

**Addendum to the  
Eighth Annual Report on Federal  
Agency Use of Voluntary  
Consensus Standards and  
Conformity Assessment**

**NBSIR 7227**

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**Appendix D – Individual, Unabridged Departmental Reports**

Note: This appendix contains the unabridged reports submitted to NIST by the Cabinet level Departments as they were submitted to NIST.

Department of Agriculture

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

0

*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

5

**Voluntary Standard**

**Government Standard**

ANSI.X9.108 2004  
FISRA  
Project Management Institute (PMI)  
Rational Unified Process (RUP)  
Reference Architecture and Common  
Application Framework

USDA/FNS Standard  
USDA/FSA Standard  
USDA/FSA Standard  
USDA/FSA Standard  
USDA/FSA Standard

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

145

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

82

*5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?*

35

**Voluntary Consensus Standards Body**

**Acronym**

Accredited Standards Committee X9  
American National Standards Institute  
American Oil Chemist's Society  
American Society for Testing and Materials  
Association of Official Analytical Chemists International

ASCX9  
ANSI  
AOCS  
ASTM  
AOACI

Codex Ad Hoc Intergovernmental Taskforce on Fruit and Vegetable Juices	CCFVJ
Codex Comm on Milk & Milk Products	CCMMP
Codex Committee on Pesticide Residues	CCPR
Codex Committee on Processed Fruits and Vegetables	CCPFV
IBM Global Services Methodology	IBM/GSM
Industry-wide Cooperative Meat Identification Standards Committee	ICMISC
International Union for the Protection of New Varieties of Plants	IUPOV
International Dairy Federation	IDF
International Organization for Standardization	ISO
International Organization for Standardization/International Electrotechnical Commission	ISO/IEC
International Seed Testing Association	ISTA
J2EE National Consortium	J2EE/NC
Joint Financial Managers Improvement Program	JFMIP
Meat and Poultry Business to Business Data Standards Organization	MPXML
Meat and Poultry Equipment Standards	MPES
National Computer Security Center	NCSC
National Fire Protection Association	NFPA
National Information Standards Organization	NISO
National Institute of Standards and Technology	NIST
National Organic Program	NOP
Organization for Economic Cooperation and Development	OECD
Project Management Institute	PMI
Rational Unified Process	RUP
Reference Architecture and Common Application Framework	RACAF
Sanitary Standards Program	SSP
Service Access and Delivery	SAD
Service Interface and Integration	SII
Service Platform and Infrastructure	SPI
UML National Consortium	UML/NC
United Nations Economic Commission for Europe WP .29/GRSP	UNECE

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

USDA suveys its agencies regarding their use of standards. We report all reported standards used and groups with agency participation.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

C

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

C

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

USDA concurs that the stands policy stated in Circular A-119 is effective in reducing duplicate standards. It effectively defines and coordinates the use of voluntary consensus standards and government-unique standards in the marketplace.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

USDA participates in the ICSP standards group.

*9. Please provide any examples or case studies of standards successes:*

No specific examples to report.

*10. Please provide any other comments you would like to share on behalf of your agency:*

As USDA interacts with other agencies and the private sector, we recognize the importance of using voluntary consensus standards in the successful implementation of our programs and services.

Concern has been expressed regarding the continued importance of this annual report.

Department of Commerce

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

0

*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

0

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

438

*5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?*

94

**Voluntary Consensus Standards Body**

**Acronym**

Acoustical Society of America	ASA
Air Conditioning & Refrigeration Institute	ARI
Air Transport Association	ATA
American Concrete Institute	ACI
American Congress on Surveying and Mapping	ACSM
American Dental Association	ADA
American Gas Association	AGA
American Institute of Aeronautics and Astronautics	AIAA
American National Standards Institute	ANSI
American Nuclear Society	ANS
American Society For Quality	ASQ
American Society of Civil Engineers	ASCE
American Society of Heating, Refrigerating, and Air-Conditioning Engineers	ASHRAE
American Vacuum Society	AVS
American Welding Society	AWS
ASME International	ASME
Association for Information and Image Management	AIIM
Association of Biomolecular Research Facilities	ABRF

ASTM International	ASTM
Basic Linear Algebra Subprograms Technical Forum	BLAS
Biometrics Application Programming Interface Consortium	BioAPI
British Standards Institution	BSI
Canadian General Standards Board	CGSB
Codex Alimentarius Commission	CODEX
Committee on Data for Science and Technology	CODATA
Common Criteria Management Committee	CCMC
Consumer Electronics Association	CEA
Council for Optical Radiation Measurements	CORM
Electronic Industries Alliance	EIA
Engineering Sciences Data Unit (ESDU) International	ESDU
Illuminating Engineering Society of North America	IESNA
Institute of Electrical and Electronic Engineers	IEEE
Inter-American Accreditation Cooperation	IAAC
Inter-American Metrology System	SIM
International Association for the Properties of Water and Steam	IAPWS
International Atomic Energy Agency	IAEA
International Bureau of Weights and Measures	BIPM
International Cartographic Association	ICA
International Civil Aviation Organization	ICAO
International Code Council	ICC
International Commission on Illumination	CIE
International Commission on Radiation Units and Measurements, Inc.	ICRU
International Committee for Information Technology Standards	INCITS
International Committee for Weights and Measures	CIPM
International Council for Science	ICSU
International Electrotechnical Commission	IEC
International Federation on Information Processing	IFIP
International Hydrographic Organization	IHO
International Imaging Industry Association	IIA
International Organization for Standardization	ISO
International Organization for Standardization/International Electrotechnical Commission	ISO/IEC
International Organization of Legal Metrology	OIML
International Telecommunication Union	ITU
International Union of Crystallography	IUCR
International Union of Laboratories and Experts in Materials, Systems and Structures	RILEM
International Union of Pure and Applied Chemistry	IUPAC
International Union of Pure and Applied Physics	IUPAP

Internet Engineering Task Force	IETF
Internet Software Consortium	ISC
IPC - Association Connecting Electronics Industries	IPC
JANNAF - Interagency Propulsion Committee	JANNAF
Java Grande Forum	JGF
JEDEC - Solid State Technology Association	JEDEC
National Academy of Sciences	NAS
National Committee for Clinical Laboratory Standards	NCCLS
National Conference on Weights and Measures	NCWM
National Council on Radiation Protection and Measurements	NCRP
National Fire Protection Association	NFPA
National Fluid Power Association	NFPA
NCSL International	NCSLI
North American Open Math Initiative	NAOMI
North Atlantic Treaty Organization	NATO
Object Management Group	OMG
Optical Internetworking Forum	OIF
Optical Society of America	OSA
Optical Storage Technology Association	OSTA
Optics and Electro-Optics Standards Council	OEOSC
Organization for the Advancement of Structured Information Systems	OASIS
Pan-American Standards Commission	COPANT
Parallel Tools Consortium	PTOOLS
Radio Technical Commission for Aeronautics, Inc.	RTCA
Robotics Industries Association	RIA
Semiconductor Equipment and Materials International	SEMI
Society for Biomaterials	SFB
Society of Automotive Engineers	SAE
Society of Motion Picture and Television Engineers	SMPTE
Telecommunications Industry Association	TIA
The Instrumentation, Systems, and Automation Society	ISA
U.S. Product Data Association	US PRO
Versailles Project on Advanced Materials and Standards	VAMAS
Video Electronics Standards Association	VESA
World Intellectual Property Organization	WIPO
World Meteorological Organization	WMO
World Wide Web Consortium	W3C

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

While Department of Commerce employees frequently participate in the development of standards, the Department very rarely uses standards. There were no uses of standards reported during FY 2004.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

D

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

D

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

D

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

No

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

E

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

None at this time.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

### **National Voluntary Laboratory Accreditation Program (NVLAP)**

The National Voluntary Laboratory Accreditation Program (NVLAP) provides third-party accreditation to testing and calibration laboratories. NVLAP's accreditation programs are established in response to Congressional mandates or administrative actions by the Federal Government or from requests by private-sector organizations. NVLAP is in full conformance with the standards of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), including ISO/IEC 17025 and Guide 58. NVLAP identifies its accredited laboratories in a published directory, NIST Special Publication 810, and on this web site

(ts.nist.gov/nvlap).

### **National Voluntary Conformity Assessment System Evaluation (NVCASE) Program**

The purpose of this program is to enable U.S. industry to satisfy mandated foreign technical requirements using the results of U.S.-based conformity assessment programs that perform technical evaluations comparable in their rigor to practices in the receiving country. Under this program, the Department of Commerce, acting through the National Institute of Standards and Technology, evaluates U.S.-based conformity assessment bodies in order to be able to give assurances to a foreign government that qualifying bodies meet that government's requirements and can provide results that are acceptable to that government. The program is intended to provide a technically-based U.S. approval process for U.S. industry to gain foreign market access; the acceptability of conformity assessment results to the relevant foreign government will be a matter for agreement between the two governments. Additional information about the NVCASE Program can be found at <http://ts.nist.gov/ts/htdocs/210/gsig/nvcase.htm>.

There are currently 2 accreditation bodies that have been recognized by NVCASE. They are the American National Standard Institute (ANSI) and the International Organic Accreditation Service (IOAS).

ANSI is recognized to evaluate prospective Telecommunication Certification Bodies (TCBs) for compliance with ISO/IEC Guide 65 and Federal Communications Commission (FCC) requirements for its TCB program. FCC requires that a TCB must have core testing capability and that the testing laboratory must be accredited to ISO/IEC Standard 17025. NIST recommends these accredited organizations to FCC for designation as TCBs.

IOAS is recognized by NVCASE to evaluate and accredit certification bodies for organic production and processing. IOAS is a non-profit independent organization which offers international oversight of organic certification, through a voluntary accreditation process for certification bodies active in the field of organic agriculture.

### **Conformity Assessment Activities under Mutual Recognition Agreements/Arrangement (MRAs)**

United States and the European Community Mutual Recognition Agreement (US - EU MRA)

The US-EU MRA is a multi-sector bilateral government-to-government agreement between the United States and the 25 Member States of the European Union. Under this MRA, NIST is responsible for designating organizations in the US Conformity Assessment Bodies (CABs) for three product sectors: 1) Electromagnetic Compatibility (EMC), 2) Telecommunications, and 3) Recreational Craft. (NIST also serves in an

advisory role for the Medical Devices sector.)After a lengthy review process, CABs that meet certain criteria are formally recognized and may operate as a CAB as described in the U.S. - EU MRA and the specific technical regulations of the EU governing the appropriate product sectors. . The U.S.-EU MRA is an important regulatory and trade agreement which provides greater market access in a more timely manner for U.S. manufacturers exporting to Europe and European manufacturers exporting to the United States. Further information can be obtained at <http://ts.nist.gov/ts/htdocs/210/gsig/mra.htm>.

