28 of ISO/IEC JTC 1 SC 7 on software and systems engineering, NIST participated in writing the ISO TC 159 SC 4 and ISO 2506x series of standards on Common Industry Formats (CIF) for Usability Reports. NIST also worked on revisions for the following documents: ISO/TR 25060 – General framework for usability-related information; ISO 25062 – Reporting usability evaluations and ISO 25066 – Evaluation report. A NIST representative is Head of Delegation for the U.S. for PC 337 WG 1, which recently completed a final draft standard, Guidelines for the promotion and implementation of gender equality. NIST staff is also involved with ISO/IEC JTC 1 SC 32 Data Management Working Group.

Virtual Reality (Immersive Visualization)

NIST staff participate in working groups of The Khronos Group related to immersive interfaces (OpenXR), advanced rendering (ANARI), and 3D Formats (g1TF). NIST also participated in two sub-groups within the OpenXR working group: namely, the OpenXR tutorial development committee, and the Monado open-source development committee. In addition, NIST recently became a member of the Metaverse Standards Forum (MSF), which is playing a key role in ensuring that the many institutions involved with standards development of the metaverse talk to each other in a productive manner. NIST actively participates in the 3D Asset Interoperability Group there. Finally, NIST was invited to join, and now participates in, the IEEE Metaverse Initiative Steering Committee.

Wireless Body Area Networks

NIST is a voting member of IEEE802.15 and actively participates in the Task Group 6ma (TG6ma). TG6ma is tasked with the revision of the standard IEEE 802.15.6–2012 on Wireless Body Area Networks (BAN). The task group objective is to enhance the dependability of BAN applications in high-density scenarios while coexisting with other wireless systems operating in the unlicensed Ultra-WideBand frequency spectrum. NIST is a contributor to the channel modeling document of TG6ma.

National Oceanic and Atmospheric Administration (NOAA)

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.

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

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

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

- NOAA is an active leader, participant, and contributor to the Federal Geographic Data Committee (FGDC), the lead entity (established by Geospatial Data Act of 2018 (GDA)) for the development, implementation, and review of policies, practices, and standards relating to geospatial data across the Federal government and the National Spatial Data Infrastructure (NSDI), which per Executive Order 12906 (Coordinating Geographic Data Acquisition and Access) is the technology, policies, standards, and human resources necessary to acquire, process, store, distribute, and improve utilization of geospatial data. NOAA leads four NSDI data themes and contributes to many others.
    - NOAA and Census co-led the Department of Commerce's response to the recently completed 2022 Department of Commerce Inspector General's GDA Audit. NOAA's Chief Data Officer is the Senior Agency Official for Geospatial Information. NOAA and Census co-developed an action plan to address the Audit's five recommendations.
- NOAA leads the Integrated Ocean Observing System (IOOS), a part of the Global Earth Observing System of Systems (GEOSS), which ascribes to the GEOSS data sharing

principles as a core capacity. The U.S. IOOS Program Office is organized into two divisions that implement policies, protocols, and standards to implement IOOS and oversee the daily operations and coordination of the System. For more information on IOOS standards, visit the IOOS Data Standards and Requirements webpage.

- NOAA's National Geodetic Survey (NGS) represents the US on the UN Committee of Experts on Global Geospatial Information Management (UN-GGIM)'s Subcommittee on Geodesy (UN SCoG), which developed the Global Geodetic Reference Frame (GGRF). The GGRF includes infrastructure, education, training, governance and the adoption of internationally accepted standards.

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

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

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

- NOAA contributes US expertise to help the global community deal with the meteorological, climatological and hydrological threats via its membership in and engagement with the World Meteorological Organization (WMO), an agency of the

Nations (UN) that serves as the international standardization organization in the fields of meteorology, hydrology, climatology and related environmental disciplines. The WMO's standards and best practices include Technical Regulations, an international framework for standardization and interoperability, which consists of standard and recommended practices and procedures adopted by World Meteorological Congress for universal application by all Members, as well as Guides, which describe practices, procedures and specifications which Members are invited to follow or implement in order to achieve compliance.

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

- NOAA applies standards set by the International Standards Organization (ISO), an independent, non-governmental international organization with a membership of 167 national standards bodies, specifically environmental management standards, to NOAA data. Examples of ISO standards in use in NOAA include:

    - ISO 14721: "Open Archival Information System (OAIS)" which defines the reference model for an open archival information system (OAIS). This standard is the basis for archival activities supporting NOAA environmental data.
    - ISO 26324: "Information and documentation - Digital object identifier system" which specifies the syntax, description and resolution functional components of the digital object identifier system. NOAA assigns unique, resolvable, and persistent identifiers to archival datasets and technical reports. Building upon this standard, NOAA recently developed a report on DOI recommendations for use across NOAA and is in the process of updating its Public Access to Research Results (PARR) Plan to also address DOIs.
    - ISO 19115: "Geographic information – Metadata" which defines the schema required for describing geographic information and services by means of metadata. NOAA participates in the ISO TC211, a committee that focuses on standardization in the field of digital geographic information, and maintains standards for Geographic information/Geomatics.
    - ISO 19139: "Geographic information — XML schema implementation" which defines XML based encoding rules for conceptual schemas specifying types that describe geographic resources. The encoding rules support the UML profile as used in the UML models commonly used in the standards developed by ISO/TC 211.

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

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

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

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

- NA

National Telecommunications and Information Administration (NTIA)

As the manager of federal spectrum and principal advisor to the President on communications and information policy, **the National Telecommunications and Information Administration (NTIA)** engages broadly in next-generation communications issues and standards development. NTIA contributes to the development and application of national and international telecommunication standards by leading, participating in, making technical contributions to, and collaborating with various voluntary national and international telecommunication standards development organizations (SDOs) such as the 3rd Generation Partnership Project (3GPP), the O-RAN ALLIANCE, International Telecommunication Union (ITU-R, ITU-T), the Institute of Electrical and Electronics Engineers (IEEE) Standards Association, WInnForum, Radio Technical Commission for Aeronautics (RTCA), and Alliance for Telecommunications Industry Solutions (ATIS).

In FY 2023, staff from five separate offices of NTIA held 102 positions in 12 standards bodies, including 18 Chair/Co-Chair/Vice-Chair positions. This hard work during FY 2023 contributed to several spectrum policy accomplishments at the ITU World Radiocommunication Conference 2023 (WRC-23) in December 2023. The U.S. delegation advanced spectrum policy for critical federal missions like aviation safety, weather, climate monitoring, and—looking to the future—lunar communication; and for the private sector in support of both licensed and unlicensed services, and in expanding space and satellite services.

- NTIA staff filled key leadership positions in the ITU, including Head of the U.S. Delegation to ITU-T Study Group (SG) 20 (Internet of Things, smart cities and communities); Head of the U.S. Delegation to ITU-R SG1 (Spectrum management), SG3 (Radiowave propagation), and SG7 (Science services); Head of Delegation to SG1 Working Party (WP) 1A; Head of Delegation to SG5 (Terrestrial services) WP 5B and 5C; International Chair of SG5 WP 5A; Deputy Head of Delegation to SG7 WP 7C; International Chair and U.S. Chair of SG3 WP 3K; U.S. Chair of Working Parties 3J, 3K, and 3L; and Chair of Correspondence Groups CG-3L-7 (Radio Noise), CG-3J-11 (Reference Standard Atmospheres), and CG-3K-3M-9 (Aeronautical Propagation).
- Within the Inter-American Telecommunications Commission (CITEL), NTIA holds the Deputy Head of Delegation to the Permanent Consultative Committee II (PCC.II) for Radiocommunications.
- NTIA's Institute for Telecommunication Sciences (NTIA-ITS) established and continues to play a significant role in the Video Quality Experts Group (VQEG), which performs technical validation that is a prerequisite to standardization of video quality metrics and subjective video quality test methods in the ITU-T.

International Telecommunications Union (ITU)

NTIA is one of the primary U.S. Government agencies engaged in the ITU, working closely with colleagues at the U.S. Department of State, Federal Communications Commission, Department

of Defense, and other interested agencies. (Because the ITU is a treaty-based organization, the Department of State acts as the Government's convener of ITU engagement.)

In FY 2023, NTIA's Office of International Affairs (OIA) followed and/or provided inputs to ITU-T Study Groups 3 (Tariff and accounting principles and international telecommunication/ICT economic and policy issues) and 20 (Internet of Things, smart cities and communities), while NTIA-ITS participated in Study Group 12 (Performance, QoS and QoE). NTIA's work in ITU-T focuses on industry-led, bottom-up, consensus-based standards and appropriately working with U.S. government colleagues to help ensure the ITU-T avoids duplication of efforts with other standards development organizations such as 3GPP and IETF.

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

In FY 2023, NTIA-ITS led seven SG3 U.S. Preparatory Meetings, ultimately leading to approval of 23 input contributions, two of which were authored or coauthored by ITS. Topics of interest in FY 2023 were the sharing of new datasets for propagation prediction inputs and agreeing on methods to reduce these sometimes voluminous datasets so that they can be ingested into the various models. Technical efforts in FY 2023 supported an ever-increasing focus on improving the accuracy of calculations, extending the frequency ranges to which ITU-R propagation models apply, and developing new modeling/prediction methods to address the increasingly complex radio environment. NTIA-ITS also participated in SG6 (Broadcasting services).

NTIA's Office of Spectrum Management (OSM), International Spectrum Policy Division (ISPD) participated in and/or led delegations to several ITU-R Study Groups and Working Parties, specifically, SG1 (Spectrum Management), SG 4 (Satellite Systems), SG 5 (Terrestrial Systems), and SG7 (Space Sciences). ISPD staff also participated in the Task Group 6/1 which is addressing broadcasting/broadband sharing in the 470-960 MHz band in Region 1 (Europe, Middle East, Africa). ISPD staff also participated in the ITU Coordination Committee for Vocabulary which works on non-regulatory definitions commonly utilized within the ITU (all three sectors).

3rd Generation Partnership Project (3GPP)

Direct participation by NTIA in the 3rd Generation Partnership Project (3GPP), the leading global consortium developing technical specifications for wireless telecommunications networks, allows NTIA to advance U.S. commercial, economic, and government interests by providing technical input to promote strong unbiased standards that support fair competition in next generation/5G cellular technologies. There is no direct membership to 3GPP; the Partnership project unites seven regional SDOs, each representing a different part of the globe and individual member delegates come to 3GPP via their organization's membership in one of

the regional SDOs; the Alliance for Telecommunications Industry Solution (ATIS) is the North American founding partner. 3GPP is organized into three technical specification groups (TSGs)—the Radio Access Network (RAN), Service & Systems Aspects (SA), and Core Network & Terminals (CT)—each of which is itself composed of multiple Working Groups (WGs) focused on specific TSG subtopics. NTIA technically holds two Individual Memberships (IMs) in 3GPP: one held by the First Responder Network Authority (FirstNet), and one held jointly by NTIA's Office of Policy Analysis and Development (OPAD), ITS, and OIA.

FirstNet's authorizing legislation explicitly tasks the organization with representing the interests of public safety users before domestic and international standards bodies. FirstNet thus represents first responders in 3GPP across the vast majority of 3GPP's Working Groups. FirstNet's focus in 3GPP is to evolve both LTE and 5G Public Safety communication features and enablers to meet First Responder needs. FirstNet's standards team also leads the work relating to LMR (land mobile radio) and LTE/5G interoperability through 3GPP, TIA, and ATIS organizations. Mission-critical services are a key part of 3GPP's work, as evident in 3GPP Releases 12 through 18.

NTIA-ITS and NTIA-OPAD are currently engaged in 3GPP TSGs for RAN and SA at a Plenary level and participate in 3GPP Working Groups for Services (SA WG1) and System Architecture and Services (SA WG2); NTIA-OPAD is engaged in SA and SA WG1; and NTIA-ITS participates in the Working Group for Security and Privacy (SA WG3), as well as RAN WG1, focused on the physical layer for LTE and 5G. NTIA-OSM attends RAN Working Groups 1 and 4. NTIA-OSM's goals are to: gain a more in-depth understanding of 3GPP standards and models used in compatibility studies; monitor 3GPP proposals that have a potential to impact federal operations; identify 3GPP spectrum standards that could be adopted for federal systems; and verify that 3GPP standards are being properly used in domestic and international spectrum sharing studies. In FY 2023, NTIA-ITS continued to brief client federal agencies on 3GPP New Radio and deployment scenarios in response to agency-specific concerns related to spectrum sharing, vehicle-to-everything communication, non-terrestrial networks, unmanned aerial vehicles, and integrated sensing and communication.

ATIS

ATIS is a member-driven organization that develops critical industry standards in information and communications technology (ICT). ATIS' NextG Alliance brings together 80 organizations and over 600 subject matter experts from industry, academia and government to advance North American mobile technology leadership. NTIA-OPAD tracks activities of the NextG Alliance, and FirstNet participates in relevant Working Groups as a NextG Alliance government member and engages in the Alliance's work related to Land Mobile Radio (LMR). FirstNet is also an active participant in the ATIS 3GPP planning meetings.

Telecommunications Industry Association (TIA)

The Telecommunications Industry Association (TIA) acts as a catalyst for the wireless industry to develop and maintain public safety standards for digital equipment and systems through TIA-

102 (also known as Project 25). This initiative is supported by industry, government agencies and public safety communications officials, including the Department of Homeland Security's National Communications System (NCS), the Department of Defense, and NTIA. FirstNet's standards team participates in Project 25 efforts, particularly as related to LMR (land mobile radio) standards interoperability with LTE and 5G mission critical services.

O-RAN ALLIANCE

The O-RAN ALLIANCE was founded in 2018 by a number of large mobile broadband network operators to develop technical specifications for Open Radio Access Network (Open RAN, or ORAN) architecture. The O-RAN ALLIANCE initially discouraged membership by governmental entities, but after extensive discussion in 2022, governmental agencies are now permitted to join as members. In FY2023, NTIA-ITS and NTIA-OPAD sent members to participate in and observe O-RAN Alliance work for the first time.

ITS led two Open Testing and Integration Center (OTIC) workshops co-located with O-RAN ALLIANCE meetings in Phoenix and Athens to work towards international consistent, repeatable testing and to understand operator concerns about the OTIC badging and certification process. The OTIC and O-RAN ALLIANCE work is a follow up to the successful 2022-2023 5G Challenge competitions focused on accelerating the adoption of open interfaces, interoperable subsystems, and modular, multi-vendor solutions. The 5G Challenge concluded with a first-of-its-kind independent, objective interoperability testing event that assessed how vendor products adhere to 3GPP standards and O-RAN ALLIANCE specifications in multi-vendor networks. Participants achieved mobility among four distinct "cold integration" vendors in a lab environment, the first known successful end-to-end mobility testing of its kind, demonstrating the potential of standards and specifications compliant over-the-counter Open RAN technologies.

Wireless Innovation Forum (WInnForum)

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

Radio Technical Commission for Aeronautics (RTCA)

RTCA is the standards body for aircraft manufacturers and operators. NTIA-OSM is a voting member of RTCA and previously co-chaired Special Committee 239 (SC-239) on Low Range Radar Altimeters. This committee continues to develop technical documentation of the future capabilities for radio altimeters towards a new RTCA standard (Minimum Operating

Performance Standard – MOPS) for radio altimeters operating in the frequency bands where new commercial 5G systems have recently begun, or shortly plan to begin, operating.

Video Quality Experts Group (VQEG)

Since the creation of VQEG in 1997, NTIA-ITS has supported VQEG with leadership and electronic working methods. VQEG conducts open meetings, which enables broad international participation from industry, academia, and governments. VQEG provides a mechanism for a wide variety of video quality experts to contribute to ITU work items. In FY2023, NTIA-ITS led an effort to update and merge three ITU-T Recommendations that describe subjective methods to assess video, audiovisual, and image quality. Over the past decade, researchers have performed extensive research on how to modify traditional subjective test methods to accommodate the rapid changes in devices and services used to create, compress, transmit, and display video. VQEG took the critical role of creating a new set of best practices for modern video systems. NTIA-ITS submitted this set of best practices to the ITU-T Study Group 12, which expects to consent an updated ITU-T Rec. P.910 in September 2023.