### **Asia-Pacific Economic Cooperation (APEC) Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment**

This Arrangement is intended to streamline the Conformity Assessment Procedures for a wide range of telecommunications and telecommunications-related equipment and hereby to facilitate trade among the parties. It provides for the mutual recognition by the importing parties of CABs and mutual acceptance of the results of testing and equipment certification procedures undertaken by those bodies in assessing conformity of equipment to the importing Parties' own Technical Regulations.

Under Phase-I of the APEC Mutual Recognition Arrangement, NIST-designated CABs are able to produce test data in their facilities that are accepted as evidence that the tested product satisfies an APEC economy's appropriate technical requirements. CABs operating under Phase-II of the MRA are able to approve products as being in compliance with the technical and administrative requirements of the importing economy. The general and specific requirements that must be met in order to be nominated as a CAB under the APEC Tel MRA, as well as the text of the MRA, can be found at [www.ts.nist.gov/mra](http://www.ts.nist.gov/mra).

### **Inter-American Telecommunication Commission (CITEL) Mutual Recognition Agreement**

The CITEL MRA is almost identical to the APEC Tel MRA in purpose and structure. The goal of the CITEL MRA is to facilitate trade among the 34 Member States of the Organization of American States. The conformity assessment activities under this Agreement have yet to become operational. When operational, NIST will serve as the Designating Authority of U.S. CABs. In the meantime, NIST continues to work towards implementation of the Agreement. More information on the CITEL Agreement can be found on <http://ts.nist.gov/ts/htdocs/210/gsig/mra.htm>.

### **NIST Committee Participation**

NIST's Standards Services Division (NIST/SSD) participates in the ANSI International Conformity Assessment Committee (ICAC), which serves as the U.S. Technical

Advisory Group (TAG) to ISO's Council Committee on Conformity Assessment (CASCO). SSD staff also participate in CASCO Working Group 25 on alignment of ISO/IEC 17025 with ISO 9000/2000, Working Group 22 on a code of good practice for conformity assessment, and Working Group 20 on the revision of ISO/IEC Guide 7 on the inclusion of conformity assessment requirements in standards. Further, SSD staff is active in a CASCO ad hoc group on Regulators Interface and in working groups of the International Accreditation Forum (IAF).

NIST/SSD personnel serve on the ANSI committee that is responsible for accrediting certification bodies and on the U.S. National Committee to the IECEE (IEC System for Conformity testing and Certification of Electrical Equipment). The latter is a worldwide scheme that allows manufacturers to obtain a test certificate from an approved U.S. National Certification Body (NCB) and to use this test report to obtain certification marks in other participating countries.

NIST/SSD also participates in the Conformity Assessment Policy Committee (CAPC) which is the primary focal point for developing, coordinating, and maintaining ANSI's policies and accreditation activities. The committee makes policy recommendations to the ANSI Board related to conformity assessment and provides oversight for ANSI's operational programs.

NIST/SSD also participates in the U.S Technical Advisory Group (TAG) to ISO TC 176, the ISO committee responsible for the development and maintenance of the ISO 9000 standards series, and in American Society for Quality (ASQ) Z-1, the U.S. committee responsible for adoption of the ISO 9000 series as U.S. national standards.

The Director, Standards Services Division serves as the Chair of the ANSI-Registrar Accreditation Board (RAB) National Accreditation Program (NAP) Environmental Management Systems (EMS) Council. The Council is responsible for accrediting registrars that assess facilities for conformance to the ISO 14001 standard.

Finally, NIST/SSD has published a number of directories and reports on conformity assessment-related issues and maintains a Web site (<http://www.ts.nist.gov/ca>) that provides a one-stop-shopping source for information on various conformity assessment issues.

*9. Please provide any examples or case studies of standards successes:*

### **Reducing Standards-Related Barriers to Trade**

A new report from the U.S. Department of Commerce released on May 18, 2004 makes more than 50 recommendations for reducing standards-related trade barriers and calls for broader collaboration across government and with U.S. industry to prevent technical obstacles that impede U.S. exports.

“Standards and related technical regulations affect an estimated 80 percent of world

trade,” Commerce Secretary Donald L. Evans told an audience of industry and standards community representatives. “The recommendations in this report can improve how we tackle standards-related issues that distort trade and undermine our competitiveness.”

“In the face of intensifying global competition, neither industry nor government can be complacent about standards-related issues,” said Under Secretary for Technology Phil Bond. “The Secretary’s Standards Initiative emphasizes best practices, provides critical education and training, expands our early warning tools, and creates greater collaboration with industry and government. Collectively, these actions will go a long way towards an effective rapid response system when standards become trade barriers.”

The new report, *Standards and Competitiveness—Coordinating for Results*, also summarizes key industry standards issues in international markets. Some of this information was gathered from more than 200 industry associations and standards organizations in 13 industry roundtables convened over the past year.

The report seeks to improve the efficiency and effectiveness of the Department’s standards-related programs and policies. Its recommendations will help the Department identify new opportunities and better ways to work with the private sector and other U.S. government agencies on standards-related issues.

In March 2003, Evans launched the Department of Commerce Standards Initiative, an eight-point plan that responds to industry concerns that divergent standards, redundant testing and compliance procedures, and regulatory red tape are becoming one of the greatest challenges to expanding exports.

The report can be accessed at <http://www.technology.gov>.

### **Improving Eye Patient Care with Telemedicine Standards**

Computer scientists at the National Institute of Standards and Technology (NIST) have teamed up with a group of medical professionals to advance the use of telemedicine.

NIST and the American Telemedicine Association developed technical standards related to the diagnosis and treatment of diabetic retinopathy, which is a complication of diabetes and a leading cause of blindness.

Telemedicine helps patients to have access to health care professionals electronically, whatever their location. It can provide fast, affordable service to people who live in isolated areas or are unable to travel.

The standards and associated guidelines are related to images of the eye that help doctors decide what problems exist and how to treat them. The standards cover how to “capture” the images, which is similar to taking a photograph. Additionally, the standards provide specific procedures for storing the images electronically, sending them across telecommunications networks and interpreting them.

The standards focus on the quality of the images rather than on what kind of cameras or film must be used. This approach gives health care professionals flexibility in choosing equipment.

The associated guidelines address issues such as who is qualified to take an image and who is qualified to interpret it. Members of the American Telemedicine Association are now reviewing the draft standard before it becomes final. Once adopted, the standards will apply to eye care professionals and equipment vendors.

*10. Please provide any other comments you would like to share on behalf of your agency:*

#### DOC BUREAUS (EXCLUDING NIST) - SUMMARY OF STANDARDS-RELATED ACTIVITIES

International Trade Administration (ITA) – The ITA participates in seven CODEX committees and one ICAO committee. This year, ITA’s work in standards furthered international civil aviation and processed food safety standards adoption and acceptance worldwide.

National Oceanic and Atmospheric Administration (NOAA) – Standardization of data acquisition and data management practices are vital to the mission at NOAA. NOAA seeks to establish voluntary standards with selected industrial associations, academia, and national organizations of state and local governments (e.g., the American Association of State Climatologists), as well as through participation in professional societies (e.g., American Meteorological Society). All NOAA line organizations participate in standards development activities. In general, standards used in many NOAA activities are established in conjunction with other federal agencies (e.g., DOD, Federal Aviation Administration, U.S. Department of Agriculture, and the Federal Geographic Data Committee) either through joint participation in international organizations such as the World Meteorological Organization, or by means of bilateral and multilateral agreements with other nations. These standardization activities apply to all phases of environmental data acquisition, processing, and distribution.

National Telecommunications and Information Administration (NTIA) – The NTIA contributes to the development and application of national and international telecommunication standards by participating and holding leadership roles in various voluntary standards committees at the national and international levels (e.g., Telecommunications Industry Association, International Telecommunication Union). These standards enhance the quality and reliability of the domestic telecommunications infrastructure, promote healthy competition in telecommunications products and services, and expand international trade opportunities for U.S. telecommunications firms.

United States Patent and Trademark Office (USPTO) - The USPTO participates and contributes to the resolution of identified requirements for international standards, primarily through the Standing Committee on Information Technologies of the World

Intellectual Property Organization. USPTO staff also participates in standardization activities of the International Patent Classification Union.

Bureau of the Census – DOC’s Bureau of the Census is active in the development of standards and specifications for: (1) the capture and storage of geographic information in computer-readable formats along with metadata documenting the characteristics of those data; and (2) the definitions of statistical, economic, and geographic terms. The Census Bureau participates in the following groups: Federal Geographic Data Committee -- various subcommittees and working groups; ANSI/NCITS-L1 Geographic Information Systems; ISO Technical Committee 211; Ad hoc Baseline Committee on the U.S. International Boundary; U.S.G.S. Spatial Data Transfer Standards (SDTS) Technical Review Board; International Cartographic Association, Commission on National and Regional Atlases; U.S.G.S. National Atlas of the United States Steering Committee; and the Open GIS Consortium (OGC).

Commercial Law Development Program (CLDP) – CLDP provides consultative and training support to developing and transitional nations that are working to enhance their economic growth by improving the legal environment for doing business in their countries. CLDP staff provided the following standards-related assistance in FY2004:

- Assisted Egyptian officials through a U.S. and Mexico City-based program aimed at demonstrating methods for running the Egyptian Enquiry Point in a manner in conformity with international standards.
- HACCP On-Site Examination Training: CLDP assisted the Egyptian Organization for Standardization & Quality Control in Cairo with the creation and implementation of a HACCP food safety system in Egypt.
- Conference on the Role of Standards in Promoting Industry and Trade: CLDP held a conference in Cairo to review Egypt’s obligations under the WTO Agreement on Technical Barriers to Trade, emphasizing the role of standards in promoting trade and industry in Egypt.
- Consultations in the U.S. on the overall U.S. standards setting process (general coordination between the private sector and government agencies as well as specific standards setting processes in seven sectors) for an inter-agency delegation of Moroccan Government officials.
- Consultations in the U.S. on U.S. automotive standards and quality control processes for a mixed delegation of Moroccan automotive suppliers and Government officials.
- Consultations in the U.S. on U.S. agribusiness standards and quality control processes for a mixed delegation of Moroccan agribusiness executives and Government officials.
- Workshop in Tirana, Albania, on the Coordination of Sanitary and Phytosanitary (SPS) Measures in Southeast Europe for SPS officials from the Stability Pact countries, with emphasis on the WTO SPS Agreement framework and implementation of obligations within it.
- Southeast Europe Accreditation Cooperation Workshop in Washington, DC. The workshop introduced accreditation officials from the Stability Pact Countries to the requirements and benefits of international accreditation and conformity assessment systems and helped them deliberate on the development of a Southeast Europe regional accreditation cooperation mechanism.