IEEE SA

The Institute of Electrical and Electronics Engineers (IEEE) is the world's largest technical professional organization dedicated to advancing technology for the benefit of humanity. The IEEE Standards Association (IEEE SA) is the consensus building body of IEEE, which develops and advances global technologies through standards development processes. NTIA-OPAD participates in the IEEE Government Engagement Program on Standards (GEPS), giving NTIA official Observer Status on the IEEE Standards Board. NTIA-ITS participates in development of individual standards as driven by its research portfolio. In 2020, for example, ITS' direct participation in IEEE 802.15.22.3 led to standardization of the Spectrum Characterization and Occupancy Sensing (SCOS) standard – allowing broader usage of spectrum sensing information from different sources by establishing architecture to support different technologies and deployments. In FY 2023, ITS staff participated in the IEEE Communications Society/Mobile Communication Networks Standards Committee (COM/MobiNet-SC) Working Group for Project P1944 to develop a new Standard for Channel Models of Wireless Systems and Chaired the Subgroup on UAV and V2V Channel Models.

Other International Standards Engagements

NTIA-OIA continues to monitor Internet Engineering Task Force (IETF) work, particularly on matters involving internet governance, including activities of the IETF's Internet Architecture Board (IAB). NTIA-OSM-ISPD staff participate in International Civil Aviation Authority (ICAO) meetings which develop international procedures for civil aviation; International Maritime Organization (IMO), a treaty level organization for development of requirements for commercial maritime operations including safety of ships and ports; and North Atlantic Treaty Organization (NATO) spectrum management committees which develop positions and recommendations for World Radio Conferences (WRCs). Finally, NTIA-OSM-ISPD staff participate in the CITEL PCC II (Radiocommunication and Broadcasting) meetings to develop

regional positions for WRC and to develop recommendations and reports on spectrum management throughout the Americas.

Standards-Related Committees and Other Fora

The American National Standards Institute (ANSI) oversees standards and conformity assessment activities in the United States and is the sole U.S. representative to the International Organization for Standardization (ISO) and to the International Electrotechnical Commission (IEC). ANSI does not issue standards, but promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the community. NTIA participates in the ANSI Government Member Forum (GMF) and generally keeps abreast of ANSI activities and developments.

The Interagency Committee on Standards Policy (ICSP) brings together officials from each of the relevant U.S. federal agencies to increase agencies' knowledge and effectiveness on key standards policy and technology issues, as required under the NTTAA. The ICSP reports to the Secretary of Commerce and has working groups on AI, advanced communications, and conformity assessment. NTIA currently participates in ICSP though the Advanced Communications Technologies Working Group (ACTWG), which aims to facilitate coordination of federal agency advanced communications technologies standards activities, respond to requests for information, and develop recommendations.

The Interagency International Cybersecurity Standards Working Group (IICS WG) was established by the National Security Council's Cyber Interagency Policy Committee to coordinate on major issues in international cybersecurity standardization and enhance federal agency participation. NTIA-OPAD attends IICS WG's periodic meetings.

NTIA-ITS participates in the U.S. National Committee (USNC) for the International Union for Radio Science (URSI), which is sponsored by the National Academy of Sciences as the U.S. adhering body of URSI. While URSI is an international scientific union affiliated to the International Council for Science (ICSU) and does not issue standards as such, a primary mission of URSI is to encourage the adoption of standardized methods of measurement and standardization of measuring instruments. NTIA-ITS holds the Chair-Elect seat at the USNC and Vice Chair of USNC Commission E (Electromagnetic Environment and Interference) and participates in Commissions C (Radiocommunication Systems and Signal Processing) and F (Wave Propagation and Remote Sensing).

United States Patent and Trademark Office (USPTO)

USPTO contributes to the development of international standards for patent and trademark information and documentation primarily through participation of USPTO scientific and technical experts to the Committee on WIPO Standards (CWS) of the World Intellectual Property Organization (WIPO). The standards developed are used by the USPTO and other international intellectual property organizations around the world to harmonize intellectual

property information practices. The standards harmonize practices regarding electronic data processing procedures with respect to filing, examination, and publication of intellectual property data. The standards facilitate the exchange, sharing, dissemination, access and retrieval of intellectual property data and documents. USPTO staff also participate in standardization activities of the International Patent Classification (IPC) Union. The IPC provides a hierarchical system for the classification of patents according to different areas of technology. The worldwide access to patent and trademark data and documents supports U.S. industry and organizations' knowledge of national and international intellectual property. https://www.uspto.gov/patents-application-process/patent-search/understanding-patent-classifications/international.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. 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 2023 Agency Report

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

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

DoD relies on voluntary consensus standards (VCS) to gain access to cutting edge technologies within the global marketplace while reducing total acquisition costs. Currently, DoD has adopted 7.822 VCS approved for use within the Department of Defense. Each of these 7,822 VCS is cataloged with an adoption notice in the ASSIST database (https://assist.dla.mil), which gives visibility of the VCS so that others within DoD may use that standard implementing systems or programs. Each adoption notice provides contact information for the adopting activity should any potential DoD users have questions regarding the technical content or how to get a copy of the document. To promote the use of VCS by DoD, publishing an adoption notice is highly encouraged, but it is not a mandatory prerequisite for their use.

Therefore, the number of adoption notices for VCS is only a partial representation of their use in DoD. Many additional VCS documents are called out in DoD acquisitions and used in defense systems. Over 5,200 VCS are cited as normative references in DoD standardization documents. Similarly, normative references to VCS are found in International Standardization Agreements, and are used by DoD in the implementation of U.S. ratified International Standardization Agreements. The extensive use of VCS allows DoD to gain access to cutting edge technologies and to be interoperable with our allies and partners.

In Fiscal Year 2023, we adopted 32 VCS in several areas, including: Soldering, Packing, Packaging, Preservation and Transportability, Human Factors, Electrical, Insulators and Insulating Materials, and Hoses and Flexible Tubing. DoD also canceled 187 military unique documents in that same timeframe and replaced 5 of those military unique items with VCS.

Our commitment to VCS continues to remain steadfast and strong. As an example, over the last several years, the Department of Defense actively been engaged with the National Security Council and other government agencies in developing the National Standards Strategy for Critical and Emerging Technologies. This strategy—which was released in September 2023— will lay the groundwork for strengthening U.S. leadership and competitiveness in critical sectors. It works to especially strengthen our standing within the

international standards arena ensuring U.S. has an integral role to play in the development of international standards which in turn will lead to greater U.S. competitiveness. As stated above, Department has made a strong commitment to participating in the VCS process and using those VCS. This has enabled the Department to ensure we have the capabilities we need while at the same time saving taxpayer money, removing impediments to getting state of the art technologies into our weapon systems, and advancing U.S. economic interests both here and abroad.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

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

Department of Energy (DOE) Fiscal Year 2023 Agency Report

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

In 2023, as in previous reporting years, the Department of Energy (DOE) relied heavily on voluntary consensus standards (VCSs) to fulfill its mission. DOE has a long history of working with the VCS community to develop standards that help the Department achieve its mission. DOE supports federal and contractor participation on appropriate VCS committees and writing bodies and tracks participation. Appropriate VCSs are referenced or invoked in our directives or contracts to meet our specific requirements.

The DOE Technical Standards Program has a detailed set of procedures called Technical Standards Program Procedures (TSPPs), which include the requirement to perform a mandatory search for existing VCSs prior to initiating a DOE Standard development, revision, or reaffirmation project. The Department continues to have a robust project justification process, which requires that a potential DOE Standard developer perform searches for existing VCSs and document not only the results of those searches, but also the methods used to perform the searches. In September 2021, the DOE acquired an online subscription to VCS access. This subscription is managed through the DOE Technical Standards Program. Having this subscription enables Department standards developers to conduct more efficient searches for VCS, which could be used in lieu of developing, revising, or reaffirming DOE Technical Standards documents. In 2022, the scope of the subscription service was further expanded in response to an increased demand for VCS access. In 2023, the subscription service was further enhanced by increasing the number of VCSs available to users for which the Department has full text access. The Department recognizes that new VCSs are always being developed and approved. Therefore, the project justification process includes the requirement to perform VCS searches when revising DOE Standards as well as when developing new DOE Standards. Lastly, DOE Standards can also be reaffirmed, meaning that the DOE Standard does not require technical changes to remain appropriate for use. The next revision of the TSPPs is scheduled to take place in CY-2024 and will include a VCS search requirement for reaffirmation. This requirement will make it mandatory to perform searches for any newly approved VCSs, which could be used in lieu of reaffirming a DOE Standard.

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

DOE Technical Standards Program Internet Link https://www.standards.doe.gov/

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

Current total GUS = 0

Table 1: Current Government Unique Standards FY2023

The Department of Energy (DOE) added zero (0) new GUS for the year 2023.

Department of the Interior (DOI) Fiscal Year 2023 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.

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

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

The Bureau of Indian Affairs (BIA) in FY 2023 Implemented the Geospatial Based Open Data Website representing all Open Data programs that support the mission of the Bureau. BIA data is harvested by Department of Interior Enterprise Data Governance tool which publishes all products if authorized to data.gov and geoplatform.gov. All BIA Open Data meets the Department of Interior metadata US Standard Data Catalog (DCAT) v1.1. All BIA Open Data products can be found at https://opendata-1-bia-geospatial.hub.arcgis.com/. Furthermore, BIA Chief Data Officer, BIA Office of Trust Services, and BIA Office of Justices Services Missing and Murdered Unit (MMU) collaboration on the implementation of the cloud-based BIA Solution Trust Accountability Tracker (BIA STAT), which catalogues information on missing person, unsolved murder cases, human tracking cases, death investigations related to Native Americans and Alaska Natives. BIA STAT allows MMU investigators to track spatial and temporal trends

in unresolved cases and facilitate the exchange of this information with BIA Office of Justice Service Districts, Tribal Criminal Investigation programs, FBI, and State/County/City law enforcement agencies having a nexus to Indian Country. BIA STAT will ultimately present case data on suspect identification that broadens public awareness of the crisis facing indigenous communities. BIA STAT data will be represented in the future on the BIA Open Data public website.

The Bureau of Land Management (BLM) supports its multiple-use and sustained yield mission by utilizing a variety of *Voluntary Consensus Standards (VCS)* to manage public lands to maximize opportunities for commercial, recreational, and conservation activities. The BLM's policy on data standards is described in BLM Handbook 1283 – Data Administration and Management and practices follow the Department of Interior Information Resource Management policy (Series: 17-INFORMATION RESOURCES MANAGEMENT (Parts 375-387), OMB Circular A-16: Coordination and Surveying, Mapping, and Related Spatial Data Activities as amended by the Geospatial Data Act of 2018, OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities, and OMB Circular A-130: Managing Information as a Strategic Resource.

BLM-specific data standards are found on the Established Data Standard site and provide a uniform and documented system for collecting and maintain geospatial datasets supporting our Geospatial Business Platform and BLM business workflows. Use of metadata standards established by the Federal Geographic Data Committee (FGDC) allow for wide reaching public availability through https://data.gov/ utilizing the DOI's Enterprise Data Inventory.

BLM actively participated in several interagency projects that required VCS in order to accurately account for BLM actions and report results. Federal Accounting Standards Advisory Board (FASAB) Statement of Federal Financial Accounting Standards (SFFAS) 59: Accounting and Reporting of Government Land required BLM to ensure consistent accounting treatment and reporting for federal land to increase transparency, comparability, consistency, and reliability of land information. BLM submitted an Agency Financial Report (AFR) to convey our commitment to sound financial management and stewardship of public funds. BLM had to standardize a process that reclassified General Property Plant and Equipment (G-PP&E) land and permanent land rights as a non-capitalized asset and define Stewardship Land (SL) using three sub-categories: Conservation and Preservation Land, Operational Land, and Commercial-use Land. Objectives of this standard approach were to determine predominant use by sub-category of federal lands, provide land information for inclusion in the BLM's financial reporting deliverables to the DOI, and strive for consistent reporting of BLM acreage in both the FASAB and Public Land Statistics data.

As part of the Bipartisan Infrastructure Law (BIL), BLM created VCSs to track and report ecosystem restoration efforts and mitigation of abandoned oil wells. Ecosystem Restoration Proposed Projects (ERPP) polygon boundaries are collected according to a bureau standard to meet the DOI reporting requirements focusing on restoring habitat connectivity and benefiting significant ecosystems. The Federal Orphaned Well database serves as a project tracking tool for Federal agencies and allows users to request funding under the BIL, track funds, and document methane levels and other contaminants.

The Inflation Reduction Act (IRA) aligns closely to ecosystem restoration efforts from the BIL. As such, the VCS ERPP noted above was modified to capture additional information about 21 Restoration

Landscapes in which to infuse $161 million for ecosystem restoration and resilience on public lands, while also strengthening communities and economies that depend on these lands. BLM will prioritize projects funded by BIL within these 21 Restoration Landscapes to maximize the return on investment.

The Modernizing Access to Our Public Land Act (MAPLand Act) directed DOI, Forest Service, and U.S. Army Core of Engineers to work together to develop, maintain, and consistently share with the public standardized and interoperable geospatial data relating to public access to Federal lands and water for outdoor recreation. BLM has taken a very hands-on approach to influencing the geospatial data standards that come out of sub-groups representing easements for access across private lands, roads, trails, and open recreational use areas, recreational shooting and hunting, general recreation opportunities.

BLM contributes to VCS maintained by other agencies. Bridge Assessments are inspected and reported according to the US Department of Transportation Federal Highway Administration National Bridge Institute's Recording and Coding Guide. Heritage resource surveys and reports are submitted according to State Historical Preservation Office data standards (State of Idaho example). Sensitive species (plants and wildlife) observations are collected, maintained and reported according to State Fish/Game/Wildlife maintained data standards (Idaho Fish and Game example). Water quality sampling data are collected, reported and maintained according to EPA standards. Timekeeping, financial, business, collections and billing (FBMS and CBS) data entry and management follows OPM data standards.

The Bureau of Reclamation (BOR) leads and participates in standards activities across the enterprise. The following highlight standards involvement in various programs and geographic locations. Our Technical Service Center (TSC) showcases its National Codes & Design Standards page (https://www.usbr.gov/tsc/techreferences/industrystandards-non_rec/nationalcodes-ds_non-rec.html), illustrating how our design activities must be performed in accordance with established Reclamation design criteria and standards, and approved national design standards. National codes and design standards provide a consistency of standard practice across a wide variety of engineering disciplines. The adoption of national codes and standards reduces the effort to develop and maintain Reclamation standards. Reclamation designers use the most current edition of national codes and design standards consistent with Reclamation design standards. This list identifies primary national codes and design standards used by Reclamation designers but does not include all codes, standards, and guidelines that may be referenced by these documents. Reclamation design standards may include exceptions to requirements of national codes and design standards.

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

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

The Bureau of Safety and Environmental Enforcement (BSEE) has a long history of using industry standards to supplement and enhance its regulatory program. As of December 2020, BSEE has incorporated by reference 125 industry standards in its regulations (see 30 CFR § 250.198). BSEE's Standards Development Section (SDS) is responsible for tracking, engaging in, and advising on, industry standards relevant to BSEE's mission. The SDS coordinates SMEs from the offshore industry and BSEE to work together through the SDOs to develop standards as required by the NTTAA. The SDS is currently monitoring 10 different SDOs in the development of 125 standards presently Included by reference (IBR). There are different SDOs that develop industry standards such as the American Society of Mechanical Engineers (ASME) or the American Petroleum Institute (API). The SDS also engages in the development of other standards in addition to the 125 incorporated standards if it is deemed a priority by BSEE. The 10 SDOs whose standards are IBR are API, ASME, NACE, ASTM, AWS, AGA, IEC ISO, and the Center for Offshore Safety.

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

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

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

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

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

ONRR uses the Professional Petroleum Data Management Association Well Identification (ppdm.org) for US Well Number Standards and the Federal Information Processing Series (FIPS) for U.S. state and county codes: INCITS 31-2009 & INCITS 38-2009.

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

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 (https://www.fws.gov/data-standards). It follows the Department of Interior Information Resource Management policy (Series: 17-INFORMATION RESOURCES MANAGEMENT (Parts 375-387) on https://www.doi.gov/elips/browse), the OMB Circular A-130: Management of Federal Information Resources (https://www.federalregister.gov/documents/2016/07/28/2016-17872/revision-of-omb-circular-no-a-130-managinginformation-as-a-strategic-resource), and OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities.