- Sanitary/Phytosanitary Standards Seminar in Moscow, Russia. The workshop introduced high-level policy makers to the international standards for plant and animal health and the importance of sound science in decision making.
- International Course on Veterinary Epidemiology in Moscow, Russia. This four-day course increased scientists and veterinarians' epidemiological skills and increased their ability to analyze and interpret field data, diagnostic test results and to design epidemiological studies.

## OTHER NIST STANDARDS ACTIVITIES

### **National Center For Standards and Certification Information (NCSCI)**

NCSCI is the U.S. source for standards and standards-related information at home and abroad. The Center provides information on U.S., foreign, regional, and international voluntary standards, mandatory government regulations, and conformity assessment procedures for nonagricultural products. Resources include an extensive collection of reference materials, including U.S. military and other Federal Government specifications, U.S. industry and national standards, international standards, and selected foreign national standards. NCSCI responds to requests for specialized standards information, provides contact points for translations of foreign standards and regulations, and disseminates information to U.S. industry concerning proposed foreign regulations and general standards issues.

In fulfillment of U.S. obligations under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) and the North American Free Trade Agreement (NAFTA), NCSCI serves as the U.S. national Inquiry Point and national Notification Authority. Signatories to the WTO TBT Agreement are required to notify the WTO Secretariat in Geneva of proposed technical regulations that could affect world trade and provide a 60-day comment period for review and comment by other WTO Members. NCSCI disseminates the WTO summary notifications at no charge through a web-based email subscription service, Export Alert! NCSCI also acquires the full text of the proposed technical regulations from the relevant foreign inquiry point and distributes it to interested U.S. industries.

In 2004, NCSCI staff handled a 90% increase in requests over 2003 for standards and technical barriers to trade information. NCSCI staff expanded standards delivery to NIST employees via a new service, SIDD (Standards Index Desktop Delivery), resulting in an almost 100% increase in use of NCSCI by NIST staff. NCSCI developed and hosted a 5-day workshop in July 2004 on operation of a WTO TBT Inquiry Point for nineteen inquiry point staff from China and ASEAN nations. NCSCI staff visited inquiry points in Canada, Mexico, and Peru for information and best practices exchange. NCSCI staff led planning for the annual observance of World Standards Day in October 2004 jointly with the American National Standards Institute (ANSI). NCSCI staff presented the U.S. program at a Special Meeting on Information Exchange of the WTO TBT Committee in November 2004.

NCSCI is the U.S. member of the International Organization for Standardization (ISO) Information Network (ISONET). NCSCI networks with other national standards organizations to exchange standards-related information and share access to foreign trade-related standards, technical regulations, and conformity assessment procedures.

### **Federal Information Processing Standards (FIPS) – FY2004**

Under the Federal Information Security Management Act (FISMA), TITLE III of the E-Government Act of 2002, the Secretary of Commerce approves standards and guidelines that are developed by NIST for federal computer systems. This includes standards and guidelines needed to ensure the cost-effective security and privacy of sensitive information in federal computer systems. These standards and guidelines are issued by NIST as FIPS for use governmentwide. FIPS are issued when there are compelling federal government requirements such as for security and interoperability and there are no acceptable industry standards or solutions. When FIPS are considered necessary, NIST announces proposed FIPS in the Federal Register for public review and comment.

During FY2004, NIST made the following FIPS announcements:

On February 10, 2004, a Federal Register notice announced that the Secretary of Commerce had approved FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, and had made it compulsory and binding on Federal agencies for the protection of unclassified, sensitive information in federal information systems. FIPS 199 provides security categorization standards for information and information systems, thus addressing one of the requirements specified in the Federal Information Security Management Act (FISMA) of 2002. NIST announced the proposed FIPS on May 16, 2003, in the Federal Register, solicited comments from industry, government, and the public, and addressed all comments received prior to submitting the FIPS for approval by the Secretary of Commerce.

On July 26, 2004, a Federal Register notice announced the Proposed Withdrawal of the FIPS for the Data Encryption Standard (DES) and requested comments. DES, currently specified in FIPS 46-3, was evaluated pursuant to its scheduled review. At the conclusion of this review, NIST determined that the strength of the DES algorithm is no longer sufficient to adequately protect Federal government information. As a result, NIST proposes to withdraw FIPS 46-3 and the associated FIPS 74, Guidelines for Implementing and Using the NBS Data Encryption Standard, and FIPS 81, DES Modes of Operation. At the end of FY2004, NIST was in the process of reviewing and addressing comments received from industry, government, and

## Department of Defense

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

This agency reports voluntary consensus standards usage on a category basis

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

97

### **Voluntary Standard**

AE-AMS-WW-T-700  
ANSI-C18.2M-part  
ANSI-C18.2M-part  
ANSI-C18.2M-part  
ANSI-C18.2M-part  
ASTM-D5363  
NASM 51862  
SAE-AMS 10137  
SAE-AMS 10139  
SAE-AMS P-83310  
SAE-AMS-P-5510  
SAE-AMS-P-5516  
SAE-AMS-QQ-W-428/1  
SAE-AMS-QQ-W-428/2  
SAE-AMS-R-83283  
SAE-AMS-S-83474  
SAE-AMS-WW-T-700/1  
SAE-AMS-WW-T-700/2  
SAE-AMS-WW-T-700/3  
SAE-AMS-WW-T-700/4  
SAE-AMS-WW-T-700/5  
SAE-AMS-WW-T-700/6  
SAE-AMS-WW-T-700/7  
SAE-AMS10133  
SAE-AMS10134  
SAE-AMS10135  
SAE-AMS10136  
SAE-AMS10141  
SAE-AMS7259  
SAE-AMS7276  
SAE-AS116961  
SAE-AS116962  
SAE-AS116963

### **Government Standard**

WW-T-700F(1) not 2  
MIL-B-55130/2 not 3  
MIL-B-55130/3 not 3  
MIL-B-55130/4 not 2  
MIL-B-55130/5 not 3  
MIL-S-22473E(8) not 1  
MS51862A not 3  
AND10137 Rev 2 not 3  
AND10139 Rev 3 not 3  
MIL-P-83310 not 2  
MIL-P-5510C not 4  
MIL-P-5516C(2) not 5  
QQ-W-428/1 not 1  
QQ-W-428/2 not 1  
MIL-R-83283A not 4  
MIL-S-83474 not 2  
WW-T-700/1E not 2  
WW-T-700/2E not 2  
WW-T-700/3F(1) not 2  
WW-T-700/4F(1) not 2  
WW-T-700/5E not 2  
WW-T-700/6F(2) not 2  
WW-T-700/7B not 2  
AND10133 Rev 2 not 3  
AND10134 Rev 3 not 3  
AND10135 Rev 3 not 3  
AND10136 Rev 3 not 3  
AND10139 Rev 3 not 3  
MIL-R-83248/2(1) not 4  
MIL-R-83248/1A not 4  
MS116961  
MS116962  
MS116963

SAE-AS116964	MS116964
SAE-AS116965	MS116965
SAE-AS116966	MS116966
SAE-AS116967	MS116967
SAE-AS116968	MS116968
SAE-AS116969	MS116969
SAE-AS116970	MS116970
SAE-AS116971	MS116971
SAE-AS116972	MS116972
SAE-AS116973	MS116973
SAE-AS116974	MS116974
SAE-AS116975	MS116975
SAE-AS116976	MS116976
SAE-AS116977	MS116977
SAE-AS116978	MS116978
SAE-AS116979	MS116979
SAE-AS116980	MS116980
SAE-AS116981	MS116981
SAE-AS116982	MS116982
SAE-AS116983	MS116983
SAE-AS116984	MS116984
SAE-AS116985	MS116985
SAE-AS116986	MS116986
SAE-AS116987	MS116987
SAE-AS116988	MS116988
SAE-AS116989	MS116989
SAE-AS116990	MS116990
SAE-AS116991	MS116991
SAE-AS116992	MS116992
SAE-AS116994	MS116994
SAE-AS116995	MS116995
SAE-AS116996	MS116996
SAE-AS116997	MS116997
SAE-AS116998	MS116998
SAE-AS116999	MS116999
SAE-AS11700	MS11700
SAE-AS20659	MS20659K not 2
SAE-AS21004	MS21004D not 2
SAE-AS23190/2	MIL-S-23190/2 not 2
SAE-AS25036	MS25036P not 2 n
SAE-AS25274	MS25274G not 1
SAE-AS27429	MS27429F not 1
SAE-AS3208	MIL-R-83248/1A not 4
SAE-AS3209	MIL-R-83248/1A not 4
SAE-AS3581	MIL-R-83248/2(1) not 4
SAE-AS5756	MIL-C-5756C not 1

SAE-AS5756/1  
 SAE-AS5756/2  
 SAE-AS5756/3  
 SAE-AS5756/4  
 SAE-AS5756/5  
 SAE-AS5756/6  
 SAE-AS81765  
 SAE-AS81765/1  
 SAE-AS81765/3  
 SAE-AS81765/4  
 SAE-AS81765/6  
 SAE-AS81765/7  
 SAE-AS9207  
 SAE-AS9399  
 SAE-AS9400  
 SAE-AS9402  
 SAE-ASM10138  
 SAE-SA81765/2

MIL-C-5756/1 not 1  
 MIL-C-5756/2(1) not 1  
 MIL-C-5756/3(1) not 1  
 MIL-C-5756/4(1) not 1  
 MIL-C-5756/5 not 1  
 MIL-C-5756/6 not 1  
 MIL-I-81765A sup 1 not 2  
 MIL-I-81765/1A not 1  
 MIL-I-81765/3A not 2  
 MIL-I-81765/4A not 1  
 MIL-I-81765/6 not 1  
 MIL-I-81765/7 not 1  
 MS9207A not 4  
 MS9399 not 2  
 MS9400 not 2  
 MS9402 not 2  
 AND10138 Rev 2 not 3  
 MIL-I-81765/2A not 2

3. Please provide the number of voluntary consensus standards used during FY 2004?

9156

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

436

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

123

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
ACI International	ACI
Aerospace Industries Association	AIA
Aerospace Industries Association of America	AIA
Air Conditioning & Refrigeration Institute	ACRI
Air Movement and Control Association	AMCA
Alliance for Telecommunications Industry Solutions	ATIS
Aluminum Association	AA
American Architectural Manufacturers Association	AAMA
American Association of State Highway and Transportation Officials	AASHTO
American Association of Textile Chemists and Colorists	AATCC
American Bearing Manufacturers Association	ABMA

American Boat and Yacht Council	ABYC
American Conference of Governmental Industrial Hygienists	ACGIH
American Dental Association	ADA
American Gas Association	AGA
American Gear Manufacturers Association	AGMA
American Hardboard Association	AHA
American Industrial Hygiene Association	AIHA
American Institute of Aeronautics and Astronautics	AIAA
American Institute of Steel Construction	AISC
American Institute of Timber Construction	AITC
American Leather Chemists Association	ALCA
American National Metric Council	ANMC
American National Standards Institute	ANSI
American Petroleum Institute	API
American Railway Engineering & Maintenance-of-Way Association	AREMA
American Society for Nondestructive Testing	ASNT
American Society for Testing and Materials International	ASTMI
American Society of Cinematographers	ASC
American Society of Civil Engineers	ASCE
American Society of Heating, Refrigerating, and Air-Conditioning Engineers	ASHRAE
American Society of Mechanical Engineers	ASME
American Society of Quality Control	ASQC
American Society of Sanitary Engineering	ASSE
American Water Works Association	AWWA
American Welding Society	AWS
American Wood Preservers Association	AWPA
APA - The Engineered Wood Association	APA
Architectural Woodwork Institute	AWI
Association for Automatic Identification & Mobility	AIM Global
Association for the Advancement of Medical Instrumentation	AAMI
BOCA International	BOCA
British Standards Institute	BSI
Builders Hardware Manufacturers Association	BHMA
Canadian General Standards Board	CGSB
Cast Iron Soil Pipe Institute	CISPI
Compressed Gas Association	CGA
Construction Specifications Institute	CSI
Cooling Tower Institute	CTI
Cordage Institute	CI
Data Interchange Standards Association, Inc.	DISAI
Deep Foundations Institute	DFI
Deutsches Institut fur Nomung - German Institute for	DIN

Standardization	
Electronic Commerce Code Management Association	ACCMA
Electronic Commerce Code Management Association	ECCMA
Electronic Components Assemblies & Materials Association	ECAMA
Electronic Industries Alliance	EIA
Electrostatic Discharge Association	EDA
FM Global	FM Global
Government Electronics & Information Technology Association	GEITA
Gypsum Association	GA
Hardwood Plywood & Veneer Association	HPVA
High Frequency Industry Association	HFIA
Human Factors and Ergonomics Society, Inc.	HFESI
IDEAlliance	IDEA
Illuminating Engineering Society of North America	IES
Institute of Clean Air Companies	ICAC
Institute of Electrical and Electronic Engineers	IEEE
Institute of Environmental Sciences & Technology	IEST
Insulated Cable Engineers Association	ICEA
International Association of Plumbing and Mechanical Officials	IAPMO
InterNational Committee for Information Technology Standards	ICITS
International Electrotechnical Commission	IEC
International Organization for Standardization	ISO
International Telecommunications Union	ITU
Internet Engineering Task Force	IETF
Joint Electron Device Engineering Council	JEDEC
Magnetic Materials Producers Association	MMPA
Manufacturers Standardization Society of the Valve and Fittings Industry	MSSVFI
Master Painters Institute	MPI
NACE International	NACE
National Association of Architectural Metal Manufacturers	NAAMM
National Association of Chain Manufacturers	NACM
National Association of Relay Manufacturers	NARM
National Conference of Standards Laboratories	NCSL
National Electrical Manufacturers Association	NEMA
National Fire Protection Association	NFPA
National Fluid Power Association	NFPA
National Hardwood Lumber Association	NHLA
National Institute of Building Sciences	NIBS
National Petroleum Management Association	NPMA
NSF International	NSFI

Optics & Electro-Optics Standards Council	OEOSC
Parachute Industry Association	PIA
Pipe Fabrication Institute	PFI
Plastics Pipe Institute	PPI
Plumbing and Draining Institute	PDI
Plumbing-Heating-Cooling Contractors Association	PHCCA
Quarter-Inch Cartridge Drive Standards, Inc.	QCDS
Rack Manufacturer Institute	RMI
Resistance Welders Manufacturers Association	RWMA
Rubber Manufacturers Association	RMA
Scientific Apparatus Makers Association	SAMA
Sheet Metal & Air Conditioning Contractors National Association	SHACCNA
Simulation Interoperability Standards Organization	SISO
Society for Protective Coatings	SPC
Society of Allied Weight Engineers	SAWE
Society of Automotive Engineers	SAE
Standards Engineering Society	SES
Steel Door Institute	SDI
Steel Founders Society of America	SFSA
Steel Window Institute	SWI
The Instrumentation, Systems & Automation Society	ISAS
The Open Group	TOG
The Soap and Detergent Association	SDA
The Tire and Rim Association, Inc.	TRA
TIA	TIA
Truck Trailer Manufacturers Association	TTMA
UN Centre for Trade Facilitation & Electronic Business	UNCTFEB
Underwriters Laboratories	UL
Western Wood Products Association	WWPA
Window and Door Manufacturers Association	WDMA
World Wide Web Consortium	W3C

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

The Department of Defense reports voluntary consensus usage on a categorical basis. The total number of voluntary consensus documents contained in the DoD database and available for use is 9156.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

The A-119 policy mandates that government agencies review at least once a year their respective voluntary consensus standards programs. This mandate is an excellent means of determining if agencies are relying on government-unique standards to a greater extent than is necessary.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

The DoD has no report to submit in the area of conformity assessment activities.

*9. Please provide any examples or case studies of standards successes:*

The following are Department of Defense FY 04 Case Studies:

Army Tactical Vehicle Blackout Lights - a standardization project which resulted in new black out light assemblies.

Hull Mechanical and Electrical Equipment Standardization Program - standardization reduced the introduction of new equipment into the fleet

Aircraft Batteries and Components - new design improvements were introduced across several battery systems greatly improving performance

Army Battery Standardization - standardization decreased the number of non-rechargeable batteries and encouraged the use of preferred military rechargeable batteries and chargers

*10. Please provide any other comments you would like to share on behalf of your agency:*

Department of Education

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

0

*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

0

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

0

*5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?*

0

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

A

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

*9. Please provide any examples or case studies of standards successes:*

*10. Please provide any other comments you would like to share on behalf of your agency:*

## Department of Energy

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

1325

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

729

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

65

### **Voluntary Consensus Standards Body**

### **Acronym**

AACE International	AACE
Acoustical Society of America	ASA
American Concrete Institute	ACI
American Glovebox Society	AGS
American Industrial Hygiene Association	AIHA
American Institute of Aeronautics and Astronautics	AIAA
American Institute of Chemical Engineers	AIChE
American Institute of Steel Construction	AISC
American National Standards Institute	ANSI
American Nuclear Society	ANS
American Society for Nondestructive Testing	ASNT
American Society For Quality	ASQ
American Society of Civil Engineers	ASCE
American Society of Heating, Refrigerating, and Air-Conditioning Engineers	ASHRAE
American Society of Mechanical Engineers	ASME
American Society of Safety Engineers	ASSE
American Water Works Association	AWWA
American Welding Society	AWS

American Wind Energy Association	AWEA
Association for Information and Image Management	AIIM
ASTM International	ASTM
Building Seismic Safety Committee	BSSC
Coalition for Responsible Waste Incineration	CRWI
Consortium for Advanced Manufacturing - International	CAMI
Construction Specifications Institute	CSI
Cooling Tower Institute	CTI
Council on Ionizing Radiation Measurements and Standards	CIRMS
Electronic Industries Alliance	EIA
Health Physics Society	HPS
Human Factors Society	HFS
Information Technology Industry Council	ITI
Institute for Interconnecting and Packaging Electronic Circuits	IPEC
Institute of Electrical and Electronic Engineers	IEEE
Institute of Industrial Engineers	IIE
Institute of Nuclear Materials Management	INMM
Instrumentation, Systems, and Automation Society	ISA
International Atomic Energy Agency	IAEA
International Building Code	IBC
International Center for Diffraction Data	ICDD
International Commission on Non-Ionizing Radiation Protection	ICNIRP
International Commission on Radiation Protection	ICRP
International Conference of Building Officials	ICBO
International Electrotechnical Commission	IEC
International Energy Agency	IEA
International Organization for Standardization	ISO
National Association of Corrosion Engineers International	NACE
National Board of Boiler and Pressure Vessel Inspectors	NBBPVI
National Conference of Standards Laboratories	NCSL
National Cooperation for Laboratory Accreditation	NACLA
National Council of Radiation Protection and Measurements	NCRPM
National Electrical Manufacturers Association	NEMA
National Fire Protection Association	NFPA
National Hydrogen Association	NHA
National Safety Council	NSC
NSF International	NSFI
Nuclear Information and Records Management Association, Inc.	NIRMAI
Project Management Institute	PMI
Robotics Industry Association	RIA

Security Industry Association	SIA
Single Ply Roofing Institute	SPRI
Society of American Value Engineers	SAVE
Society of Automotive Engineers	SAE
Standards Engineering Society	SES
Underwriters Laboratories	UL
Welding Research Council	WRC

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-5 DOE does not report the use of non-ANSI-accredited standards. However, DOE does track the use of consortia standards, primarily in the information technology area where about 35 consortia standards have been noted.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

A

7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:

OMB A-119 continues to be adequate.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

This is essentially unchanged from the previous years.

*9. Please provide any examples or case studies of standards successes:*

None to report.

*10. Please provide any other comments you would like to share on behalf of your agency:*

None.

Department of Health and Human Services

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

2

**1) Government 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

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**2) Government Standard: FR Notice dated June 17, 1994 Tentative Final Monograph for Health Care Antiseptic Drug Products; Proposed Rule [Incorporated: 1997]**

**Voluntary Standard**

ASTM Standard E1115 - Test Method for Evaluation of Surgical Hand Scrub Formulations

**Rationale**

Sensitivity and bias of the ASTM Standard has not been established.

ASTM Standard E1173-93 - Standard Test Method of an Evaluation of Preoperative, precatheterization, or Preinjection Skin Preparations

Sensitivity and bias of the ASTM Standard has not been established.

ASTM Standard E1174-00 - Standard Test method for the Evaluation of the Effectiveness of Health Care Personnel or Consumer Handwash Formulations

Sensitivity and bias of the ASTM Standard has not been established.