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

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

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

The U.S. Geological Survey (USGS) employs a variety of Voluntary Consensus Standards (VCS) in managing a plethora of scientific data and information that support the mission of the Bureau. The USGS Survey Manual Chapter 502.2 - Fundamental Science Practices: Planning and Conducting Data Collection and Research addresses data and metadata standards states: "The data collected, and the techniques used by USGS scientists conform to or reference national and international standards and protocols if they exist and when they are relevant and appropriate. For datasets of a given type, and if national or international metadata standards exist, the data are indexed with metadata that facilitate access and integration." Examples can be found on the USGS Data Management Website (https://www.usgs.gov/data-management/data-standards) and include use of standards such as the International Organization for Standardization (ISO), Darwin Core, Climate, and Forecast CF-Conventions, US Topo Maps, USGS National Geospatial Program Standards and Specifications, Federal Geographic Data Committee (FGDC), DCAT 1.1 US, National Data Standards Publications, Open Geospatial Consortium, Vegetation Classification: United States National Vegetation Classification (USNVC), Biological Taxonomy: Integrated Taxonomic Information System (ITIS), geographic locations descriptors, geologic time data standards such as Divisions of Geologic Time – Major Chronostratigraphic and Geochronologic Units, and Date/Time standards.

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

Current total GUS =0

Table 1: Current Government Unique Standards FY2023

Department of Justice (DOJ) Fiscal Year 2023 Agency Report

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

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

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

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

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

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

The Federal Bureau of Investigation (FBI) remains compliant in carrying out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The FBI has not currently identified the need for any government unique standards in lieu of consensus-based standards. The FBI's Science & Technology Branch (STB) ensures the FBI is represented in appropriate Standards Development Organizations (SDOs) and bodies to position the FBI to develop and exploit technology in ways that recognize and protect civil liberties, allows for auditing of use, and enables the FBI mission. The FBI's centralized SDO authority resides with the Internet Governance (IG) and 5G Program Office led by an FBI Senior Leader. STB and its corresponding divisions, including Criminal Justice Information Services Division (CJIS), Operational Technology Division (OTD) and the Laboratory Division (LD) follow the policies of OMB Circular A-119 by regularly participating with commercial and private-sector on standard development of voluntary consensus standards via committees, working groups, meetings, conferences, and other engagements. FBI STB regularly participates in the following SDOs and bodies:

- **Internet Corporation for Assigned Names and Numbers (ICANN**). International nonprofit responsible for the management of the Domain Name System (DNS). The FBI is an active, engaging participant in ICANN recurring meetings.
    - **Governmental Advisory Committee (GAC)**. An advisory committee to ICANN established via ICANN Bylaws and provides advice to ICANN on public policy aspects of ICANN's Domain Name System responsibilities. FBI participation provides direct access to the ICANN Board on public policy/LE-related issues. Enables early access to weigh in on development processes and ensure consistency with laws and national security interests. Provides access to experts across the national and international spectrum to engage on implications and mitigation strategies (if needed).
    - **Public Safety Working Group (PSWG)**. ICANN Governmental Advisory Committee (GAC) Working Group devoted to evaluating policies and procedures that implicate the safety of the public. Current strategies include developing DNS abuse and cybercrime mitigation capabilities of the ICANN and LE communities, preserving and improving domain registration directory services effectiveness, and leveraging stakeholders to influence balanced ICANN-level governance. The FBI directly contributed to development of a voluntary standard "framework"** for law enforcement referrals to domain registry operators of bulk lists of domain names linked to command and control of criminally operated botnets. Additionally, the FBI continues to provide public safety input to ongoing policy development for a replacement to the worldwide web's "WHOIS" system.
        - **Framework on Domain Generating Algorithms (DGAs) Associated with Malware and Botnets, link
- **International Telecommunications Union (ITU).** The FBI regularly attends meetings in ITU which allocates global radio spectrum and satellite orbits, develops the technical standards that ensure networks and technologies seamlessly interconnect, and strive to improve access to ICTs to underserved communities worldwide.
- **Internet Governance Forum (IGF).** The FBI continues to be an active participant in this global forum hosted by the United Nations Department of Economic and Social Affairs (UNDESA) and administered by the Multi-stakeholder Advisory Group (MAG).

  - **Internet Governance Forum USA (IGF-USA)**. The FBI continues to be an active participant in the IGF-USA recurring general meetings as well as working group meetings to illuminate issues and cultivate constructive discussions about the future of the internet.
- **The 3rd Generation Partnership Project (3GPP).** The FBI continues to participate in development of service-based interception capabilities for 5G-based communication services in 3GPP. This participation is meant to satisfy the industry consultation requirements of the Communications Assistance for Law Enforcement Act (CALEA) for the development of industry standards for covered services.
- **International Organization for Standardization (ISO)**. FBI is represented in the Committees/Working Groups of the ISO. ISO is an independent, non-governmental international organization with a membership of 167 national standards bodies. The ISO brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.
- **International Committee for Information Technology Standards (INCITS).** FBI is represented in the Working Groups of the INCITS. INCITS is the central U.S. forum dedicated to creating technology standards for the next generation of innovation.
- **Iris Experts Group (IEG)** within the newly formed **Organization of Scientific Area Committees** - part of the **Facial Identification Subcommittee**. The IEG is a forum for the discussion of technical questions of interest to US government (USG) agencies and their staff that are employing or may employ iris recognition to carry out their mission. FBI continues to be represented. The **Facial Identification Subcommittee** focuses on standards and guidelines related to the image-based comparisons of human facial features.
- **ASTM E30 Committee on Forensic Sciences**. FBI-OTD SME chairs semi-annual meetings of E30 as well as meetings of the Executive Committee. The Committee has jurisdiction over 60 standards, published in the Annual Book of ASTM Standards, Volume 14.02. E30 has 5 technical subcommittees that manage these standards.
- **Organization of Scientific Area Committees for Forensic Science (OSAC).** FBI-OTD SME participated in (2) meetings of the OSAC FSSB Outreach task group, which is currently focused on engaging with forensic science stakeholders to adopt OSAC standards. The OSAC addresses a lack of discipline-specific forensic science standards. OSAC fills this gap by drafting proposed standards and sending them to SDOs which further develop and publish them.
  - **Digital Multimedia Scientific Area Committee (DMSAC)**. FBI serves as a member of DMSAC. The Committee sets development standards for forensic analysis of multimedia and digital evidence, to include image, video, audio/voice, and computer/digital data.
    - **Speaker Recognition Subcommittee (SR).** Works in the development of standards specific to forensic analysis of human voice data. The SR subcommittee reports to the DMSAC committee. FBI-OTD SME has served as the chair of SR for the past three years and conducts monthly meetings for the advancement of documents supporting the establishment of standards in forensic speaker recognition.
  - **National Information Exchange Model (NIEM).** FBI-OTD SME participates in bi-weekly meetings to advise the NIEM for the exchange of audio and voice information. The NIEM defines standard terminology, models, and relationships for the exchange of data across public and private organizations.
  - **Telecommunications Industry Association (TIA) Engineering Committee (TR8).** FBI SMEs are represented and engage in TIA's work to formulate and maintain standards for private radio communications systems and equipment for both voice and data applications. TR-8

addresses all technical matters for systems and services, including definitions, interoperability, compatibility and compliance requirements.

- **APCO Project 25 Interface Committees (APIC).** FBI SMEs are represented. APIC is an ad hoc committee of the Private Radio Section (PRS) in the Wireless Communication Division (WCD) of the TIA. The APIC task groups are not standard formulating groups. The APIC task groups do develop documents that are reviewed by users and industry representatives, decisions based on consensus.
- **Federal Partnership for Interoperable Communications (FPIC).** Serves as a coordination and advisory body to address technical and operational wireless issues relative to interoperability within the public safety emergency communications community, interfacing with voluntary representatives from federal, state, local, territorial, and tribal organizations to include the FBI
    - **Federal Partnership for Interoperable Communications (FPIC) Security Subcommittee**. FBI SMEs are being represented. In coordination with the National Law Enforcement Communications Center (NLECC) and other public safety agencies, developed a standardized SLN assignment list for National Encrypted Interoperability.
- **Alliance for Telecommunications Industry Solutions (ATIS).** FBI participated in regard to Packet Technology and Systems Committee (PTSC) and lawfully Authorized Electronic Surveillance (PTSC LAES). ATIS is a standards organization that develops technical and operational standards and solutions for the ICT industry.

- **Internet Engineering Task Force (IETF)**. Engineering group that develops technical standards of the internet's architecture including encryption, cybersecurity, network security, routing and other key protocols. The FBI has engaged over many years to build alliances. Primary attenders are industry along with academia and organizations such as NIST, NTIA, NSA, FBI and UK/NCSC.
- **SAFECOM**. FBI SMEs are represented. Through collaboration with emergency responders and elected officials across all levels of government, SAFECOM works to improve emergency response providers' inter-jurisdictional and interdisciplinary emergency communications interoperability across local, regional, tribal, state, territorial, international borders, and with federal government entities. SAFECOM works with existing federal communications programs and key emergency response stakeholders (to include the FBI) to address the need to develop better technologies and processes for the coordination of existing communications systems and future networks.
    - **National Council of Statewide Interoperability Coordinators (NCSWIC).** Established by the Department of Homeland Security's (DHS) Cybersecurity and Infrastructure Security Agency (CISA), the NCSWIC supports Statewide Interoperability Coordinators (SWIC) from the 56 states and territories, by developing products and services to assist them with leveraging their relationships, professional knowledge, and experience with public safety partners involved in interoperable communications at all levels of government to include the FBI.
- **3D Toolmark Technologies Technical Working Group (TWG).** FBI SMEs are represented. The TWG provides guidance and recommendations to the Firearms/Toolmarks community in instrument assessment and Virtual Comparison Microscopy (VCM). Creating standards for the F/T community to establish acceptable measuring practices, methodology/Standard Operating Procedures (SOPs), and quality assurance protocols that can be utilized to access a laboratory's compliance during accreditation.

- **American Academy of Forensic Sciences-Academy Standards Board.** FBI SMEs are represented. SDO with the purpose of providing accessible, high-quality science-based consensus forensic standards.
- **American Society for Testing and Materials (ASTM) International.** FBI-LD SMEs are represented. International SDO that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services.
- **International Society for Forensic Genetics.** FBI SMEs are represented. The society aims to promote scientific knowledge in the field of genetic markers as applied to forensic science. This is mainly being achieved through regular meetings regionally or internationally and their journal Forensic Science International: Genetics and the work of our expert DNA commissions.
- **National Fire Protection Association.** FBI SMEs are represented. International nonprofit organization in standards development devoted to eliminating death, injury, property and economic loss due to fire, electrical and related hazards.
- **Scientific Working Group-DNA Analysis Methods (SWGDAM).** FBI SMEs are represented. Serves as a forum to discuss, share, and evaluate forensic biology methods, protocols, training, and research to enhance forensic biology services as well as provide recommendations to the FBI Director on quality assurance standards for forensic DNA analysis.
- **Scientific Working Group-Seized Drugs (SWGDRUG).** FBI SMEs are represented. Maintains a database of reference mass spectra, or "molecular fingerprints" of controlled substances. This database is a cornerstone in the fight against illicit drugs, including newly emerging fentanyl analogues and other synthetic opioids. NIST scientists perform rigorous quality assurance on all new mass spectra added to the database, giving confidence to forensic chemists that the results they obtain using this database are accurate and reliable.
- **United States Technical Advisory Group-Technical Committee 272.** FBI SMEs are represented. The Committee is at the forefront of standardization and guidance in the field of Forensic Science. This includes the development of standards that pertain to laboratory and field based forensic science techniques and methodology in broad general areas such as the detection and collection of physical evidence, the subsequent analysis and interpretation of the evidence, and the reporting of results and findings.

The National Institute of Justice (NIJ) continues to operate its NIJ Compliance Testing Program. In calendar year (CY) 2023, approximately 190 models of ballistic-resistant body armor were submitted for testing. In addition to initial testing, follow-up inspection and testing was conducted on approximately 260 models complying with NIJ Standard 0101.06, Ballistic Resistance of Body Armor. NIJ continues to participate in ASTM International and National Fire Protection Association (NFPA) committees to develop standardized methods and practices to test ballistic-resistant and other life safety equipment as well as standards for testing law enforcement public order personal protective equipment. Through ANSI, NIJ also supports ISO/IEC JTC 1/SC 37 Biometrics, which focuses on the standardization of generic biometric technologies pertaining to human beings to support interoperability and data interchange among applications and systems. More about NIJ's standards and conformity assessment activities can be found at: https://nij.ojp.gov/equipment-standards-and-conformity-assessment.

The Department's Office of the Chief Information Officer actively applies the ISO 20000 and 27001 standards for the delivery of IT and information security services and has undergone formal audits to obtain ISO certification for compliance with these standards. The Department recertified its IT service management certification originally obtained in 2017 to the updated ISO/IEC 20000-1:2018 standard and achieved initial certification under the ISO 27001:2013 information security management standard.

Application of these standards has significantly improved delivery of OCIO enterprise IT and cybersecurity services, ensuring the continuous evaluation of service performance and use of standard practices as defined by criteria well-recognized across industry and government.

The Civil Division participates in a number of efforts in support of the development and use of Voluntary Consensus Standards and Conformity Assessment Activities. This includes:

- **Data Architecture Working Group (DAWG):** CIV is an active participant in the Department's efforts to develop consistent data governance standards within the DOJ across a number of key areas. This includes in the procurement and use of Commercially Available Information (CAI), data lexicons, Data Management Plans, and other areas of alignment. These standards and assessment relate to the DOJ Data Governance Board oversight efforts and incorporate industry data standards, federal statutes and other authorities. DAWG activities are captured here: https://doj365.sharepoint.us/sites/JMD-DGB/SitePages/Data-Architecture-Working-Group.aspx?sw=auth

- Additionally, CIV personnel participated in the **Deputy Attorney General's eLitigation Modernization Effort.** This cross-component commission supported work to assess the development and use of consensus standards across litigation activities to support modernization, compliance and workforce development efforts. These efforts are based in part of federal statutes and authorities, industry standards and Department policies and practices. https://dojnet.doj.gov/elitigation/docs/eLitigation-Modernization-Working-Group-October-2023-Proposal-Addenda-for-official-DOJ-use-only.pdf

- A third area of participation relates to the handling of Privileged Litigation materials. The Department empaneled a cross-component working group to assess current operating standards, challenges, risks, and opportunities. This group is working to develop a set of standards on the handling, review, and remediation of privileged litigation materials, as well as workforce development. This effort is being coordinated through the Attorney General's eLitigation Steering Committee. POC: John Haried, Director of eLitigation.

The U.S. National Central Bureau (USNCB) is responsible for ensuring that its stewardship of INTERPOL data adheres to the Rules on Processing Data (RPD). INTERPOL's current RPD was adopted by INTERPOL's General Assembly (plenary session of all representatives from member countries) in 2011 and entered into force in July 2012. They have since been continually updated to keep pace with technological developments and evolving international data protection standards. The RPD was substantively updated at the General Assembly in 2023. The RPD govern all data processing in the INTERPOL Information System, including that surrounding the publication and circulation of Red Notices. This robust set of rules ensures the efficiency and quality of international cooperation between criminal police authorities through INTERPOL channels as well as due respect for the basic rights of the individuals who are subjects of this cooperation. USNCB has not created a derivative set of rules. The RPD is publicly available: https://www.bing.com/ck/a?!&&p=c23a1ebb3109f6efJmltdHM9MTcxMTY3MDQwMCZpZ3VpZD0wMzY3OTA4MC0yNzRkLTYyMTAtMzZjYi04NGNmMjY4YTYzN2QmaW5zaWQ9NTIyMQ&ptn=3&ver=2&hsh=3&fclid=03679080-274d-6210-36cb-84cf268a637d&psq=interpol+rules+processing+of+data&u=a1aHR0cHM6Ly93d3cuaW50ZXJwb2wuaW50L2NvbnRlbnQvZG93bmxvYWQvNTY5NC9maWxlL0lOVEVSUE9MJTIwUnVsZXMlMjBvbiUyMHRoZSUyMFByb2Nlc3NpbmclMjBvZiUyMERhdGEtRU4ucGRm&ntb=1 (will open as a pdf).

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

Current total GUS = 0

Table 1: Current Government Unique Standards FY2023

Department of Labor (DOL) Fiscal Year 2023 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 record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded.**

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

Current total GUS: 17

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

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

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

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

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

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

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

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

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

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

Voluntary Standard
ASME B30.2-2005
ASME B30.5-2004
ASME B30.7-2001
ASME B30.14-2004

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

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

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

Voluntary Standard
SAE J1194-1999

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

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

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

Rationale
MSHA issued a final rule in June 2011 that finalized an Emergency Temporary Standard (ETS) on Maintenance of Incombustible Content of Rock Dust in Underground Bituminous Coal Mines. The basis of the ETS and final rule was a recommendation of the National Institute for Occupational Safety and

Health contained in their Report of Investigations 9679 published in 2010. The ASTM consensus standards do not include the NIOSH recommendations or address the specific hazard covered in the MSHA ETS and final rule.

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

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

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

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

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

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

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

Voluntary Standard
Life Safety Code, NFPA 101-2000

Rationale
The OSHA standard addresses only workplace conditions whereas the NFPA Life Safety Code goes beyond workplaces. However, in the final rule OSHA stated that it had evaluated the NFPA Standard 101, Life Safety Code, (NFPA 101-2000) and concluded that it provided comparable safety to the Exit

Route Standards. Therefore, the Agency stated that any employer who complied with the NFPA 101-2000 instead of the OSHA Standard for Exit Routes would be in compliance.

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

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

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

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

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

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

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

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

Rationale
Rationale for not using: OSHA’s standard includes a number of requirements that differ from the specifications in the ASTM standard because the requirements in the OSHA standard better effectuate

the purposes of the OSH Act and protect employees from the significant risks posed by exposures to respirable crystalline silica (silica). The major differences include:

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

Differences between the medical surveillance programs include, the ASTM standard triggers medical surveillance for employees exposed above the PEL or other occupational exposure limit for 120 or more days a year, while the OSHA standard triggers medical surveillance for employees who are required to use a respirator under the silica standard for 30 or more days a year. Medical examinations to be conducted within 30 days, spirometry testing is mandatory, an X-ray classification of 1/0 triggers referral to a specialist, tuberculosis testing for the initial examination of all employees who qualify for medical surveillance, allows employees to make their own placement decisions and the OSHA standard withholds medical information from the employer because of privacy concerns.

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

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

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

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

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

The OSHA standard gives employers required to do exposure assessment a choice between complying with a scheduled monitoring approach or a performance-oriented approach, requires employers to

establish regulated areas, requires a written plan to be reviewed annually and made available to employees, their representatives, and OSHA and NIOSH upon request.

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

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

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

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

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

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

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

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

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

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

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

Voluntary Standard
ANSI/ASSE Z359.0-2012
ANSI A14.1-2007
ANSI A14.2-2007
ANSI A14.3-2008
ANSI A14.5-2007
ANSI A14.7-2011
ANSI/TIA 222-G-1996
ANSI/TIA 222-G-2005
ASTM C 478-13
ASTM A 394-08
ANSI/ASSE A1264.1-2007
NFPA 101-2012
ICC IBC-2012
ANSI/ITSDF B56.1-2012
ASME/ANSI MH14.1-1987
ANSI MH30.1-2007
ANSI MH30.2-2005
ANSI/ASSE Z359.4-2012
ANSI/IWCA I-14.1-2001
ANSI/ASSE A10.18-2012

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

Department of State (State) Fiscal Year 2023 Agency Report

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

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

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

The Bureau of Economic and Business Affairs

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

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

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

Web site: Bureau of Economic and Business Affairs - United States Department of State

The Bureau of Cyberspace and Digital Policy

The Bureau of Cyberspace and Digital Policy (CDP) leads and coordinates the Department's work on cyberspace and digital diplomacy to encourage responsible state behavior in cyberspace and advance policies that protect the integrity and security of the infrastructure of the Internet, serve U.S. interests, promote competitiveness, and uphold democratic values. CDP addresses the national security challenges, economic opportunities, and values considerations presented by cyberspace, digital technologies, and digital policy and promotes technology standards and norms that are fair, transparent, and support our values.

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

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

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

Web site: Bureau of Cyberspace and Digital Policy - United States Department of State

The Bureau of Overseas Building Operations

The Bureau of Overseas Buildings Operations (OBO) directs the Department's worldwide overseas building program. Coordinating both internally and externally with other Federal agencies and industry groups, OBO delivers safe, secure, functional, and resilient facilities that represent the U.S. government to host nations worldwide and support the achievement of U.S. foreign policy objectives abroad.

In developing and maintaining the governing standards for design and construction, OBO adheres to the same strategy as many other Federal, State, and local agencies, which is to adopt model codes developed by industry organizations, and supplement or modify them only as required to reconcile unique needs and circumstances applicable to our remote projects overseas (e.g., enhanced security, logistical and maintainability limitations.) The Department of State has adopted the International Code Council (ICC) model building codes and the National Fire Protection Association (NFPA) model codes and standards, including the National Electrical Code (NEC), as the basis for its codes, incorporating them into its contract standards by reference.

Likewise, functional design requirements and specifications defer to industry standards whenever possible. When OBO has specific requirements to suit OBO's unique mission, we follow Construction

Specification Institute standards and utilize templates common in the industry, such as MasterSpec by the American Institute of Architects, and the Unified Facilities Guide Specifications by the Department of Defense, both of which incorporate standards developed by common industry groups by reference. Using industry standards saves time for our private sector partners (e.g., architects, engineers, and contractors), because they are familiar and consistent with industry norms. At overseas locations, OBO strives to meet a variety of standards and attempts to identify local equivalents to provide a high degree of reliability and safety.

These codes and specifications are updated periodically. The Foreign Affairs Manual in provision 15 FAM 900 incorporates consensus standards into the overseas safety, health, and environmental management program. OBO also applies the Secure Embassy Construction and Counterterrorism Act (SECCA) statutory requirements and participates on the Overseas Security Policy Board (OSPB) as all agencies under Chief of Mission authority must comply with OSPB standards set forth in the classified section of the Foreign Affairs Handbook, 12 FAH-6.

Web site: Bureau of Overseas Buildings Operations - United States Department of State

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1 (below): Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded.**

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

Current total GUS: 1

Table 1: Current Government Unique Standards FY2023

(1) Government Unique Standard
2023 OBO Design Standards (annual update, retitled OBO Project Standard Requirements going forward)

Rationale
The majority of the OBO Design Standards incorporate industry codes and standards (which are Voluntary Consensus Standards (VCS)) by reference to the degree they support OBO's mission. When it is necessary to amend, modify, or focus industry codes and standards to address unique considerations relevant to Department of State overseas facilities, the strategy of using "code supplements" is used to modify VCS model building codes is consistent with the practice of domestic state and local jurisdictions. It is also practical for the Department of State to further transform and standardize some VCS 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. Of the ten OBO Codes, all but one are supplements to VCS model codes. The OBO Telecommunications Code is considered a Government Unique Standard (GUS) because there are no VCS available suitable to reference for the broad requirements and contexts applicable to Department of State overseas facilities.

Department of Transportation (DOT) Fiscal Year 2023 Agency Report

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

The U.S. Department of Transportation (DOT) and its Operating Administrations rely upon a transparent and collaborative regulatory and guidance program to support the Department's strategic goals: safety, economic strength and global competitiveness, equity, climate and sustainability, and transformation. We employ our infrastructure and safety grants, training programs, and enforcement authorities for automobiles, aviation, highways, railroads, trucks, motorcoaches, maritime operators, public transit, pipelines, and hazardous materials as effectively as possible to reduce transportation-related fatalities and serious injuries across the transportation system. DOT uses voluntary consensus standards and conformity assessment activities as potent tools in our regulatory, guidance, safety advisory, enforcement 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 advanced air mobility (AAM) -- and to advance the state of practice across all modes of transportation.

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

• The National Highway Traffic Safety Administration (NHTSA) issued a final rule amending the Federal Motor Vehicle Safety Standard (FMVSS) regarding child restraint systems (car seats). The amendments increase child safety in transportation by adding requirements for add-on school bus-specific child restraint systems, adding a new FMVSS that updates NHTSA tests of child restraint systems for compliance with frontal crash performance requirements. This Final Rule draws on multiple voluntary consensus standards and incorporates the results of crashworthiness research.

• The Federal Railroad Administration (FRA), in the wake of the Norfolk Southern derailment in East Palestine, OH and similar previous derailments, issued a Safety Advisory FRA recommending that railroads expand application of Association of American Railroads (AAR) Circular OT–55 (Recommended Railroad Operating Practices for the Transportation of Hazardous Materials), as a matter of guidance.

• The Pipeline and Hazardous Materials Safety Administration (PHMSA) enhanced safety requirements for transport of lithium batteries by air, revising the Hazardous Materials Regulations to prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; required lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge aboard cargo-only aircraft when not packed with or contained in equipment; and limited the use of alternative provisions for smaller lithium cell or battery shipments to one package per consignment. This final rule harmonized the U.S. with the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transportation of Dangerous Goods by Air, which are based on multiple voluntary consensus standards and incorporate the results of fire prevention research on lithium batteries and cells.

• The Federal Aviation Administration (FAA) accepted SAE Designation AS6960 ‘‘Performance Standards for Seat Furnishings’’, as a means of compliance with regard to the design of seat furnishings. This is a significant step in addressing the safety issue of lithium batteries in cell phones and other consumer electronics catching fire in flight when passengers lose such devices in older designs of seats that do not meet performance standards.

• The Pipeline and Hazardous Materials Safety Administration (PHMSA) improved the safety of transport of explosives by all modes of transportation by terminating the approvals to transport explosives of over 100 entities for failing to comply with UN Test Series 6(d) of Part I of the UN Manual of Tests and Criteria (UN 6(d) testing) as required by 49 CFR 172.102, Special Provision 347. The UN Manual is based on internationally-harmonized voluntary consensus standards, and includes recognized conformity assessment methods.

• The Federal Motor Carrier Safety Administration (FMCSA) amended its Hazardous Materials Safety Permits regulations to incorporate by reference the April 1, 2022, edition of the Commercial Vehicle Safety Alliance’s (CVSA) handbook (the handbook) containing inspection procedures and Out-of-Service Criteria (OOSC) for the inspection of commercial motor vehicles used in the transportation of transuranic waste and highway route-controlled quantities of radioactive material. The OOSC provide enforcement personnel nationwide, including FMCSA’s State partners, with uniform enforcement tolerances for these safety inspections.

Information on the Department’s regulatory and enforcement programs using standards and conformity assessment may be found at “Regulatory Information” (https://www.transportation.gov/regulations). The Federal Aviation Administration’s (FAA) use of standards and conformity assessment in operational activities beyond regulation and enforcement may be found at “Regulations & Policies” (https://www.faa.gov/regulations_policies).

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY): 11

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

Voluntary Standard
SAE J915

Rationale
This regulation was issued on July 1, 2005. SAE J915, “Automatic Transmissions- Manual Control Sequence,” published on July 1, 1965, and updated on March 9, 2017. NHTSA has not incorporated this standard because its content currently relies on 49 CFR 571.102 and 571.114, and the SAE J915 abstract also states that some portions of the standard are unique and may not represent current common practices within the user community. NHTSA is evaluating industry standards to inform the next steps of any revisions to its regulations.

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

Voluntary Standard
SAE J2948

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

(3) Government Unique Standard
49 CFR 571.123, Motorcycle controls and displays [Incorporated: 2016]

Voluntary Standard
ISO 2575

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

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

Voluntary Standard
SAE J918c

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

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

Voluntary Standard
SAE J2657

Rationale
NHTSA published this regulation on April 8, 2005. SAE J2657, Tire Pressure Monitoring Systems for Light Duty Highway Vehicles, was published on December 16, 2004. While SAE J2657 was not incorporated in the final rule, the regulation has many commonalities. However, SAE J2657 does not contain requirements or test procedures for a malfunction indicator and requires different levels of rigorousness. NHTSA is evaluating industry standards to inform the next steps of any revisions to its regulations.

(6) Government Unique Standard
49 CFR 571.207, Seating Systems [Incorporated: 2016]

Voluntary Standard
SAE J879
SAE J879B

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

(7) Government Unique Standard
49 CFR 571.226, Ejection Mitigation [Incorporated: 2010]

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

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

(8) Government Unique Standard
49 CFR 571.302 Flammability of Interior Materials (1971) [Incorporated: 2016]

Voluntary Standard
ASTM D5132
SAE J369

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

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

Voluntary Standard
SAE J1766

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

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

Voluntary Standard
SAE J1698–1
IEEE P1616

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

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

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

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

Environmental Protection Agency (EPA) Fiscal Year 2023 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 Fiscal Year (FY) 2023 the U.S. Environmental Protection Agency (EPA) collaborated with the U.S. Department of Commerce (DOC), National Institute for Standards and Technology (NIST) to develop a standards training program for EPA staff. Through this program, 175 contact hours of training were delivered to EPA staff in October 2023.

For additional information on EPA's implementation of Section 12(2) of the National Technology Transfer and Advancement Act (NTTAA), Please refer to EPA's standards-specific website: www.epa.gov/vcs

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

There are no new Government-Unique Standards (GUS) used in lieu of VCS to report during FY 2023.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded.**

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

Current total GUS: 39

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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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 2023 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, the Commission uses consensus standards for certifying wireless handset models as hearing aid-compatible. The latest certification standard is the 2019 ANSI Standard which was developed and is maintained by the ANSI C63®–Electromagnetic Compatibility Committee (ANSI Committee). At the request of the ANSI Committee, the Commission incorporated by reference the 2019 ANSI Standard into the wireless hearing aid compatibility rules (47 CFR § 20.19) in February 2021 (FCC 21-28). This consensus standard references the TIA 5050 Volume Control Standard which is another consensus standard developed by a related ANSI Committee. Along with incorporating by reference the 2019 ANSI Standard into the Commission's wireless hearing aid compatibility rules, the Commission also incorporated by reference the TIA 5050 Volume Control Standard into the wireless hearing aid compatibility rules as part of the February 2021 order. The 2019 ANSI Standard and the related TIA 5050 Volume Control Standard became the exclusive testing standards for determining the hearing aid compatibility of wireless handset models in December 2023. These standards replaced older ANSI standards that the ANSI Committee had previously requested that the Commission use to determine wireless hearing aid compatibility.

As another example, in August 2024, the Commission adopted a Report and Order that enables initial uncrewed aircraft system (UAS) operations in the 5030-5091 MHz band. The Report and Order adopted service rules that will provide operators the ability to obtain direct frequency assignments in a portion of the 5030-5091 MHz band, including certain technical rules mandating compliance with standards incorporated by reference to RTCA DO-362A, "Command and Control (C2) Data Link Minimum Operational Performance Standards (MOPS) (Terrestrial)."

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

Also, on October 2, 2017 the European standard for wireless microphones ETSI EN 300 422-1 V1.4.2 (2011-08): “Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wireless Microphones in the 25 MHz to 3 GHz frequency range; Part 1: Technical characteristics and methods of measurement, was incorporated by reference in Section 15.38 of the FCC rules. This standard is used for the evaluation of the out-of-band emissions of wireless microphones.

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

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

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

Federal Energy Regulatory Commission (FERC) Fiscal Year 2023 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.

FERC uses voluntary consensus standards (VCSs) to achieve its regulatory mission. As described below, FERC primarily uses standards provided by the North American Energy Standards Board (NAESB) [1] and North American Electric Reliability Corporation (NERC). [2] FERC's use of the NAESB standards in the context of natural gas pipelines can be found here: https://www.ferc.gov/industries-data/natural-gas/overview/natural-gas-pipelines/standards-business-practices-interstate, and FERC's use of NERC standards is described here: https://www.ferc.gov/electric-reliability.

NAESB

FERC has relied on business practice standards developed and promoted by NAESB to facilitate well-functioning wholesale gas and electric markets. NAESB, an American National Standards Institute accredited consensus standards development organization, develops and adopts voluntary standards and model business practices designed to promote competitive and efficient natural gas and electric service. FERC's use of NAESB-developed wholesale gas and electric standards ensure that the incorporated business practices and technical guidelines have broad industry development, involvement, and endorsement. From time to time, as FERC considers appropriate, select NAESB standards applicable to wholesale natural gas and wholesale electric business practices are incorporated by reference into FERC's regulations.[3]

NERC

Pursuant to separate statutory authority provided in section 215 of the Federal Power Act, FERC reviews reliability standards developed by NERC, which are not subject to the reporting requirement in OMB Circular A-119. [4] NERC reliability standards define the reliability requirements for planning and

[1] NAESB's website may be found at http://www.naesb.org/.

[2] NERC's reliability standards may also be found here at https://www.nerc.com/pa/Stand/Pages/default.aspx.