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

711

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

503

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

182

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
Accredited Standards Committee X12	ASC X12
Acoustical Society of America	ASA
Almond Board of California	ABC
American Society for Photobiology	ASP
American Academy of Pediatrics	AAP
American Association for Laboratory Accreditation	A2LA
American Association of Blood Banks	AABB
American Association of Cereal Chemists	AACC
American Association of Food Hygiene Veterinarians	AAFHV
American Association of Physicists in Medicine	AAPM
American Association of Tissue Banks	AATB
American College of Nuclear Physicists	ACNP
American College of Radiology	ACR
American College of Surgeons	ACOS
American Committee on Immunization Practices	ACIP
American Conference of Governmental Industrial Hygienists	ACGIH
American Dental Association	ADA
American Foundation for the Accreditation of Haematopoietic Cell Therapy	FAHCT
American Industrial Hygiene Association	AIHA
American Institute of Ultrasound Manufacturers	AIUM
American National Standards Institute	ANSI
American Oil Chemists Society	AOCS
American Public Health Association	APHS
American Red Cross	ARC

American Society for Blood and Marrow Transplantation	ASBMTT
American Society for Gene Therapy	ASGT
American Society for Reproductive Medicine	ASRM
American Society for Testing and Materials International	ASTMI
American Society of Agricultural Engineers	ASAE
American Society of Clinical Oncology	ASCO
American Society of Heating, Refrigerating, and Air-Conditioning Engineers	ASHRAE
American Society of Mechanical Engineers	ASME
American Society of Sanitary Engineering	ASSE
American Society of Mass Spectrometry	ASMS
American Veterinary Medical Association	AVMA
Association for the Advancement of Medical Instrumentation	AAMI
Association for the Assessment and Accreditation of Laboratory Animal Care	AAALAC
Association of Food and Drug Officials	AFDO
Association of Official Analytical Chemists International	AOACI
Baking Industry Sanitary Standards Committee	BISSC
British Pharmacopeia	BP
California Strawberry Commission	CSC
Cantaloupe Board of California	CBC
Central Laboratory for Blood Transfusion	CCLBT
Chocolate Manufacturers Association	CMA
Clinical Data Interchange Standards Consortium	CDISC
Codex	CODEX
Collaborative Committee on the Validation of Alternative Methods	CCVAM
College of American Pathologists	CAP
Commercial Refrigerator Manufacturers Association	CRMA
Conference for Food Protection	CFP
Corn Refiners Association	CRA
Cosmetic Ingredient Review	CIR
Cosmetic Toiletry and Fragrance Association	CTFA
Council for International Organizations of Medical Sciences	CIOMS
Council on Ionizing Radiation Measurements and Standards	CIRMS
Designated Standards Maintenance Organizations	DSMO
Deutsches Institut für Normung - German Institute for Standardization	DIN
Digital Imaging Communications in Medicine	DICOM
European Center for Validation of Alternative Methods	ECVAM
European Committee for Standardization	CEN
European Directorate for Quality of Medicines	EDQM
European Pharmacopeia	EP

External RNA Controls Consortium	ERCC
Eye Bank Association of America	EBAA
Food and Agriculture Organization of the United Nations	FAO
Foundation for Accreditation of Cellular Therapies	FACS
Fresh Fruit and Vegetable Association	FFVA
Fresh Produce Association of the Americas	FPA
Gelatin Manufacturers of America	GMA
Global Harmonization Task Force	GHTF
Health Physics Society	HPS
Health Protection Branch, Health Canada	HPB
High Level Seven	HLS
Honey Board	HB
Independent Cosmetic Manufacturers and Distributors	ICMAD
Industrial Safety and Equipment Association	ISEA
Institute for Reference Materials and Manufacturers	IRMM
Institute of Electrical and Electronic Engineers	IEEE
Institute of Food Technologists	IFT
Interagency coordinating Committee on the Validation of Alternative Methods	ICCVAM
International Association for Food Protection	IAFP
International Association of Cancer Registrars	IACR
International Association of Color Manufacturers	IACM
International Association of Environmental Mutagen Societies	IAEMS
International Atomic Energy Agency	IAEA
International Blood Group Reference Laboratory	IBRGL
International Bottled Water Association	IBWA
International Commission for Illumination	CIE
International Commission on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Veterinary Use	VICH
International Committee for Cosmetic Harmonization and International Cooperation	CHIC
International Conference on the Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use	ICH
International Crystal foundation	ICF
International Dairy Federation	IDF
International Dairy Foods Association	IDFA
International Electrotechnical Commission	IEC
International Federation of Fruit Juice Producers	IFFJP
International Fragrance Association	IFRA
International Fresh-cut Produce Association	IFPA
International Life Sciences Institute	ILSI
International Natural Sausage Casing Association	INSCA
International Nomenclature Committee	INC

International Organization for Standardization	ISO
International Organization for Standardization in Microbiology	ISOB
International Pharmaceutical Excipients Council	IPEC
International Society for Analytical Cytology	ISAC
International Society for Blood Transfusion	ISBT
International Society for Cardiovascular Surgery	ISCVS
International Society for Cell Therapy	ISCT
International Society for Measurement and Control	ISA
International Society on Thrombosis and Haemostasis	ISTH
International Sprout Growers Association	ISGA
International Testing Services	ITSETL
International Union Against Cancer	UICC
International Union of Pure and Applied Chemistry	IUPAC
International Workshop on Genetic Toxicology	IWGT
International Regulatory Alternatives Group	IRAG
Interstate Shellfish Sanitation Conference	ISSC
Joint FAO/WHO Expert Committee on Food Additives	JECFA
Lead Industries Association	LIA
Life Sciences Research Organization	LSRO
Logical Observation Identifier Name Codes	LOINC
National Advisory Committee for Acute Exposure to Hazardous Substances	NACAEHS
National Association of Photographic Manufacturers	NAPM
National Automatic Merchandising Association	NAMA
National Bison Association	NBA
National Cancer Registrars Association	NCRA
National Committee for Clinical Laboratory Standards	NCCLS
National Committee on Vital and Health Statistics	NCVHS
National Conference on Interstate Milk Shipments	NCIMS
National Cooperation for Laboratory Accreditation	NACLA
National Coordinating Council for Cancer Surveillance	NCCCS
National Council of Prescription Drug Programs	NCPDP
National Council of Radiation Protection and Measurements	NCRPM
National Dialog on Cancer	NDC
National Egg Regulators Association	NERA
National Electrical Manufacturers Association	NEMA
National Environmental Health Association	NEHA
National Fire Protection Association	NFPA
National Food Processors Association	NFPA
National Institute for Biological Sciences and Controls	NIBSC
National Marrow Donor Program	NMDP
National Oilseed Processors Association	NOPA
National Sanitary Foundation	NSF
National Skill Standards Board	NSSB

National Toxicology Program	NTP
National Uniform Billing Committee	NUBC
National Uniform Claim Committee	NUCC
North American Association of Central Cancer Registries	NAACCR
North American Deer Association	NADA
North American Elk Breeders Association	NAEBA
North American Millers Association	NAMA
Northwest Horticulture Council	NHC
Organization for Economic Cooperation and Development	OECD
Organization for the Advancement of Structured Information Standards	OASIS
Pan American Network for Drug Regulatory Harmonization	PANDRH
Parenteral Drug Association	PDA
Produce Marketing Association	PMA
Product Quality Research Institute	PQRI
Reesearch Institute for Fragrance Materials	RIFM
Rehabilitation Engineering and Assistive Technology Society of North America	RESNA
Society for Glassware and Ceramic Decorations	SGCD
Society of Automotive Engineers	SAE
Society of Cosmetic Chemists	SCC
Society of Toxicological Pathologists	STP
Society of Toxicology	SOT
Standard for Exchange of Nonclinical Data	SEND
Strategic National Implementation Process Subgroups for HIPPA Standards Implementation	SNIP
Tea Association of America	TAA
Technical Committee for Juice and Juice products	TCJJP
Tuft's Conference on Modified Fats	CMF
U.S. Adopted Names Council	USANC
Underwriters Laboratories	UL
United Egg Producers	UEP
United Fresh Fruit and Vegetable Association	UFFVA
United States Pharmacopoeia	USP
US Animal Health Association	USAHA
US Egg and Poultry Association	USEPA
Western Growers Association	WGA
Workgroup for Electronic Data Interchange	WEDI
World Health Organization	WHO
World Trade Organization	WTO

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

Question 6.2 - FDA's reported numbers reflect the number of citations of voluntary consensus standards in FDA regulations, guidances and/or product specifications. FDA has no mechanism for capturing the use of these standards by the regulated industry in product approval applications or for other regulatory purposes. FDA recommends that the definition of "uses" in this report be clarified and strengthened to differentiate between standards referenced as part of regulation vs. standard cited in procurement documents.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

U.S. Food and Drug Administration - The policy and recommendations contained in Circular A-119 are consistent with FDA's framework for standards management as announced in the Federal Register on October 11, 1995, and enhanced by the Food and Drug Administration Modernization Act (FDAMA). Resource constraints oblige the agency to focus attention on the highest priority activities and to strive to make its participation in those activities very effective. FDA participates in several hundred standards development activities (the exact number is not known as there is not established procedure to gather this information) within 165 voluntary consensus standards bodies.

The central purpose for FDA involvement in the development and use of standards is to assist the agency in fulfilling its domestic public health and regulatory missions. The agency participates widely in the development of standards, both domestic and international, and adopts or uses standards when this action enhances its ability to protect consumers and increases the effectiveness or efficiency of its regulatory efforts. Further, using standards, especially international ones, is a means to facilitate the harmonization of FDA regulatory requirements with those of foreign governments, and thus to improve domestic and global public health protection. Therefore, FDA encourages participation in the development of standards as a useful adjunct to regulatory controls.

FDA has been involved in standards activities for more than twenty years. In January 1977 the agency promulgated a final regulation now found at 21 CFR 10.95 covering participation by FDA employees in standards development activities outside the agency. This regulation encourages FDA participation in standards activities that are in the public interest, and specifies the circumstances under which FDA employees can participate in various types of standards bodies. The agency built upon that rule with a final policy statement published in the Federal Register on October 11, 1995, entitled International Harmonization; Policy on Standards. It provides the agency's overall policy on development and use of standards for all product areas regulated by the agency.

For FDA, voluntary consensus standards are most relevant for medical devices, where they are used extensively in the agency's regulatory work and where the majority of the agency's standards activities are centered. In the areas of human and veterinary pharmaceuticals, biological products and foods, voluntary consensus are generally not available nor being developed. Here FDA works within other national and international organizations such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO), the Organization for Economic Cooperation and Development (OECD), the United States Pharmacopeia, and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) to develop standards.