[3] *See, e.g.,* 18 C.F.R. Part 38 titled Business Practice Standards and Communication Protocols for Public Utilities, and 18 C.F.R. § 284.12 titled Standards for Pipeline Business Operations and Communications.

[4] *See* Office of Management and Budget, *OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*, p. 17 (January 22, 2016) (stating the reporting requirement does not apply to independent agencies "subject to separate statutory requirements regarding the use of voluntary consensus standards."); 16 U.S.C. § 824o(d) (providing separate statutory authority regarding reliability standards). Accordingly, these NERC reliability standards are referenced exclusively for informational purposes.

operating the North American bulk power system. NERC develops the reliability standards using an industry-driven American National Standards Institute (ANSI) accredited process that ensures the process is: (1) open to all persons who are directly and materially affected by the reliability of the North American bulk power system; (2) transparent to the public; (3) demonstrates the consensus for each standard; (4) fairly balances the interests of all stakeholders; (5) provides for reasonable notice and opportunity for comment; and (6) enables the development of standards in a timely manner. Upon review, FERC can either approve the proposed standards or remand them back to the electric reliability organization for further consideration. The reliability standards become mandatory and enforceable only after they are approved by FERC.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. 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):

FERC has one Government Unique Standard from FY2023.
Updating Regulations for Engineering and Design Materials for Liquefied Natural Gas Facilities Related to Potential Impacts Caused by Natural Hazards, 185 FERC 61050 (Oct. 23, 2023) (codifying FERC's existing practice that requires applicants to file information as needed pursuant to sections 3 or 7 of the Natural Gas Act in order for staff to evaluate the natural hazards and design criteria related to a proposed LNG facility).

Rationale
The Final Rule does not adopt voluntary consensus standards related to natural hazard evaluation and design criteria for Liquefied Natural Gas (LNG) structures, systems, and components because adopting such standards would be impractical. FERC's evaluation and analysis of LNG applications, which propose technically diverse types of facilities, must consider the unique locations in which the LNG facilities will be sited, constructed, and operated. Over 2,500 standards exist that could be applicable to an LNG structure, system, or component. To ensure that all types of proposals are covered by a single standard would require that FERC codify every potential consensus standard that could apply in its various LNG proceedings. Such an effort would be infeasible and would confuse applicants about which standards FERC expects them to apply to their proposal.

By having LNG applicants identify all federal regulations, codes, and standards that apply to their project-specific and site-specific proposal, FERC may evaluate applications for LNG facilities on a case-by-case basis and consider the federal regulations, codes, and standards that apply (including any voluntary consensus standards that are adopted into those regulations). Based on this information, FERC can more effectively coordinate with other federal agencies that have jurisdiction over the proposal; evaluate whether the identified regulations, codes, and standards contain informational gaps; and recommend modifications or conditions to be included in FERC’s authorization. This approach reduces the risk of adverse effects to the public and the environment.

Federal Trade Commission (FTC) Fiscal Year 2023 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 record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

Current total GUS = 0

Table 1: Current Government Unique Standards FY2023

General Services Administration (GSA) Fiscal Year 2023 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: https://www.gsa.gov/buy-through-us/purchasing-programs/requisition-programs/gsa-global-supply/supply-standards/index-of-federal-specifications

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Current total GUS: 3

(1) Government Unique Standard

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

Voluntary Standard

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

Rationale

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

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

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

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

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

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

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

(2) Government Unique Standard

FF-L-2937 [Incorporated: 2006]

Voluntary Standard

UL 768

Rationale

Federal Specification FF-L-2937 – Combination Lock, Mechanical used in lieu of UL 768 Combination Locks. The lock covered by the GUS is used for the protection of classified information and weapons. The UL specification did not meet identified government needs for dialing tolerance and bolt end pressure.

(3) Government Unique Standard

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

Voluntary Standard

SAE/AMS 2431 - Peening Media, General Requirements

Rationale

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

Government Publishing Office (GPO) Fiscal Year 2023 Agency Report

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

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

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

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

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

Below, please find the GPO reported links:

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

CS Printing Procurement Regulations_7-22 (gpo.gov)

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

vendors/contractors_holding_psi.pdf?sfvrsn=2
CS http://www.gpo.gov/gporestarget.pdf

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

Below is all new from Standards Inventory:

FIPS 201-3, Personal Identity Verification (PIV) of Federal Employees and Contractors
https://csrc.nist.gov/pubs/fips/201-3/final

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 0

Health and Human Services (HHS) Fiscal Year 2023 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.

1) Agency for Healthcare Research and Quality (AHRQ)

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

AHRQ Quality Indicators - https://qualityindicators.ahrq.gov/
AHRQ Data Tools – MEPS and HCUP https://datatools.ahrq.gov/nhqdr/

2) Centers for Disease Control and Prevention (CDC)

National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Division of STD Prevention (DSTDP)

Building on previous years' work, DSTDP's Surveillance and Data Science Branch has been exploring a syphilis registry model leveraging Fast Healthcare Interoperability Resources (FHIR) and open-source common data models. This registry would be helpful for case investigations of syphilis and consolidating the information retrieved from EHRs. Syphilis-related patient information was retrieved for diagnoses, laboratory test types and results, treatment, and pregnancy status.

Division of Tuberculosis Elimination (DTE)

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

National Institute for Occupational Safety and Health (NIOSH)

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

Center for Laboratory Systems and Response (CLSR)

Division of Laboratory Systems (DLS)

DLS leads CDC's Public Health Laboratory Electronic Test Orders and Results (ETOR) Initiative. A key component of this work is implementing standard vocabulary, format, and transport mechanisms to ensure data interoperability between partners. Standards in use are listed below.

DLS supports the Laboratory Response Network (LRN) by providing comprehensive informatics and data exchange solutions to move data from LRN member laboratories to CDC. Standards in use are listed below.

DLS manages the review of LOINC In Vitro Diagnostic (LIVD) Test Code Mapping files used to identify and facilitate reporting of laboratory test results between laboratories and public health agencies. Standards in use are below.

- **Health Level Seven (HL7)**
  - CDC utilizes several different resources to work within HL7 global standards for transferring clinical and administrative health data between application; applied in work with ETOR and LRN DE.
  - Laboratory Orders from EHR (LOI) Release 1, STU Release 4 - US Realm
  - Laboratory Results Interface (LRI), Release 1 STU Release 4 - US Realm
  - HL7 Vocabulary
  - Electronic Laboratory Reporting (ELR) HL7 v 2.5.1 Implementation Guide: ELR Reporting to Public Health (US Realm), Release 2, HL7 Informative Document (May 2014)
- **Logical Observation Identifiers Names and Codes (LOINC)**
  - Representing Laboratory Tests (includes Ordered, Performed) and clinical observations, including surveys and ask at order entry (AOE) questions; or,

when using the LOINC Answer codes also result values or answers to survey/ask AOE questions. Oversight from Regenstrief and used within DLS for LRN DE and ETOR.
    - LOINC (Logical Observation Identifiers Names and Codes)
- **Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT)**
    - Representing Laboratory Values/Results, specimen and could be other clinical concepts like symptoms, diseases etc.; used within DLS for LRN DE and ETOR.
    - SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms)
- **Unified Code for Units of Measure (UCUM)**
    - Representing units of measure in a standardized way, with oversight from Regenstrief and use within DLS for LRN DE and ETOR.
    - Unified Code for Units of Measure (UCUM)
- **Logical Observation Identifiers Names and Codes (LOINC) In Vitro Diagnostic (IVD) Mapping (LIVD) on FHIR or from IICC**
    - Representing details for Laboratory IVD Tests - performed test, includes ordered test, result values, specimen type, with use within DLS for LIVD webpage
    - Logical Observation Identifiers Names and Codes (LOINC) In Vitro Diagnostic (IVD) Mapping (LIVD) on FHIR or from IICC
- **Blood Culture Contamination Quality Measure**
    - Quality measure to protect patients during the diagnostic process by monitoring adult blood culture contamination (BCC) rates.
    - Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals | CDC
- **Laboratory Quality Standards**
    - The Clinical Laboratory Improvement Amendments of 1988 (CLIA) has several requirements for establishment or verification of clinical test method performance. The Clinical & Laboratory Standards Institute (CLSI) creates voluntary guidelines for sensitivity, accuracy, precision, and linearity of test methods. In addition, CLIA uses a quality systems approach and CLSI has a suite of relevant quality management system (QMS) documents that can be used to meet CLIA requirements. Several DLS personnel participate in document development committees that create and update evaluation protocols and QMS documents, and other documents that describe best practices for CLIA laboratories that are used by CDC and others.
- **Next-Generation Sequencing Quality Initiative**
    - The CDC/Association of Public Health Laboratories NGS QI (Next-Generation Sequencing Quality Initiative) utilizes the CLSI QMS standards to ensure the accuracy, reliability, and consistency of NGS testing processes. These standards are applied and built upon to ensure quality in all stages and steps of laboratory testing for public health and clinical applications.

        - Standards for reporting and interoperability of metadata include those promulgated by the American College of Medical Genetics (ACMG) and Global Alliance for Genomics and Health (GA4GH). These standards help promote transparency, reproducibility, and interoperability in NGS research.
    - **CMS to CDC Data Stream**
        - DLS is utilizing a design standard, representation state transfer (REST) for its application programming interface (API) as an architecture for data transfer from the Centers for Medicare & Medicaid Services to CDC.
    - For analysis of population-level data for public health trending and interventions, DLS/QSSB data analysis utilizes Observational Health Data Sciences and Informatics (OHDSI) and the OMOP Common Data Model.

Office of Public Health Data, Surveillance, and Technology (OPHDST)

- National Notifiable Diseases Surveillance System (NNDSS)
    - Specific Notifiable Disease Reporting to Public Health (Final Guides): https://ndc.services.cdc.gov/message-mapping-guides/
    - 2024 NNDSS Event Code List (Release 1): https://ndc.services.cdc.gov/wp-content/uploads/National_Notifiable_Diseases_Surveillance_System_Event_Code_List_2024_v1_2023DEC01.xlsx
    - PHIN VADS Value Set Link to the NNDSS 2024 Event Code List: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=DAA542A7-9D50-4706-9AA6-1DBFDDFF9D2D
- National Syndromic Surveillance Program (NSSP)
    - HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm, Standard for Trial Use, July 2019; **Current Document searchable at HL7.org*: http://www.hl7.org/; ***login or sign up required for download;* Access Instructions: go to Standards and then Standards for Trial Use, scroll to or search Syndromic Surveillance guide (close date July 26, 2021).
    - PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 (April, 2015): https://www.cdc.gov/nssp/documents/guides/syndrsurvmessagguide2_messagingguide_phn.pdf
    - 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, 2015: https://www.cdc.gov/nssp/documents/guides/erratum-to-the-cdc-phin-2.0-implementation-guide-august-2015.pdf
    - PHIN 2.0 Implementation Guide Meaningful Use Clarifying Document (PDF available on NIST Website): https://hl7v2-ss-r2-testing.nist.gov/ss-r2/api/documentation/doc?name=NIST-SS-Clarifications-and-Validation-Guidelines-V1-6.pdf

Data Policy and Standards (DPSD)

The Centers for Disease Control and Prevention's (CDC) new Data Policy and Standards Division (DPSD) in the Office of Public Health Data Surveillance and Technology (OPHDST) is working collaboratively across the centers and externally to improve data sharing and interoperable data exchange between state, tribal, local, and territorial (STLT) federal, and health care partners. The focus of the work includes:

- Ensure Core Data Sources are more complete, rapidly exchanged to support collective ability to detect, monitor, investigate and respond to public health threats
- Ensure access, exchange and use of interoperable data across the healthcare and public health ecosystem

DPSD plays an active role in the CDC Advisory Committee to the Director (ACD) Data and Surveillance Workgroup (DSW) Report, including developing consensus based defining definitions for the minimum data necessary (MDN) to support emergency response for six core areas of public health surveillance including**: case data; laboratory-based diagnostic testing data, syndromic surveillance/emergency department data; immunization/vaccine administration data; hospital capacity data; and death data/vital statistics**. These established MDN data sets reduce the burden on our STLT partners in the beginning of an emergency response by establishing standardized data collection across CDC for the exchange of data on confirmed, probable, and suspected cases.

In addition to establishing standardized MDN requirements, the OPHDST coordinates comments and feedback to the Office of the National Coordinator for Health IT (ONC) on United States Core Data for Interoperability (USCDI) and USCDI+ for public health specific use cases, across the Agency. The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. Healthcare data is a large dataset that Public Health can leverage to identify and respond to emerging health threats and apply interventions.

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

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

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 data standards can be found here: https://www.cdc.gov/cancer/npcr/standards.htm.

CDC Diabetes Prevention Recognition Program (DPRP)

The Centers for Disease Control and Prevention established the CDC Diabetes Prevention Recognition Program (https://www.cdc.gov/diabetes/prevention/lifestyleprogram/index.html) as part of the National Diabetes Prevention Program (National DPP) (https://www.cdc.gov/diabetes/prevention/index.html). The DPRP is the quality assurance arm of the National DPP. It provides information about the location and performance of type 2 diabetes prevention programs across the US. This includes organizations delivering the National DPP lifestyle change program in-person, online, via distance learning, and through a combination of these delivery modes. The purpose of the DPRP is to recognize organizations that have demonstrated their ability to effectively deliver a proven type 2 diabetes prevention lifestyle change program.

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

The DPRP has three key objectives:

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

Program delivery organizations must also track results and send data to CDC every 6 months based on requirements in the DPRP Standards CDC reviews these data and provides feedback to each organization. DPRP evaluation data to date show evaluated participants attended an average of 18 core sessions (organizations are required to offer a minimum 22 core sessions) and 9 core maintenance sessions (organizations are required to offer a minimum 6 core maintenance sessions) in the National DPP lifestyle change program. Participant risk reduction, determined using outcomes associated with weight, physical activity minutes, and HbA1c, was seen in 52.8% of all evaluated participants. This risk reduction included 48.5% who achieved at least a 5% weight loss; 34.5% who achieved at least a 4% weight loss combined with at least 150 min/week on average, of physical activity; and 1% to date who had at least a 0.2% reduction in HbA1c (of those who submitted HbA1c information*). As of March 11, 2024, there are 1,499 CDC-recognized organizations that have collectively enrolled 753,764 participants nationwide since the program's inception.

*Note: The CDC Diabetes Prevention Recognition Program Standards and Operating Procedures describe in detail the DPRP requirements and explain how an organization may apply for, earn, and maintain CDC recognition (https://www.cdc.gov/diabetes/prevention/pdf/dprp- standards.pdf) to offer the National DPP lifestyle change program. The current (2021) DPRP Standards are undergoing revision; we expect the 2024 Standards to be finalized and made available to the public in May.

Division for Heart Disease and Stroke Prevention (DHDSP):

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

National Center for State, Tribal, Local, and Territorial Public Health Infrastructure and Workforce (NCSTLTPHIW)

The Centers for Disease Control and Prevention (CDC) National Center for State, Tribal, Local, and Territorial Public Health Infrastructure and Workforce (NCSTLTPHIW) has been a key supporter in the development, launch and support of the voluntary accreditation program for public health departments. The Public Health Accreditation Board (PHAB), a non-profit accrediting body, leads the accreditation program which launched in September 2011. Until the establishment of PHAB, there had been no national accreditation program for public health departments. The initial national consensus standards were released in July 2011 (Version 1.0), an update (Version 1.5) was released in 2014, and PHAB released the Version 2022 Standards and Measures in FY22 with support from CDC to produce and vet the new standards. CDC has been involved as a partner and funder of this initiative to provide support to

PHAB's accreditation and continuous improvement activities as evidenced through its accreditation page at (https://www.cdc.gov/publichealthgateway/accreditation/). The first cohorts of health departments were accredited in early 2013. As of the end of FY 2023:

- PHAB has accredited 434 health departments—41 states, six tribes, and 387 local health departments (including 320 individually accredited local health departments and 67 county health departments through a centralized state application).
- 88% of the U.S. population is served by an accredited health department (HD).
- PHAB began reaccrediting sites in 2018; 108 sites have been reaccredited.
- 531 HDs, including 43 SHDs, are formally in the accreditation process (applied or accredited) and are demonstrating how they meet the national standards.