FDA/Center for Devices and Radiological Health (CDRH) - The Food and Drug Administration Modernization Act of 1997 (FDAMA) enabled the agency to "recognize" voluntary consensus standards established by international and national standards development organizations that may be used to satisfy identified portions of device pre-market review submissions or other regulatory requirements. CDRH has available a standards relevant document on their web-site. The document, "CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition," establishes internal CDRH procedures for the identification and evaluation of consensus standards for recognition through publication of a notice in the Federal Register. CDRH continues to maintain a database to track the standards activities of its employees and has established and uses searchable ROM databases of voluntary consensus standards to facilitate reference to current voluntary consensus standards by agency reviewers. CDRH continues to participate in Steering Committee and Study Group Activities of the Global Harmonization Task Force (GHTF), an

intergovernmental consortium to foster medical device regulatory harmonization. During FY 2001, FDA published draft guidance on a pilot program that will be used to evaluate the feasibility of using the Summary Technical Document (STED) and an Essential Principles Document instead of standard CDRH procedures for certain premarket submissions. Finally, the GHTF has a Memorandum of Understanding with ISO TC 210, the ISO Committee responsible for many regulatory aspects of device standards.

FDA/Center for Drugs Evaluation and Research (CDER) / Center for Biologics Evaluation and Research (CBER)- As noted previously, few voluntary consensus standards are applicable to pharmaceutical and biological products. CDER and CBER, therefore, have limited involvement in such activities, but do participate on relevant committees of a number of voluntary consensus standards bodies. FDA supports the concept of working within our agency, with other government agencies, the private sector, and other governments to avoid duplication in standards setting activities. Within FDA, Centers coordinate in the development of Guidances to Industry. We also coordinate our activities with other agencies such as the Environmental Protection Agency, U.S. Fish and Wildlife Service, Consumer Product Safety Commission, Drug Enforcement Agency, and National Institute for Standards and Technology (NIST). CDER is currently exploring opportunities for expanded standards development with ASTM. Finally, a majority of our standards setting activities are focused on interactions with national and international standards setting bodies such as U. S. Pharmacopeia (USP), International Conference on Harmonization (ICH), Organization for Economic Cooperation and Development (OECD), World Health Organization (WHO), and Pan American Health Organization (PAHO). An innovative approach to harmonizing international standards is being undertaken with PAHO. We are providing them with training based on our current standards in hopes that they will elect to adopt our standards.

Both CDER and the CBER participate in the ICH. This ongoing project, begun in 1989, has been undertaken by government agencies responsible for regulation of pharmaceuticals and by industry trade organizations. The European Union (EU), Japan, and the U.S. bring together regulatory authorities and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of new product registration. The work products, created in working groups of experts from the regulatory agencies and industry, consist of a series of consensus guideline documents to harmonize pharmaceutical testing guidelines.

FDA officials also participate in a consensus standards development activity sponsored by the Council for International Organizations of Medical Sciences that is aimed at standardizing the safety-related terminology used in adverse experience reporting. FDA/CBER and FDA/CDER actively participate with the WHO in developing international standards for ensuring the quality of pharmaceutical and biological products. ICH, OECD, USP and WHO do not meet the definition of voluntary consensus standard bodies under the Circular A-119. However, substantial agency resources are devoted to the development of standards with these organizations. This work is the core part of FDA's overall standards activities for pharmaceutical and biological products.

FDA/Center for Food Safety and Applied Nutrition (CFSAN) / Center for Veterinary Medicine (CVM)- The principal international standards activities in the areas of food and veterinary medicine fall under the activities of the Codex Alimentarius Commission of the FAO and the WHO, as well as the Office of International Epizootics (for veterinary medicine). FDA experts from CFSAN, CVM, and other parts of the agency are actively involved in Codex Alimentarius activities, and in activities of methods validation organizations on which Codex Alimentarius relies, such as ISO, the Association of Official Analytical Chemists (AOAC) International and the International Dairy Federation (IDF). CFSAN has provided the U.S. Delegate or Alternate Delegate to 80% (17 out of 21) of the technical committees and task forces and also provided technical experts to assist on the work of developing more than 90 Codex standards and guidelines. CVM has also provided numerous technical experts to assist on Codex task forces, especially those related to the Codex Committee on Residues of Veterinary Drugs and Foods (CCRVDF). Currently, the Director of CVM serves as the chair of the CCRVDF. Voluntary consensus standards have limited relevance to food and veterinary medicine products. However, since the standards activities of multilateral organizations such as the WHO, FAO, the World Trade Organization (WTO) and the OECD are important in these areas, CFSAN and CVM are actively engaged in standards and policy development with these organizations. CFSAN is also engaged in standards review in the International Organization for Standardization in Microbiology.

CVM is active in a harmonization initiative similar to the ICH for human pharmaceuticals, that is, developing harmonized requirements for the registration of veterinary pharmaceuticals and biological veterinary medicinal products. It is known as VICH, for Veterinary ICH. Agency employees participate on numerous committees that are drafting VICH guidelines related to veterinary pharmaceuticals.

International/Treaty Standards-Related Activities - FDA takes part in a variety of international standards activities that fall under treaty organizations, and thus are not reportable under the provisions of Circular A-119. These standards activities are nonetheless important to the agency in fulfilling its public health regulatory mission. Some of these are referred to above, i.e. WHO, FAO, and OECD.

The agency participates in international trade discussions within the WTO, specifically with committees on the Agreement on Technical Barriers to Trade (TBT), and the Agreement on the application of Sanitary and Phytosanitary (SPS) Measures; with the implementation of the counterpart committees of the North American Free Trade Agreement (NAFTA); and with the negotiation of an upcoming trade agreement by 2005 for the Free Trade Area of the Americas where sanitary and phytosanitary measures fall within the scope of the negotiations. FDA is engaged in these negotiations to ensure that the agency's requirements are preserved and its regulatory practices can remain focused on fulfilling the agency's mission to protect the public health while being supportive of emerging, broader U.S. government obligations and policies. FDA has participated in several initiatives that are part of the Asia Pacific Economic Cooperation (APEC) forum.

Centers for Disease Control - All areas of CDC work extensively with outside partner organizations for routine work. The Circular wording constrains our reporting to just that activity with Standard Development Organizations as formally defined by the circular. The effect of this constraint is an under-reporting of our activity with outside partners. Complete reporting of our activities with outside partners, however, would be burdensome and impossible to obtain as essentially all professional staff interacts with a diverse group of partners on a daily basis. If the main intent of the circular is to report the use of outside SDO developed standards for commerce, the data in this report reflects that information. If the intent of the Circular is to reflect government interactions with all non-government organizations involved in policy decisions our data reflects severe under-reporting.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

U.S. Food and Drug Administration - FDA inspects manufacturers of regulated products (pharmaceuticals, veterinary drugs, medical devices, biologicals) for compliance with current Good Manufacturing Practice (cGMP) and/or Quality System (QSR) Regulations requirements. FDA inspects laboratories that provide pivotal animal studies for drug approvals for compliance with Good Laboratory Practice (GLP). FDA participates on the ANSI Accreditation Committee, the ANSI International Conformity Assessment Committee, ANSI Board Committee on Conformity Assessment, and ASTM Committee E-36 on Conformity Assessment. Within FDA, the Center for Devices and Radiological Health allows a medical device manufacturer to submit a Declaration of Conformity to a "recognized standard" as described in ISO/IEC Guide 22 in its standards recognition program and has developed an MRA with the European Union on mutual recognition of each other's conformity assessment procedures related to manufacture and marketing of medical devices. The FDA Office of Regulatory Affairs (FDA/ORA) actively participates with the National Cooperation for Laboratory Accreditation (NACLA), serving as a member of the NACLA Executive Board of Directors and participating in the NACLA Recognition Committee for Accrediting Bodies who apply for mutual recognition. Other FDA officials participate with NACLA in the evaluation of accrediting bodies under ISO/IEC 58 and ISO/IEC 17025 and sit on NACLA technical committees.

CDER - The conformity assessment activities in which the Center has been involved as described in the Federal Register, Vol. 65, No. 155, Thursday, August 10, 2000, Guidance on Federal Conformity Assessment Activities, and the 9/7/00 NIST document "Information on Voluntary Reporting on Federal Conformity Assessment Activities for the Agency Annual Report.

CFSAN - Conformity Assessment Activity participation included:

a. Grade A Milk Laboratory Certification Program - The Grade A Milk safety laboratory certification program relies on on-site inspection as well as annual proficiency testing Evaluation forms developed through common agreement by all parties are used to review records,

facilities, and analysts' performance of tests. The proficiencies cover the range of testing for which the laboratories are certified and the results are evaluated statistically. This program has enhanced public health protection by:

- o verifying analysts' abilities to perform testing successfully;
- o improving the quality of the work performed by the analysts, analysts' knowledge, and the credibility of results;
- o more rapidly and accurately identifying pathogens leading to earlier and more successful treatment; and
- o keeping drugs out of the milk supply.

With the idea of enhancing international credibility and recognition, CFSAN is moving towards ISO accreditation of its own laboratories that perform regulatory work.

b. Retail food managers' certification program - Via participation in the Conference for Food Protection (CFP), CFSA was involved in a certification / accreditation program. The CFP now owns copyrighted Food Manager Certification Standards which are administered by ANSI under contract with the CFP. An FDA employee sits on an ANSI/CFP accreditation committee to ensure those Standards are administered, consistent with CFP's intent. This is the culmination of over 20 years of work to arrive at legally defensible national standards to which all the stakeholders have agreed; meaningful certification; a basis for reciprocity among the 3000+ regulatory agencies in the U.S.; a single process for industry; and a straightforward method of fulfilling the FDA model Food Code.

*9. Please provide any examples or case studies of standards successes:*

Centers for Disease Control - The Agency is very involved in the voluntary standards process and has been for a number of years. See <http://www.cdc.gov/phinf/> for an example of a current system using voluntary consensus standards.

Centers for Medicare & Medicaid Services - CMS is participating with the National Quality Forum (NQF) in the endorsement of standards for performance measures of quality among providers. This effort brings all stakeholders together to make a determination founded in a membership-driven NTAA-compliant consensus process. The NQF endorsed quality measures for nursing homes quality and hospitals in FY 2003. In FY 2004, CMS submitted measures to the NQF for endorsement in the home health and ambulatory settings. CMS incorporated NQF endorsed quality measures into its demonstrations, public reporting or quality improvement activities.