All documents related to the accreditation program (the standards, assessment process guidance, glossary, etc.) are available at www.phaboard.org. Annual evaluation findings consistently report short- and long-term benefits to participating in accreditation. June 2023 evaluation data indicate that the program has stimulated quality improvement (95% of accredited health departments agree), improved accountability and transparency (88%), improved the capacity of the department to provide high-quality programs and services (81%), and improved collaboration across units within the health department (88%) one year after accreditation. Four years after accreditation, accredited health departments report that the program has helped health departments use health equity as a lens for identifying and addressing health priorities (73%), strengthened the utilization of resources (63%), and strengthened relationships with key partners in other sectors (e.g., health care, social services, education) (76%). More information about the accreditation program can be found at (http://www.phaboard.org) and aggregate accreditation data about health department capacity, searchable by PHAB domain, theme, and health department characteristics, can be found at the PHAB data portal at (www.phabdata.org).

3) Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) works with partners in a voluntary manner to develop, evaluate, and apply national standards and consensus-based standards. Below is a summary of significant standards at CMS used to increase the electronic exchange of health information between covered entities and to measure performance for quality initiatives including healthcare provider public reporting and value-based purchasing programs.

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

adoption of electronic standards by all covered entities, including those organizations in the private and public sector, as electronic transaction standards will increase efficiency in health care.

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

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

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

The Quality Measurement and Value-Based Incentives Group (QMVIG) in the Center for Clinical Standards and Quality (CCSQ) at CMS selects performance measures for use within its various quality initiatives including healthcare provider public reporting and value-based purchasing programs.

CMS prefers selecting performance measures (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualitymeasures) that have been reviewed through a consensus process, and can be considered consensus-based standards. Battelle Memorial Institute (Battelle), a not- for-profit, nonpartisan organization offering free membership to participate in consensus-based entity (CBE) activities, meets the NTTAA definition of a consensus-based organization. CMS currently contracts Battelle to execute a public and transparent consensus development process to endorse and maintain performance measures.

Battelle's Endorsement & Maintenance (E&M) process (https://p4qm.org/EM) includes an open call for candidate consensus standards (i.e., performance measures); multi-stakeholder review of scientific and statistical evidence against the established endorsement criteria; discussion and evaluation of measures by multi-stakeholder experts including patients and caregivers; and opportunities for stakeholder feedback and public comments throughout the process. The E&M process also includes an opportunity for stakeholders and the public to appeal a decision on measures after they receive consensus-based endorsement. These processes are consistent with the NTTAA and OMB Circular A-119.

- CMS Quality Measures: https://mmshub.cms.gov/
- Partnership for Quality Measurement: https://p4qm.org

4) Food and Drug Administration (FDA)

FDA is responsible for protecting public health by helping to bring safe and effective medical products and foods to the U.S. public; and advancing public health by ensuring the public has the most accurate, science-based information they need to use medicines and foods to improve and maintain their health. Standards help to ensure data and process consistency and enable use of advanced technology and analytics in FDA's performance of its mission. Where feasible, FDA participates in the development of, and uses voluntary consensus standards to help facilitate consistent and predictable product manufacturing and assessment, regulatory testing, clinical trial data exchange, and product labeling, just to name a few examples. Information exchange with our stakeholders promotes efficiency and awareness in the standards setting processes. The Agency looks for the appropriate time, process, and forum by which we can engage with standard development organizations. By doing so, FDA can facilitate standard setting activities and not hinder or duplicate efforts that are already underway in complementary bilateral or multilateral discussions. The use of voluntary consensus standards can increase predictability, streamline premarket review, and facilitate market entry for safe and effective products, including products of emerging technologies, under FDA regulatory authority.

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

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

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

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

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

Center for Devices and Radiological Health (CDRH)

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

During FY2023, 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 2023e:

Date	Federal Register Notice
August 2, 2023	FR Notice (List #59) [Docket No. FDA-2004-N-0451] https://www.govinfo.gov/content/pkg/FR-2023-08-02/html/2023-16418.htm
August 7, 2023	FR Notice (List #60) [Docket No. FDA-2004-N-0451] https://www.govinfo.gov/content/pkg/FR-2023-08-07/html/2023-16770.htm

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.

Effective September 19, 2023, the U.S. Food and Drug Administration's Accreditation Scheme for Conformity Assessment (ASCA Program) was converted from a pilot to a permanent program as authorized by Medical Device User Fee Amendments of 2022 (MDUFA V). 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 Program 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. 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 ASCA Program continues to be implemented through guidances outlining program specifications that can be found on the ASCA Pilot web page and listed below:

- **ASCA Pilot program guidance:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance*
- **Basic Safety and Essential Performance standards-specific guidance:** *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*
- **Biocompatibility standards-specific guidance:** *Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*

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

As of November 20, 2023, CDRH has provided ASCA recognition to 5 Accreditation Bodies and granted ASCA-accreditation to 101 testing laboratories under the scope of standards and methods included in the ASCA Pilot.

CDRH will continually report annually on the progress of the ASCA Program and work with stakeholders for further input on programmatic improvements and/or considerations for expansion.

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

The FDA Food Safety Modernization Act (FSMA) gives the Agency explicit authority to establish a program for accreditation of conformity assessment bodies (identified in the statute as third-party auditors) to conduct food safety audits and issue certifications of foreign food facilities for FDA-regulated food, which includes human food, and animal food. In 2015, FDA issued regulations (21 CFR Part 1 subpart M) establishing the Accredited Third-Party Certification Program. The regulations describe the framework, procedures, and requirements for accreditation bodies seeking recognition by the FDA, as well as requirements for third-party certification bodies seeking accreditation, under the

program. Accreditation bodies and third-party certification bodies may use documentation of their conformance with ISO/IEC 17011:2004, ISO/IEC 17021:2011, and ISO/IEC 17065:2012 in meeting the requirements of the regulations, supplemented as necessary (e.g., to meet the conflict of interest, reporting, and notification standards in section 808 of the FD&C Act). FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under the voluntary third-party certification program are contained in a guidance document entitled, "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff."

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 FY23, the FDA has recognized 4 accreditation bodies which have accredited 11 certification bodies. FDA maintains an online registry of accreditation bodies recognized, and certification bodies accredited, under this program.

FSMA also gives us express authority to establish a laboratory accreditation program for the analyses of human and animal foods. FDA issued a final rule in December 2021 establishing the Laboratory Accreditation for Analyses of Foods (LAAF) program. The final rule specifies the oversight, uniformity, and standards necessary to help ensure that the results of certain food testing of importance to public health are reliable and accurate. Under the LAAF program, FDA recognizes accreditation bodies that accredit laboratories to the standards established in the final rule ("LAAF accredit"); only LAAF-accredited laboratories may conduct the food testing covered by the final rule. The final rule incorporates by reference two voluntary consensus standards: ISO/IEC 17011:2017 forms the foundational requirement for accreditation bodies, and ISO/IEC 17025:2017 forms the foundational requirement for food testing laboratories. As of the end of FY23, FDA has recognized 7 accreditation bodies that have accredited 23 testing laboratories. FDA maintains an online registry of accreditation bodies recognized, and laboratories accredited, under this program.

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

Office of Regulatory Affairs (ORA)

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

Within the framework of a current FDA-USP Cooperative Research and Development Agreement (CRADA), ORA/ORS Laboratories also conduct analytical work aimed at updating USP pharmaceutical analysis monographs using USP reference materials.

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

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

ORA/ORS Laboratories are also active members of the Integrated Consortium of Laboratory Networks (ICLN) 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 advances the nationally integrated food safety system (IFSS) specifically with regards to microbiological and chemical food analyses. This includes preparing state laboratories for accreditation enhancements. Data generated by awarded state laboratories will be available to inform FDA in its enforcement actions, surveillance, and response to foodborne outbreaks. These ISO accredited laboratories aid FDA with additional resources and exceptional data to maintain the safety of the food chain.

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

- Manufactured Food Regulatory Program Standards
- Flexible Funding Model
- National Integrated Food Safety System – Laboratory Capacity Building
- Voluntary National Retail Food Regulatory Program Standards
- Animal Feed Regulatory Program Standards

Center for Biologics Evaluation and Research (CBER)

In September of 2023, 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." Minor deficiencies identified during the audit have no impact on the integrity of testing or standards production. The reference materials produced and calibrated by DBSQC included influenza antigens and sheep antisera for influenza vaccine potency testing, as well as tetanus and diphtheria antitoxin for flocculation tests. Reagents for egg-propagated, cell-propagated and recombinant A(H1N1)pdm09, A(H3N2) and B/Victoria-lineage seasonal influenza vaccine components as well as A(H2N3), A(H5N6), A(H5N8), A(H7N9) and A(H9N2) pandemic reagents were prepared and calibrated by CBER; DBSQC also collaborated with the WHO Essential Regulatory Laboratories at MHRA, UK; TGA, Australia; and NIID, Japan to calibrate influenza reagents produced to support influenza vaccine manufacturing world-wide.

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 re-accreditation in September 2023; no deficiencies were identified. The scope of accreditation for the LIB covers the "ELISA Competition Assay for Quantitative Determination of Relative Potency of Allergenic Extracts." Additionally, LIB has reviewed over 393 protocols for lot release in conjunction with ELISA potency tests and shipped over 4,000 references to manufacturers of allergenic products during FY 2023.
CBER coordinates with CDER to implement data standards related to the following:

- Real World Data and Real World Evidence
- Identification of Medicinal Products
- CDISC standards for clinical and nonclinical study data and terminologies (e.g., MedDRA, SNOMED CT, WHO Drug Global)
- HL7 v3 and FHIR for exchange of data for numerous use cases including labeling, drug registration and listing, and other use cases
- HL7 ICSR for adverse event data
- ICH eCTD v 4 for content of regulatory submissions
- Pharmaceutical Quality (PQ) and Chemistry & Manufacturing Controls (CMC) data standards
- Bioresearch Monitoring Data Standards
- BioCompute Objects for High-throughput Sequencing Data
- For more information, see Study Data for Submission to CDER and CBER | FDA and FDA Data Standards Advisory Board | FDA
- ICH Q1/Q5C Guidance on stability: This revision will combine CBER regulated complex biologics such as vaccines and Cell and Gene Therapy product to the list of small molecules and well characterized biological products regulated by CDER, to provide harmonized advice to sponsors.

The 21st Century Cures Act was signed into law in December 2016. Section 3036 directs the FDA to collaborate with the National Institute of Standards and Technology (NIST) and FDA stakeholders to coordinate and prioritize standards development for regenerative medicine and regenerative medicine advanced therapies. CBER awarded a contract to Nexight Group and the Standards

Coordinating Body (SCB) in 2017 to establish a collaboration consisting of FDA, NIST, and stakeholders, to coordinate the development and implementation of the processes and criteria to identify and prioritize standards that have a high impact on the quality and safety of regenerative medicine products and determine whether the development of any specific standard is feasible. This contract has been extended to 2024 with deliverables to include the identification of needed standards, the conduct of feasibility assessments for needed standards, maintenance of the standards web portal that allows for stakeholders to search form standards under development and standards available, and stakeholder outreach to experts for input on standards under development.

To encourage the use of standards for regenerative medicine products, CBER published the final guidance Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies on October 19, 2023 (https://www.fda.gov/media/159237/download). This guidance describes a standards recognition program for regenerative medicine therapies (SRP-RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. CBER encourages the use of appropriate standards in the development of CBER-regulated products. The use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. This program is modeled after the formal standards and conformity assessment program or S-CAP for medical devices. CBER will post a list of recognized standards on the regenerative medicine therapies portion of the FDA website https://www.fda.gov/vaccines-blood-biologics/standards-development-regenerative-medicine-therapies .

Center for Drug Evaluation (CDER)

CDER launched the pharmaceutical quality standards recognition program on July 26, 2023. This program allows internal FDA staff and external stakeholders to propose pharmaceutical quality standards for recognition by CDER, providing industry with additional resources for pharmaceutical development and manufacturing. CDER issued the final guidance for this program, CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality and launched a new portal (https://cdernextgenportal.fda.gov) to facilitate submission of standards for potential recognition. This program is intended to promote innovation in pharmaceutical development and manufacturing. Additional information can be found on the program's webpage (https://www.fda.gov/drugs/cder-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality-cder-quality).

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

As part of the 21st Century Cures directives, FDA is to create a framework establishing the RWE program, along with Guidance documents for industry, informed by communications with stakeholders from industry and the public. To fulfil these mandates, in 2017 CDER established a committee and associated workgroups dedicated to this effort with participation from multiple FDA Centers. Throughout 2017 and 2018, these groups have (1) developed a draft RWE Framework that was published in December 2018; (2) established workgroups to develop Guidance on a range of topics pertinent to the use of this data; (3) reviewed the range of RWE already in use for FDA submission; (4) and engaged with stakeholders from industries and the public through participation in meetings and workshops focused on the use of RWE for clinical research and regulatory submissions. Meetings were facilitated by stakeholders including the Margolis Center for Health Policy at Duke University and the National Academies of Sciences. Attending stakeholders at various meetings included a spectrum of representatives from the pharmaceutical industry, healthcare, academia, patient organizations, standards development organizations such as Health Level 7 (HL7) and Clinical Data Interchange Standards Consortium (CDISC), and other members of the general public. In 2019 the Center began examining the ability of current submission data standards to accommodate real-world data and develop a roadmap to optimizing these standards in the future for real-world data submission. As with other FDA data standards activity, consensus-based standards such as those from CDISC and HL7 are being explored. In 2020, FDA developed the draft guidance "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products" that was published in September 2021. Another draft guidance focusing on data standards considerations for submission of studies containing RWD was developed in 2021. In 2022, FDA has collated and addressed all public comments for the draft RWD guidance and is revising the document to prepare for publication of the final guidance. FDA further explored opportunities to adapt HL7 Fast Healthcare Interoperability Resources (FHIR) for Real World Data submissions through engagement with HL7 Vulcan Accelerator Track, resulting in the development of draft Implementation guides (IG) for two use cases (Acute Coronary Syndrome and Anti-TNFa Treatment in Patients with Crohn's Disease). In 2023, the final RWD guidance was completed and is expected to publish by the end of first quarter in 2024. FDA continued its engagement with the HL7 Vulcan Accelerator testing and refining the FHIR RWD Implementation Guide (IG). The IG was balloted and published as Standard for Trial Use (STU) in May. FDA will continue to explore and evaluate approaches to standardize RWD for regulatory submission in 2024 and beyond.

FDA is also working to standardize submissions for the information submitted in Electronic Common Technical Document (eCTD) Module 3 covering Pharmaceutical Quality, Chemistry, Manufacturing, and Controls (PQ/CMC). In 2017, a Federal Register Notice was published documenting structured data and associated vocabularies for approximately one-third of Module 3 information. In 2019, development began for Phase 1 of the PQCMC effort by using HL7 FHIR as the exchange standard to represent an initiate set of eCTD Module 3 structured data for submissions. In 2020, the Center initiated Phase 2 of the development effort to standardize the remaining information for eCTD Module 3. Development continued into 2021 and a Federal Register Notice (FRN) detailing the FHIR mapping of all Phase 1 PQ/CMC data elements is in the clearance process. In 2022, FDA published a FRN requesting for comments on the Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Exchange, and later addressed public comments resulting in revisions to PQCMC Phase 1 data elements and the completion of the PQ/CMC Phase 1 Interim Implementation Guide. In 2023, FDA published a FRN announcing the establishment of an open docket on matters related to PQ/CMC Data Elements and Controlled Terminologies, which entails a new process for release of relevant information for public comment where each update will be made available on the public-facing FDA

PQCMC webpage designated as a new “Chapter” that contributes to a growing set of draft data elements and terminology. The Agency completed development of all Phase 1 PQCMC data elements, and the standardization of the remaining Phase 2 elements is underway and will continue in 2024.

ISO Identification of Medicinal Product (IDMP) is a suite of five related standards to identify and describe medicinal products and to exchange of product information between partners to support pharmacovigilance, product shortage, and other regulatory activities. The Integrity Product Domain and Global Substance Registration System are built based on ISO 11615/ISO 11616 and ISO 11238 respectively to be the master repository for CDER regulated medicinal products and FDA regulated substances. To enable pharmacovigilance across multiple jurisdictions or at global level, FDA continues to participate in the revision and enhancement of IDMP standards with ISO TC 215, and to collaborate with other regulators for harmonized approach for IDMP development. In 2022, FDA jointly established the Global IDMP Working Group (GIDWG) with WHO-UMC and EMA to conduct and report on projects leading to the establishment of a framework for the global implementation of the ISO IDMP standards and maintenance of global identifiers. The GIDWG initiated 5 pilot projects to identify challenges and mitigation to establish common grounds, business rules, and processes to facilitate global IDMP implementation. In 2023, FDA published the final IDMP Guidance: “Identification of Medicinal Products: Implementation and Use”. This guidance explains the FDA’s position and progress on aligning the Agency’s standards to IDMP standards, with the goal of harmonizing the standards for international exchange of medicinal product data. FDA continues to collaborate with EMA, WHO, WHO-UMC to establish a framework for maintenance of Global Substance and Global Pharmaceutical Product Identifiers.