The CMS Administrator has a permanent seat on the Board of Directors of the NQF and participates through and appointed designee. As a dues paying member of the NQF, CMS also participates on the Purchaser Council.

The Consolidated Health Informatics (CHI) initiative is a collaborative effort to adopt federal government-wide health information interoperability standards (health vocabulary and messaging standards). Three federal departments lead the initiative: Department of

Health and Human Services (DHHS), Department of Defense (DoD), and Department of Veterans Affairs (VA). To date, the CHI work has led to the adoption of eleven sets of standards covering twenty healthcare specific domains. This wide spread adoption of standards marks the first time the entire federal health enterprise has committed to use the same vocabularies to enable exchange of health information.

Food and Drug Administration - All FDA Centers have taken significant steps to integrate voluntary consensus standards into their regulatory programs. Recently, however, the issue of overlap or duplication of standards by different SDOs has become an issue. In development of standards for foods and medical devices, ISO seems to be creating development processes parallel to those that already exist. This has created some uncertainty in the regulated industry and, with the resource limitations in the government, considerable problems in the Agency.

FDA/CBER - In addition to the formal reporting obligations under OMB Circular No. A-119, it should be noted that the overwhelming majority of CBER's standards setting activities are with outside national and international organizations and non U.S. governmental regulatory - groups which do not meet all of the requirements of the OMB Circular No. A-119 definition of a voluntary consensus standards body. Due to the diversity of established and emerging technologies and products types regulated by CBER (e.g., cellular therapies, gene therapies, tissue-engineered products), CBER participates with a variety of organizations and in various national and international venues to establish appropriate standards. These include activities with established organizations (e.g., WHO; GHTF, USP, ICH) and interacting with or developing newer groups that include broad representation from governmental and nongovernmental interested parties, including the regulated industry and academic laboratories. These interactions have yielded standards and should provide additional standards in future that can facilitate product development and regulatory approval if used appropriately. Some of these activities result in or should result in consideration as international standards for several different products.

CBER also has created unique opportunities to develop standards. For examples, CBER organized an Adenovirus Reference Materials Working Group that developed an adenoviral virus reference material that was released in August 2002. This material was developed in a unique collaborative effort with donations from multiple organizations academic and corporate institutions. The reference material is used to define the particle unit and infectious units for adenovirus vectors used in gene therapy. A similar effort is also underway for an adenovirus-associated vector in this reporting year. A collaborative approach involving several professional organizations is also underway for development of standards for some cellular therapies, and standards for blood grouping reagents.

FDA/CDER – FDA Center for Drug Evaluation and Research has been instrumental in the establishment of a new voluntary consensus standards committee to develop standards for the Application of Process Access Technology in Pharmaceutical Manufacturing. This new effort has attracted participants from more than 250

representatives of pharmaceutical firms, instrument and equipment suppliers, raw material suppliers and academia. The success of this effort will manifest in reduced manufacturing costs and waste for this industry.

While the data provided earlier in this report indicate only limited involvement with voluntary consensus standard setting organizations, they are not reflective of CDER's true involvement with standard setting organizations. The majority of CDER's standards setting activities are with groups which do not meet OMB's definition of a voluntary consensus standards body: United States Pharmacopeia (USP), International Conference on Harmonization (ICH), Organization for Economic Cooperation and Development (OECD) and the World Health Organization (WHO). The primary standards setting organization for CDER is the United States Pharmacopeia (USP). The Food, Drug and Cosmetic Act recognizes USP and mandates CDER's involvement with the USP. OMB Circular No. A-119 states that its definition of standard does not include a standard created under other legal authority, such as those contained in the United States Pharmacopeia and the National Formulary. CDER is also active with the ICH. This group does not qualify as a voluntary standard setting organization since it is a treaty or government-to-government organization. Finally, due to the lack of a true consensus process, the WHO does not meet the criteria for a voluntary consensus standard body.

#### USP:

The USP is a private, voluntary, not-for-profit organization of health care professionals, recognized authorities in medicine, pharmacy, and allied sciences. USP revises and publishes the United States Pharmacopeia (USP) and the National Formulary, the legally recognized compendia of drug standards in the United States of America. There are about 650 elected scientists and practitioners comprising USP's scientific decision-making body by serving as members of the Council of Experts (COE) or on expert committees.

#### ICH:

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

The objective of such harmonization is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.

## OECD:

The Organization for Economic Cooperation and Development is composed of 30 member countries. The OECD is a treaty organization which promotes policies designed to:

- Achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries, while maintaining financial stability, and thus to contribute to the development of the world economy;
- Contribute to sound economic expansion in Member as well as non-member countries in the process of economic development; and
- Contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

## WHO:

The World Health Organization is a specialized agency of the United Nations. WHO promotes technical cooperation for health among nations, carries out programs to control and eradicate disease and strives to improve the quality of human life. WHO has four main functions:

- Give worldwide guidance in the field of health
- Set global standards for health (WHO sets standards to ensure the quality of biological and pharmaceutical preparations)
- Cooperate with governments in strengthening national health programs
- Develop and transfer appropriate health technology, information and standards

## PAHO:

The primary mission of the Pan American Health Organization (PAHO) is to strengthen national and local health systems and improve the health of the peoples of the Americas. In the Americas there is a need to promote harmonization to facilitate the availability of safe, effective, and good quality pharmaceuticals and thereby protect public health. The regulation of pharmaceuticals and harmonization of technical standards have emerged as an important component of the economic integration. As a result, a Pan American Network for Drug Regulatory Harmonization (PANDRH) with biennial Pan American conferences was established. The mission of the Network is accomplished by conferences which promote regulatory harmonization for all aspects of quality, safety and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of countries of the Americas.

Harmonization in this context is understood to be the search for common ground within the framework of recognized standards, taking into account the existence of different political, health, and legislative realities among the countries of the region. A steering committee was formed to enable progress between conferences by coordinating, promoting, facilitating and monitoring harmonization processes in the Americas. A major aspect of PANDRH is to provide training to the regulatory agencies of the Americas. It is

felt that training to the same standards will eventually lead to harmonized standards.

FDA/CVM - CVM staff members participate in the activities of the Codex Alimentarius Commission of the FAO and the WHO, as well as the Office of International Epizootics (for veterinary medicine). Experts from CVM and other parts of the agency are actively involved in activities, and in activities of methods validation organizations on which Codex Alimentarius relies, such as ISO and AOAC International. Voluntary consensus standards have limited relevance to veterinary medicine products. However, since the standards activities of multilateral organizations such as the WHO, FAO, and the OECD are important in these areas; CVM is engaged in standards and policy development with these organizations. CVM publishes significant approvals in the Federal Register and includes information on chemical tolerance levels. This can be compared to the tolerance levels established by CODEX. CVM requests that sponsors submitting antimicrobial susceptibility data use the methods described in the NCCLS for generating their data. CVM is active in the VICH, a harmonization initiative similar to the ICH initiative for human pharmaceuticals. CVM publishes as FDA guidance all VICH guidelines. Through VICH, CVM has finalized 30 harmonized guidelines and is developing several more for the registration of veterinary pharmaceuticals.

FDA/ORA - The Office of Regulatory Affairs (ORA) actively participates with the National Cooperation for Laboratory Accreditation (NACLA). An ORA official is a member of the NACLA Executive Board of Directors and has the role of participating in the NACLA Recognition Committee for Accrediting Bodies who apply for mutual recognition. Other FDA officials participate with NACLA in the evaluation of accrediting bodies under ISO/IEC 58 and ISO/IEC 17025 and sit on NACLA technical committees. An ORA official is the FDA Liaison to the Board of Directors of the American Association for Laboratory Accreditation (A2LA).

ORA officials are also involved with Codex Alimentarius activities, especially in the area of pesticide residues, which relies on methods development by ISO and AOAC. Other activities include participation and the coordination of Federal-State conferences to develop uniformity in the reporting of food testing results. The ISO/IEC 17025 standard is the foundation in this coordination effort.

Agency for Healthcare Research and Quality - AHRQ funds and participates with the National Quality Forum (NQF) in the endorsement of standards for performance measures of quality among various providers. This effort brings all stakeholders together to make a determination founded in a membership-driven NTAA-compliant consensus process. In 2003, AHRQ incorporated NQF standards in its National Quality Report that was mandated by Congress and is in clearance within HHS. The AHRQ Director has a permanent seat on the Board of Directors of NQF and participates in the endorsement of the consensus driven standards (measures) through a voting process. AHRQ provides support to NQF.

AHRQ is a member and supports the meetings of the ANSI Health Informatics Standards Board, a board that coordinates the U.S. standards developing organizations for health

information exchange. Other federal agencies, professional health organizations, and vendors are members. Duplication and overlap of health data standards domains and other issues are voluntarily resolved through ANSI HISB.

AHRQ is a member and supports the meetings of the U.S. Technical Advisory Group to ISO Technical Committee 215, Health Informatics. The U.S. TAG formulates and reaches consensus on the U.S. position on health data issues taken at ISO TC 215 meetings.

AHRQ supported the Institute of Medicine's letter report recommending eight functions be included in the definition of an electronic health record. These functions were used by Health Level 7 to produce a balloted standard on the functional definition of an EHR in September 2003. The ballot has reached consensus in 2004 and is beginning to be used by clinical information software vendors to disclose their support of specific functions defined in these standards.

AHRQ participates as a liaison to the National Committee on Vital and Health Statistics (NCVHS), an advisory committee that advises the Secretary of HHS on health information policy. NCVHS recommended adoption of four ANSI standards to the Secretary for use in federal health program information exchange. On February 21, 2003, the Secretary adopted 5 messaging standards. In FY 2004, NCVHS will recommend a core set of terminology standards to the Secretary for adoption. The Secretary adopted 15 more clinical data standards in the Spring 2004 for federal government sector use. AHRQ participates in one of the administration's 24 e-Government initiatives—the Consolidated Health Informatics (CHI) initiative. In 2003, CHI recommended four messaging standards and one terminology standard to the Secretary of HHS for adoption. He adopted all five. CHI is working selecting voluntary consensus standards for a total of 24 domain areas.

AHRQ supported the founding of the Health Level 7 Special Interest Group on Patient Safety to begin the process of developing standards for reporting patient safety events across the nation in a uniform format.