5) 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 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, 2015 Edition, and 2015 Edition Cures Update standards published by the Office of the National Coordinator for Health Information Technology (ONC). This has allowed IHS, Tribal and Urban Indian healthcare organization hospitals and providers to qualify for various Centers for Medicare and Medicaid Services (CMS) Meaningful Use incentives authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act and to participate in CMS Quality Payment Programs. IHS has certified to the requirements that were due in 2023 for the ONC 2015 Edition Cures Update per ONC's timeline in the Federal Register. The IHS is continuing work to comply with the requirements due in 2024 as well. The IHS has utilized and incorporated numerous information technology standards promulgated by development organizations and specified in the various ONC Final Rules in order to meet the rigorous certification requirements.

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

6) National Institutes of Health

National Cancer Institute (NCI)

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

The mission of the NCL is to advance the science of nanoparticle characterization. As part of these efforts, the NCL has developed 82 assays and 5 characterization guides for nanomaterial characterization, termed NCL's Assay Cascade. All NCL assays are published on the NCL website and are free to download: https://www.cancer.gov/nano/research/ncl/protocols-capabilities

Over 500 nanomaterials of varied platform types have passed through the NCL Assay Cascade. The laboratory updates existing assays on a regular basis and develops and validates new assays to meet the needs of the nanotechnology research community. This year, one new protocol was added to our catalogue:

- PCC-23: Detection of Residual DMSO in nanoformulations using gas chromatography with direct injection and flame ionization detection

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

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

NCL team members are active participants of the standards organizations ASTM International and ISO, which develop voluntary consensus standards. Several of the NCL's protocols have been adapted as ASTM standards:

- ASTM E2524-22: Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
- ASTM E2525-22: Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
- ASTM E2526-22: Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells
- ASTM E3351-22: Standard Test Method for Detection of Nitric Oxide Production In Vitro

Efforts are also ongoing to bring two additional NCL protocols through ASTM as Standard Methods or Standard Guides. These efforts are continuing into 2024. The standards under development are:

- ASTM WK76862: Standard Guide for Identification of Nanoparticle's Ability to Induce Infusion Reactions
- ASTM WK76860: Method for the Preparation and Analysis of Culture Supernatants for the Presence of Cytokine Biomarkers by Nanoparticles in Human Whole Blood Cultures

NCL staff also serve as subject matter experts in various nanotech-related working groups within these organizations. In addition to working to promote NCL's assay to standards, the NCL also contributed to the development of several other standards:

- ISO 29701:2010 Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems — Limulus amebocyte lysate (LAL) test
- ISO TS 21362: Nanotechnologies — Analysis of nano-objects using asymmetrical-flow and centrifugal field-flow fractionation.
- ASTM E3297-21: Standard Test Method for Lipid Quantitation in Liposomal Formulations

Using High Performance Liquid Chromatography (HPLC) with a Charged Aerosol Detector (CAD)
- ASTM E3324-22: Standard Test Method for Lipid Quantitation in Liposomal Formulations Using Ultra-High-Performance Liquid Chromatography (UHPLC) with Triple Quadrupole Mass Spectrometry (TQMS)

Staff are also currently working with ASTM International and ISO on the preparation and adoption of new standards:

- ASTM standard for endotoxin measurements in nanoformulations
- ASTM WK68060: Analysis of Liposomal Drug Formulations using Multidetector Asymmetrical- Flow Field-Flow Fractionation
- ASTM WK75607: Standard Guide for Characterization of Encapsulation, Extraction, and Analysis of RNA in Lipid Nanoparticle Formulations for Drug Delivery
- ASTM WK76861: Standard Practice for In vivo analysis of nanoparticle-mediated physiological changes accompanying hypersensitivity reactions
- ASTM WK83164: Analysis of Lipid Nanoparticle Formulations Using Multi-Detector Asymmetrical-Flow Field-Flow Fractionation
- ASTM WK86057: New Standard Test Method for Measuring Sulfate and Ammonium Ion Concentrations in Liposome Drug Formulations
- ISO standard, Nanotechnologies—Total and free drug quantitation in doxorubicin hydrochloride liposomal formulations
- ISO/DTS 4958: Nanotechnologies - Vocabulary – Liposomes

National Library of Medicine (NLM)

The National Library of Medicine (NLM) is a leader in biomedical informatics and computational health data science research and the world's largest biomedical library. With a mission to acquire, collect, preserve, and disseminate materials relevant to research, medicine, and public health, NLM makes the world's biomedical data and information discoverable and accessible to all: scientists, clinicians, students, educators, librarians, and the public. NLM's biomedical information services enable data- driven scientific discovery, health care, and public health. In addition, NLM's innovative research programs develop and apply novel computational approaches to accelerate biomedical discovery and advance health care across disease areas.

As the central coordinating body within the U.S. Department of Health and Human Services for clinical terminology standards for health data interoperability, NLM plays a critical role in promoting health data interoperability through the development, maintenance, and dissemination of health data standards. In this role, NLM works across the National Institutes of Health and Federal Government to advance the interoperable exchange of health data for care and quality reporting in support of federal health information technology (IT) interoperability requirements, and of research.

In FY 2023, NLM continued to support improvements in health data standards, services for standards- based information sharing, and use of standards in its literature services.

NLM continued to support the improvement of three standards used to assure the precise and current representation of terms and codes needed for clinical care and research:

1) SNOMED CT® (Systematized Nomenclature of Medicine Clinical Terms): Supported expansion by adding nearly 10,000 concepts and the addition of over 550 concepts to enable users to capture information specific to the U.S. health care system.
2) LOINC® (Logical Observation Identifiers, Names and Codes): Added nearly 2,600 new terms to support the provision of high-quality interoperable laboratory information
3) RxNorm: Added nearly 250 new terms to facilitate the prescription and monitoring of therapeutics and vaccinations in electronic health record (EHR) systems that support payment as well as care management.

NLM also continued to support services that facilitate standards-based information sharing for health care and public health.

1) MedlinePlus Connect provides patients and clinicians with direct, tailored access to MedlinePlus resources automatically through EHR systems, patient portals, and other health information technology (IT) systems at the point of care. In FY 2023, MedlinePlus Connect responded to nearly 190 million electronic requests from health IT systems.

2) Value Set Authority Center is a repository and authoring tool for value sets, or lists of codes and corresponding terms, from NLM-hosted standard clinical vocabularies (such as SNOMED CT®, LOINC®, and RxNorm), that define clinical concepts to support effective and interoperable health information exchange. In FY 2023, in collaboration with the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology, NLM published value set specifications for the 2023 electronic clinical quality measures (eCQMs); the Health Level Seven International (HL7) Consolidated Clinical Document Architecture (C-CDA) value sets; and, a trial release of the HL7 Fast Healthcare Interoperability Resources (FHIR®) eCQM value sets in preparation for CMS's planned 2025 public release of the FHIR eCQM value sets.

Lastly, NLM continued to employ use of and provide support for the Journal Article Tag Suite (JATS), an application of NISO Z39.96-2021, which defines a set of XML elements and attributes for tagging journal articles and describes three article models. NLM hosted the JATS-Con Conference in support of JATS users in June 2023. NLM also supported the NISO JATS Standing Committee as it worked on the next version of JATS, which is expected to be released in 2024.

7) Office of the National Coordinator for Health Information Technology (ONC)

Standards are an integral component of ONC's mission to support the development of a nationwide health information technology (health IT) infrastructure that allows for electronic use and exchange of information in a scalable manner, promotes the adoption of interoperable health IT in a cost-effective manner, and provides leadership in the development, recognition, and implementation of standards and certification of health IT products. The consistent use of health IT standards is a necessary requirement to achieve interoperability of health information, which is a central key to reducing health care costs.

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

One of the standards used in certification criteria is the United States Core Data for Interoperability (USCDI) which is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. It establishes a baseline set of data that can be commonly exchanged across care settings for a wide range of uses. In 2020, ONC published USCDI Version 1 and created an annual process for updating the USCDI based on public input. In 2023, ONC published USCDI Version 4 after going through the annual process and is now working on developing USCDI Version 5.
Additionally, ONC continues to use the Health Information Technology Advisory Committee (HITAC) to review proposed drafts of the USCDI as one means to get expert feedback before finalizing each version.

The USCDI’s impact is not limited to health IT products certified under the ONC Health IT Certification Program. The ONC Cures Act Final Rule provisions related to “information blocking” also reference the USCDI as the initial scope of electronic health information (EHI) healthcare providers, health information networks and exchanges, and developers of certified health IT need to consider when it comes to the access, exchange, and use of EHI. Please see the USCDI webpage and the USCDI Fact Sheet for more information.

The Standards Version Advancement Process (SVAP) enables health IT developers to voluntarily incorporate newer versions of specific ONC-regulated standards and implementation specifications into their products under the ONC Health IT Certification Program, including future versions of the USCDI. The SVAP advances interoperability by permitting developers of certified health IT to implement newer versions of standards and specifications than currently adopted in regulation. In 2020, ONC established an annual public comment process for SVAP-eligible standards and implementation specifications. In 2023, ONC announced the “Approved Standards for 2023,” which includes USCDI v3. Please see the SVAP Approved Standards on the ONC Certification Program SVAP webpage.

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

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

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

Related Links

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

8) Substance Abuse and Mental Health Services Administration (SAMHSA)

The Substance Abuse and Mental Health Services Administration (SAMHSA) works closely with other Department of Health and Human Services (HHS) agencies, including the Centers for Medicare and Medicaid Services' (CMS), contracted consensus-based entity (CBE), in matters related to quality measures and alignment of those measures. The current CBE for quality measurement is Battelle's Partnership for Quality Measurement (PQM)™. The PQM uses a consensus-based process involving a variety of experts - clinicians, patients, measure experts, and health information technology specialists - to ensure informed and thoughtful endorsement reviews of qualified measures to be used for federal reporting.

SAMHSA collaborates with a number of federal partners, including, CMS, as well as private and other public stakeholders, as part of workgroups and governance groups that provide input to HHS on quality measures that will be included in CMS and SAMHSA public reporting efforts. Specifically, SAMHSA is a federal liaison or working group member working with CMS and other stakeholders on the following:

- Child and Adult Health Care Quality Measures that are the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set). The most current iterations of these measures can be found at:

  2023 and 2024 Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set): https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child- health-care-quality-measures/adult-health-care-quality-measures/index.html

  2023 and 2024 Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set): https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult- and-child-health-care-quality-measures/childrens-health-care-quality-measures/index.html

- Health Home Quality Measures, the most current iteration of which may be found at:

  2023 and 2024 Core Set of Health Care Quality Measures for 1945 Medicaid Health Home Programs (1945 Health Home Core Set): https://www.medicaid.gov/sites/default/files/2023-

03/2023-health- home-core-set_0.pdf

- Electronic Clinical Quality Measures (eCQM) governance group. Information about CMS eCQMs may be found at https://ecqi.healthit.gov/ecqms

Some of these measures have been used in different stages of "Meaningful Use" and are now part of the Merit-based Incentive Payment System (MIPS). The 2024 MIPS Quality Measures can be found at: https://qpp.cms.gov/resources/resource-library

SAMHSA also collaborates with both CMS and the Office of the Assistant Secretary for Planning and Evaluation, to update and revise the Behavioral Health Clinic (BHC) quality measures used for the Certified Community Behavioral Health Clinic (CCBHC) demonstration. The vast majority of those measures are derived from the Adult and Child Medicaid Core Set and MIPS measures, nearly all of which are consensus-based.

In the past year, SAMHSA also has been working under an Interagency Agreement with CMS to maintain three CBE-endorsed measures in the substance use disorder treatment field.

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded. The rationale can be simply the name of the VCS replacing the GUS.**

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

Current total GUS = 1

Table 1: Current Government Unique Standards FY2023

(1) Government Unique Standard

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

Voluntary Standard

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

Rationale

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

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
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Table 1: Current Government Unique Standards FY2023

(1) Government Unique Standard

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Department of Housing and Urban Development (HUD) Fiscal Year 2023 Agency Report

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

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

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded.**

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

Current total GUS: 1

Table 1: Current Government Unique Standards FY2023

(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 FY2023: In 2023, HUD continued finalizing rule by reviewing and addressing public comment on 2022 proposed rule that will update the Manufactured Home Construction and Safety Standards. HUD continues working with the Home Innovation Research Labs to support the Manufactured Housing Consensus Committee in its work for providing recommendations to HUD for future updates to the standards.

National Archives and Records Administration (NARA) 2023 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 2023, 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."

2. . Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. 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):

NARA RESPONSE:

NARA promulgated no rules in FY 2023 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/files/federal-register/write/handbook/ibr.pdf

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

PROPOSED NARA REPONSE:

Current total GUS = 0

National Aeronautics and Space Administration (NASA) Fiscal Year 2023 Agency Report

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

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

NASA encourages participation in VCS developing bodies and collects data on participation in development and revision of VCS. During this reporting period, 124 NASA representatives participated in 860 VCS development/revision activities in 30 Standards Developing Bodies. NASA's participation in VCS development/revision activities remained consistent from FY2022 to FY2023, although some participants and documents in work changed.

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

NASA-STD-6016C, Standard Materials and Processes Requirements for Spacecraft, cites as requirements for test methods 4 ASTM standards, 10 American Welding Society (AWS) standards, 26 SAE International (SAE) standards, 2 Government Electronics and Information Technology Association (GEIA) (SAE International) standards, 2 National Aerospace Standards (NAS) standards, and 1 Battelle Memorial

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

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

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

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

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

U.S. Nuclear Regulatory Commission Fiscal Year 2023 Agency Report

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

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

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

As an initiative to enhance agency use of standards and to exchange standards information with external stakeholders, in September 2023, the NRC hosted the seventh NRC Standards Forum. The goals of the NRC Standards Forum are to facilitate discussions on codes and standards needs within the nuclear industry and explore how to collaborate in accelerating the development of codes and standards and the subsequent NRC endorsement of codes and standards. Our intent is to shorten the lengthy standards development cycle by encouraging collaboration among stakeholders including researchers producing technical information and standards writers who build upon their findings. The Standards Forum meetings are usually held once a year. A summary and related documents for the September 2023 Standards Forum can be found at https://www.nrc.gov/about-nrc/regulatory/standards-dev/standards-forum/2023.html.

The NRC is working, and intends to continue working, with multiple standards development organizations to close technical and regulatory gaps through development and application of consensus standards. These standards may be applied to regulatory activities for existing light-water reactors or new nuclear plant designs including advanced reactor technologies and

small modular reactors. Standards continue to provide a critical element in our safety mission. For more information, the NRC website on standards development is at: https://www.nrc.gov/about-nrc/regulatory/standards-dev.html. Additionally, the NRC webpage at the following link, https://www.nrc.gov/reading-rm/doc-collections/cfr/incorporated-ref.html, provides a list of standards incorporated by reference into chapter I of title 10 of the code of federal regulations.

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2023. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY):

Current total GUS: 2

(1) Government Unique Standard

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

Voluntary Standard

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

Rationale

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

(2) Government Unique Standard

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

Voluntary Standard

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

Rationale

(ANSI) N 13.2-1969, “Guide for Administrative Practices in Radiation Monitoring,” had been endorsed in RG 8.2, with the same title, issued in February 1973. The standard has not been revised since its inception, and it now refers to obsolete technical practices and outdated requirements. Therefore, Revision 1 of RG 8.2, published in May 2011, removed endorsement of ANSI N 13.2-1969. Guidance is now provided through two referenced NRC reports, that

could be considered Government-unique standards: NUREG-1556, “Consolidated Guidance about Materials Licenses,” and NUREG-1736, “Consolidated Guidance: 10 CFR Part 20—Standards for Protection against Radiation.”

Department of Agriculture (USDA) Fiscal Year 2023 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, specialty crops, livestock, poultry, seed, tobacco, and grain. AMS supports these services by maintaining commodity quality standards on its website at https://www.ams.usda.gov/. The grade standards provide a common language of trade between buyers and sellers and are voluntarily used by the supply chain to promote orderly and efficient trade of agricultural products. AMS grading services certify products according to these standards or to contract terms. In addition, AMS purchases a variety of food products for Federal nutrition assistance and international food aid programs. These purchases provide food to those in need and help stabilize agricultural commodity prices by balancing supply and demand. Fresh and processed food purchased under these programs includes fruits and vegetables, nut products, beef and pork, poultry and egg products, fish, dairy products, grain products, and oilseed products. To support the procurement process, AMS maintains a series of purchase specifications on its website at https://www.ams.usda.gov/commodity-procurement that are used by contractors to produce and deliver food products and by graders and inspectors within the U.S. Department of Agriculture (USDA) to determine product acceptability. If purchase specifications require laboratory analyses, only official standard analytical methods are used.

USDA also offers voluntary, independent food safety audits of specialty crops suppliers throughout the production and supply chain. USDA's Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audits verify that fresh fruits, vegetables, and nut products are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial food safety hazards. USDA GAP and GHP audits verify adherence to the recommendation in the U.S. Food and Drug Administration's (FDA) Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables and industry-recognized food safety practices. In FY 2023, USDA's Specialty Crops Program (SCP) and its licensed auditors performed more than 3,600 food safety audits (primarily GAP and GHP audits) on more than 100 different commodities in 49 states, Puerto Rico and Canada.

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

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

- Committee on Processed Fruits and Vegetables (CCPFV): SCP chairs this committee. In FY 2023, though the CCPFV is adjourned, proposals were made to develop new standards and to review an existing one.
- Committee on Fresh Fruits and Vegetables (CCFFV): In FY 2023, SCP participated in electronic working groups developing new standards for fresh curry leaves and fresh dates.
- Codex Committee on Spices and Culinary Herbs (CCSCH): In FY 2023, SCP participated in the 6th Session of the CCSCH at which three new standards were completed, two undergoing development and three new ones approved for development.
- Codex International Outreach: SCP continuously undertakes outreach activities to maintain technical relationships on Codex standards and issues with foreign countries. In all three Codex commodity committees, SCP leads the working groups that select the priority commodities to be standardized.

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

- UNECE Specialized Section on Standardization of Fresh Fruits and Vegetables (SSSFFV): In FY 2023, SCP participated in the SSSFFV meeting where four existing standards and an explanatory brochure (inspection manual) were revised. Work commenced on two new standards.
- UNECE Specialized Section on Standardization of Dry and Dried Produce (SSSDDP): SCP chairs and heads the U.S. delegation to the annual meeting. In FY 2023, three new standards were completed, two new standards are being evaluated prior to final adoption, and two explanatory posters are ongoing development.
- UNECE Outreach: SCP conducted international outreach to government and industry officials to build support for U.S. positions related to fresh, dry, and dried produce standards being addressed by the UNECE.

In FY 2023 SCP coordinated conformity assessment activities 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' by modernizing the U.S. standards for grades of processed raisins to reflect the industries' current processing capabilities. SCP partnered with the USDA Agricultural Analytics Division (AAD) to develop a study to compare USDA inspection results for capstems. Simultaneously, SCP engaged with the Codex Committee on Processed Fruits and Vegetables on the draft revision. SCP contacted leading UNECE member countries Turkey and Germany, Europe's largest importer and consumer of U.S. raisins. Based on these findings, SCP published the proposed revisions in the Federal Register, received limited comments, and moved forward with the Final Rule to revise the standard.

The USDA National Organic Program (NOP) did not use any Government Unique Standards In lieu of Voluntary Consensus Standards in FY 2023. NOP also did not participate in any Voluntary Consensus Standards Activities during FY 2023.

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

1. ASTM D5988-12 ("ASTM D5988"), "Standard Test Method for Determining

Aerobic Biodegradation of Plastic Materials in Soil," approved May 1, 2012.

2. ASTM D6400-12 ("ASTM D6400"), "Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities," approved May 15, 2012.
3. ASTM D6866-12 ("ASTM D6866"), "Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis," approved April 1, 2012.
4. ASTM D6868-11 ("ASTM D6868"), "Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities," approved February 1, 2011.
5. EN 13432:2000: E ("EN 13432"), September 2000, "Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging."
6. EN 14995:2006: E ("EN 14995"), December 2006, "Plastics - Evaluation of compostability - Test scheme and specifications."
7. ISO 17088:2012(E), ("ISO 17088"), "Specifications for compostable plastics," June 1, 2012.
8. ISO 17556:2012(E) ("ISO 17556"), "Plastics—Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved," August 15, 2012.

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

https://www.astm.org/
https://www.ams.usda.gov/grades-standards/cotton
https://www.astm.org/get-involved/technical-committees/committee-d13/subcommittee-d13#

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

In 2023, the U.S. delegation to the UNECE Working Party on Agricultural Quality Standards, Specialized Section on the Standardization of Meat was led by LP staff members. UNECE's Specialized Section on Meat is a voluntary international standards development organization that focuses on developing global standards for egg, meat, and poultry products. The 2023 meeting of the Specialized Section was

held in-person in Geneva Switzerland and provided opportunities to strengthen relations. In attendance were delegations from Australia, Morocco, Poland, the Russian Federation, the United States of America, and Uruguay as well as representatives from non-government organizations. These proceedings covered topics of discussion on proposed revisions to and the digitalization of the bovine meat standards, alignment of UNECE cut codes with the Harmonized Commodity Description and Coding System, the development of standards for eating quality, sustainable considerations in the meat sector, the development of an international language for bovine livestock, capacity building and promotion, and the election of officers. An AMS staff person was elected as the chairperson of this organization during the meeting session.

The USDA, Marketing and Regulatory Programs, AMS, Livestock and Poultry Program (USDA, MRP, AMS, LP) is the only USDA Agency involved in managing standard development voting and standard body guidance for the International Organization for Standardization (ISO). USDA, MRP, AMS, LP provides a conduit for representation to all other USDA and federal agencies and American stakeholders through the American National Standards Institute (ANSI) via technical advisory group administration of three ISO technical committees: ISO technical committee (TC) 34 Food Products/subcommittee (SC) 5 Milk and milk products, ISO TC 34/SC 6 Meat, Poultry, Eggs, Fish and their products and ISO TC 34/SC 17 Management systems for food safety. These three technical committees encompass 103 international standards bodies responsible for over 260 international standards many of which are used voluntarily or incorporated by reference in federal code and regulations. USDA, MRP, AMS, LP is responsible for the development of the US positions relative to standard development voting and standard body guidance for each of these committees.

USDA, MRP, AMS, LP also provides voluntary staffing for executive management of ISO TC 34/SC 16 Horizontal methods for molecular biomarker analysis. In this role USDA, MRP, AMS, LP provides oversight and support for all of this ISO committee's functions. The ANSI delegated host of ISO TC 34/SC 16 is the American Oil Chemist's Society (AOCS). AMS refers to standards produced by this committee in guidance for testing methods. Within ISO, USDA, MRP, AMS, LP is represented as experts in ISO TC 34/ SC 9 Microbiology of the food chain, ISO TC 34/SC 17 Management systems for food safety, ISO/TC 212 Clinical laboratory testing and *in vitro* diagnostic test systems, ISO/TC 255 Biogas, ISO TC 215 Health Informatics, ISO/TC 276 Biotechnology, ISO/TC 347 Data Driven Agri Food Systems, ISO/PC 343 Sustainable development goals management and recently as the elected co-convener of a new committee, ISO TC 34/SC 9/AHG 5 to brainstorm a one health approach to rapid biomolecular detection methods for antimicrobial, antibiocide and antiviricide resistance genes in bacteria, viruses and fungi.

The USDA, MRP, AMS, LP participates in standards development for AOAC international and serves as a member of the AOAC international board of directors. The AOAC International was originally chartered in 1884 by the USDA and FDA to provide standard methods of analysis for foods and feed products. USDA, MRP, AMS, LP led the development of new AOAC standards for next generation DNA sequencing, metagenomics and biothreat agent detection. USDA, MRP, AMS, LP also serves on the statistics board of AOAC, guiding appropriate statistical analytical applications for AOAC international method development.

USDA's Dairy Program (DP) administers and chairs the U.S. TAG to ISO for the Technical Committee 34, Subcommittee 5 for Milk and Milk Products (TC34/SC5). ANSI, the U.S. member body to ISO, relies on U.S. TAGs as national mirror committees to support the development of voluntary, consensus-based international standards used in the global marketplace. DP concurrently engages in and facilitates

TC34/SC5 U.S. TAG activities to determine consensus positions from members representing all sectors of the U.S. dairy industry in the development, approval, reaffirmation, revision, and withdrawal of international ISO standards. Since the TAG was accredited in November 2019, it has provided the U.S. consensus position for approximately 175 voting events for ISO standards at various stages of development. DP organizes the U.S. delegation for ISO meeting attendance and oversees the nomination of experts to represent the U.S. on ISO technical committees. In October of 2023, members of the TAG representing the U.S. delegation participated in the 8th ISO TC34/SC5 meeting. Moreover, the TAG has nominated 15 U.S. experts to 15 technical working groups developing and/or revising ISO standards for the evaluation of milk and milk products.

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

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

Relevant Websites:

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

USDA's Fair Trade Practices Program (FTPP), Packers and Stockyards Division (PSD) participated in Voluntary Consensus Standards Activities during FY 2023. PSD enforces regulation 201.71(a) promulgated under the Packers and Stockyards Act. The regulation includes Section 5.59, "Electronic Livestock, Meat, and Poultry Evaluation Systems and/or Devices," of the National Institute of Standards and Technology (NIST) Handbook 44 (2013). The rule became effective and enforceable on June 30, 2014. No amendments to the regulation have been made since this date.

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

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

REFERENCE DOCUMENTS

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

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

FTPP's Food Disclosure and Labeling Division (FDLD) also participates in review of ISO and Codex Alimentarius Standards. FDLD provides guidance referencing such standards to comply with Mandatory Country of Origin Labeling (COOL) and the National Bioengineered Food Disclosure Standard (NBFDS).

FDLD, as part of the oversight of the NBFDS, in 2020, published guidance on testing and validation of processes for regulated entities to satisfy the recordkeeping requirements of the regulation. Guidance on testing suggests the use of validated methods accepted by ISO, Codex Alimentarius, or AOAC International.

These recommendations include:

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

The guidance provides examples of acceptable methods for regulated entities that wish to demonstrate that their products do not contain bioengineered ingredients. These well-established methods would satisfy recordkeeping requirements under the NBFDS.
The FDLD staff represents the USDA as a member of the U.S. TAG to the ISO Technical Committee ISO/TC276 for Biotechnology. The committee works closely with related committees to identify standardization needs and gaps and collaborate with other organizations to avoid duplications and overlapping standardization activities. FDLD staff participated in the following working groups:

- ISO/TC276/WG6 - Biotechnology — General requirements for nucleic acid- and protein-based bio-devices.
- ISO/TC276/WG3 - Analytical methods, changed to a subcommittee: ISO/TC276/SC1 Analytical methods. The scope of the new SC would be the same as that of WG3, and there would initially be three working groups within the SC: gene delivery, cell characterization, and nucleic acids characterization.

- ISO/TC276 WG4 – Bioprocessing, requirements for sample containers for storing biological materials in biobanks.

Also, the FDLD staff represents the USDA as a member of the ANSI/ISO Technical Committee 34 Food Products/(TC 34) Standardization in the field of human and animal foodstuffs, covering the food chain from primary production to consumption, as well as animal and vegetable propagation materials but not limited to, terminology, sampling, methods of test and analysis, product specifications, food and feed safety and quality management and requirements for packaging, storage, and transportation. The Subcommittee 16 (SC 16) standardization of biomolecular testing methods applies to foods, feeds, seeds, and other propagules of food and feed crops, including methods that analyze nucleic acids [e.g., polymerase chain reaction (PCR), genotypic analysis and sequencing], proteins [e.g., enzyme-linked immunosorbent assay (ELISA)], and other suitable methods—finally, the variety of identification and detection of plant pathogens. FDLD staff participated in the following working groups:

- ISO/TC 34/SC 16/WG14 – Genetically engineered content detection and quantification.
- ISO/TC 34/SC 16/WG15 – Single laboratory validation of qualitative real-time PCR.

FDLD Staff review and provide comments and feedback to Codex Alimentarius circular letters pertinent to their expertise and regulatory responsibilities. Most frequently comments are provided on initiatives within the Codex Committee on Food Labeling (CCFL) and Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).

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

The NTEP is a verification program administered by the NCWM to ensure measurement devices are manufactured in accordance with U.S. standards. Standards, policies, and test procedures are developed by industry and technical experts who meet annually to maintain consensus. Devices maintaining an active NTEP Certificate of Conformance are deemed metrologically equivalent according to these standards and are authorized for establishing cost in commercial trade applications. Authorization is dependent on individual state laws and can vary across U.S. states. Related Websites:
https://www.ncwm.com/ntep-about

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

USDA's Science and Technology Program, Seed Regulatory and Testing Division (SRTD) serves as the United States Designated Member/Authority for the Organization for Economic Cooperation and Development (OECD) Seed Schemes and the International Seed Testing Association (ISTA). These international organizations develop standards and policies that affect the movement of seed in international markets. These organizations are made up of member governments that make decisions based on the best interest of their seed industries. Each year, international government representatives

submit proposals that are voted on at annual meetings. As the Designated Member, SRTD is responsible for casting the U.S. vote. Prior to the annual meetings, SRTD collects input from relevant domestic stakeholders and develops the U.S. position for each proposal. The final standard or policy approved becomes the new requirement for international seed shipments.

The OECD Seed Schemes (https://www.ams.usda.gov/rules-regulations/fsa/oecd-schemes) promotes the use of internationally standardized and certified agricultural seed. OECD certified seed is produced and officially controlled according to agreed-upon standards in participating countries. OECD Seed Schemes labels are recognized worldwide and are required for certified seed imports into many countries. The United States meets OECD certification standards for and participates in the following crop groupings: Grasses and Legumes Crucifers and other Oil or Fiber Species; Cereals; Fodder Beets and Sugar Beets; Maize; and Sorghum seed schemes.

The ISTA (https://www.seedtest.org/en/) produces internationally agreed rules for seed sampling and testing, accredits laboratories, promotes research, provides international seed analysis certificates and training, and disseminates knowledge in seed science and technology. This facilitates seed trading nationally and internationally and contributes to food security.

USDA's Science and Technology Program, Plant Variety Protection Office (PVPO) serves as the United States representative on the International Union for the Protection of New Varieties of Plants (UPOV; https://www.upov.int/portal/index.html.en). UPOV is a division of the World Intellectual Property Organization (WIPO) of the United Nations. The mission of UPOV is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society. The International Convention for the Protection of New Varieties of Plants (UPOV Convention) provides the basis for member countries to encourage plant breeding by granting breeders of new plant varieties intellectual property rights, known as the breeder's rights or Plant Variety Protection (PVP) in the US. The breeder's rights are granted by the individual member (country) of the UPOV Convention.

The UPOV develops Test Guidelines (TGs) for grow-out trials and characterization of most species of plants. These documents ensure standardized procedures are followed for the protection of new varieties of plants. PVPO has adopted UPOV TGs for 220 crops covering 400 species. This ensures alignment of the US standards for PVP with the other 78 countries that are members of UPOV.

PVPO participated in the UPOV Technical Working Party (TWP) meetings for agricultural, fruit, ornamental, and vegetable crops. In FY 2023, the TGs for more than 40 crops were revised. PVPO held stakeholder meetings prior to the TWP meetings to solicit input and feedback concerning crops of interest. The TGs that were updated in 2023 were for the following: amaryllis, barley, beets, blueberry, brussels sprouts, cabbage, carrot, cucumber, cauliflower, cherry, chicory, corn, corn salad, ginkgo, goji, grapevine, hazelnut, hemp, kale, kohlrabi, lavender, lettuce, leucanthemum, lotus, magnolia, melon, mulberry, mung bean, oxypetalum, parsley, passion fruit, pea, pepper, poinsettia, radish, rapeseed, raspberry, rutabaga, safflower, spinach, squash, sugarcane, tomato, watermelon, weigela, and zoysia grass.

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.
Start by reviewing Table 1: Current Government Unique Standards FY2023.
To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded.**

Please record below the total number of GUS currently in use. This number should include the previous total plus any new GUS added, and minus any GUS rescinded:
Current total GUS: 1

Table 1: Current Government Unique Standards FY2023

(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.