AHRQ supports ASTM's Continuity of Care standard for health information to be exchanged among providers and given to patients following an office visit. AHRQ devoted \$10 million of its \$300 million budget in 2004 to the development and implementation of health care data standards to improve patient safety and quality of care. This includes funding FDA's development of an electronic structured product labeling system, an electronic product listing of all products approved by FDA for sale in the US, a coding system for all drug components—active and inactive ingredients, and improvements in the National Drug Code; and funding for transmission of this information in electronic form to the National Library of Medicine (NLM). Additionally, AHRQ funded NLM to develop a system to post this information on its DailyMed web site quarterly and to map selected terminologies (ICD, CPT, MedDRA, others) to SNOMED. Also AHRQ funded NIST and CMS to develop web-based, publicly available systems for displaying the landscape of standards developing activities in the US and the data components of specific data standards. AHRQ is studying how patient safety event

data reported by 24 states may use existing American National Standards and what ANS standards need to be developed to make this information more uniform and accurate.

*10. Please provide any other comments you would like to share on behalf of your agency:*

Centers for Medicare & Medicaid Services - CMS will be submitting Hospital CAHPS (HCAHPS) – a survey developed to measure patient perspectives of care following discharge from a hospital – to the National Quality Forum (NQF) to go through their endorsement process. The NQF brings all stakeholders together to make a determination founded in a membership drive NTAA—compliant consensus process. CMS will be submitting HCAHPS to the NQF in early November.

Food and Drug Administration - As noted in the response to Question 6, this survey is not very instructive regarding the way that regulatory agencies use standards. HHS, in addition to using standards for procurement purposes, uses standards to describe characteristics of products and manufacturing processes which help insure the safety and efficacy of products manufactured to those standards. The survey does not reflect this latter use accurately. CBER laboratories which conduct official product testing are in the process of becoming ISO/IEC 17025 accredited. The CBER has conducted staff training, is in the process of writing a Laboratory Quality Assurance Manual centrally documenting Center policies and procedures related to the official testing of regulated biological products, is implementing a quality management software tool to assist in the effort, under direction of quality assurance managers hired to coordinate the implementation of an ISO 17025-based quality system.

Centers for Disease Control - All areas of CDC work extensively with outside partner organizations for routine work. The Circular wording constrains our reporting to just that activity with Standard Development Organizations as formally defined by the circular. The effect of this constraint is an under-reporting of our activity with outside partners. Complete reporting of our activities with outside partners, however, would be burdensome and impossible to obtain as essentially all professional staff interacts with a diverse group of partners on a daily basis. If the main intent of the circular is to report the use of outside SDO developed standards for commerce, the data in this report reflects that information. If the intent of the Circular is to reflect government interactions with all non-government organizations involved in policy decisions our data reflects severe under-reporting.

Agency for Healthcare Research and Quality - AHRQ has supported voluntary consensus standards development and processes for many years because uniform information exchange can lead to better research data having more powerful findings and because informatics tools can better access the knowledge to improve patient safety, quality of care, the cost of care, and access to care. In 2004 AHRQ increased its pace of support for health data standards and code sets by \$10 million.

Department of Homeland Security

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

13

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

10

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

7

**Voluntary Consensus Standards Body**

**Acronym**

American Society for Testing and Materials

ASTM

AOAC

AOAC

INCITS

INCITS

Institute of Electrical and Electronic Engineers

IEEE

International Organization for

ISO/IEC

Standardization/International Electrotechnical

Commission

National Fire Protection Association

NFPA

NIOSH

NIOSH

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

B

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

The standards policy stated in Circular A-119 is effective in reducing duplicate systems of standards. It effectively defines the role and coordinates the use of government-unique standards in the marketplace.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

none

*9. Please provide any examples or case studies of standards successes:*

Press Release

February 26, 2004

Contact: Michelle Petrovich or Kristin Gossel

202-282-8010 michelle.petrovich@dhs.gov kristin.gossel@dhs.gov

U.S. DEPARTMENT OF HOMELAND SECURITY ISSUES FIRST STANDARDS  
FOR PERSONAL PROTECTIVE EQUIPMENT FOR FIRST RESPONDERS

WASHINGTON, D.C. – The U.S. Department of Homeland Security’s Science and Technology division today adopted its first standards regarding personal protective equipment developed to protect first responders against chemical, biological, radiological and nuclear incidents. These standards, which will assist state and local procurement officials and manufacturers, are intended to provide emergency personnel with the best available protective gear.

“Secretary Ridge and I are delighted to release the Department’s standards for personal protective equipment for chemical, biological, radiological and nuclear incidents,” said Dr. Charles McQueary, Under Secretary, Science and Technology. “We know these guidelines will be helpful to state and local first responders as they use technology to protect themselves and our citizens from these potential threats.”

Homeland Security is adopting these standards, developed in partnership with the National Fire Protection Association (NFPA) and the National Institute for Occupational Safety and Health (NIOSH). These guidelines, which have also been adopted by the Interagency Board for Equipment Standardization and Interoperability, include NIOSH standards for CBRN three main categories of respiratory protection equipment and five current NFPA standards for protective suits and clothing to be used in responding to chemical, biological and radiological attacks.

“President Bush, Secretary Ridge and I are committed to our nation’s first responders and the communities they serve,” said Michael D. Brown, Under Secretary of Homeland Security for Emergency Preparedness and Response. “Developing these standards in equipment used by our first responders will enable them to better prepare our nation against natural and man-made disasters and protect them as they respond to any hazard.”

Homeland Security’s standards are designed to assist state and local officials in procurement decisions related to first responder equipment. In addition, these guidelines will assist manufacturers by providing performance standards and test methods. This provides the manufacturing community with minimum performance requirements for equipment, and the test methods to confirm that the required performance levels are achieved.

These standards reflect the continuing support of a multi-year program in Homeland Security’s Science and Technology division, managed by the National Institute of Standards and Technology, to develop chemical, biological, radiological and nuclear and explosive protective equipment standards. This program, which transitioned from the Department’s Office of Domestic Preparedness in 2003, continues to facilitate the development of performance standards and test methods for first responder protective and operational equipment.

The U.S. Department of Homeland Security’s Science and Technology division serves as the primary research and development arm of the Department, utilizing our nation’s scientific and technological resources to provide federal, state and local officials with the technology and capabilities to protect the homeland.

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U.S. DEPARTMENT OF HOMELAND SECURITY  
Science and Technology

FOR IMMEDIATE RELEASE February 27, 2004

U.S. DEPARTMENT OF HOMELAND SECURITY ISSUES  
FIRST RADIOLOGICAL AND NUCLEAR DETECTORS STANDARDS

WASHINGTON, D.C. – The U.S. Department of Homeland Security’s Science and Technology division today adopted its first radiological and nuclear detectors standards. The standards were developed in partnership with the Department’s Office of Domestic Preparedness. These standards are designed to assist federal agencies, state and local officials, and manufacturers in procurement decisions related to radiological and nuclear detection equipment. These guidelines provide performance standards and test methods, as well as minimum characteristics for four classes of radiation detection equipment ranging from hand-held alarming detectors to radiation portal monitors for cargo containers. Officials receiving DHS grants through the Office of Domestic Preparedness will use these standards as technical guidance on performance specifications for detectors.

“Secretary Ridge and I are delighted to release the Department’s standards for radiological and nuclear detectors,” said Dr. Charles McQueary, Under Secretary, Science and Technology. “We know these guidelines will be helpful to homeland security officials and first responders across the nation as they use technology to protect themselves and our citizens from these potential threats.”

Homeland Security developed these standards in partnership with the Department of Commerce’s National Institute of Standards and Technology and the Department of Energy’s National Laboratories; specifically, Pacific Northwest, Oak Ridge, Los Alamos and Lawrence Livermore. Because of the Department’s commitment to engaging the private sector in standards development, these guidelines were developed in conjunction with the Institute for Electrical and Electronics Engineers (IEEE), a standards development organization accredited by the American National Standards Institute (ANSI). ANSI has subsequently approved the four standards documents as American National Standards. Homeland Security and its partners will convene on a regular basis to revise these standards as detection technology evolves.

"The Department, through Customs and Border Protection, has already moved forward with deploying state of the art radiation detection technologies at key installations on our nation's borders. These standards will facilitate our ability to ensure that equipment meets rigorous standards, and supports the quick deployment of the best equipment available", said Under Secretary Asa Hutchinson.

The standards reflect the continuing support of a multi-year program in Homeland

Security's Science and Technology division, managed by the National Institute of Standards and Technology, to develop detection equipment for use by federal, state and local employees for the detection of radiological and nuclear material. The four standards documents, which list performance specifications for radiation detectors, are available from IEEE ([www.ieee.org](http://www.ieee.org)) and from ANSI ([webstore.ansi.org](http://webstore.ansi.org)).

The U.S. Department of Homeland Security's Science and Technology division serves as the primary research and development arm of the Department, utilizing our nation's scientific and technological resources to provide federal, state and local officials with the technology and capabilities to protect the homeland.

###

*10. Please provide any other comments you would like to share on behalf of your agency:*

Department of Housing and Urban Development

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

2

**1) Government Standard: 24 CFR 200.935 - Administrator qualifications and procedures for HUD building products and certification programs [Incorporated: 2000]**

<b>Voluntary Standard</b>	<b>Rationale</b>
ANSI A119.1 N - Recreation Vehicles	HUD Building-Product Standards & Certification Programs. HUD was required by legislation to “establish Federal construction and safety standards for manufactured homes and to authorize manufactured home safety research and development”. Recently, HUD retained a private consensus body (NFPA) to update and modernize the Manufactured Home Standards. At the conclusion of the development process, NFPA will submit the revised standard to HUD for regulatory adoption.

---

**2) Government Standard: 24 CFR 3280 - Manufactured Home Construction and Safety Standards [Incorporated: 2000]**

<b>Voluntary Standard</b>	<b>Rationale</b>
ANSI A119.1 - Recreation Vehicles and NFPA 501C - Standard on Recreational Vehicles	HUD-Unique Manufactured Home Construction & 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”. Recently, HUD retained a private consensus body (NFPA) to update and modernize the Manufactured Home Standards. At the conclusion of the development process, NFPA will submit the revised standard to HUD for regulatory adoption.

---

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

300

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

10

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

5

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
American Society for Testing and Materials	ASTM
Federal Geographic Data Committee	FGDC
International Code Council	ICC
National Committee for Information Technology Standards	NCITS
National Fire Protection Association	NFPA

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

No

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

D

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

This policy continues to be effective in replacing Federal Standards with publically developed standards. This has resulted in more up-to-date and technically accurate standards. The Department of Housing and Urban Development (HUD) suggests Circular A-119 use stronger language to encourage agencies to be more active in determining which standards are applicable to the agency activities and when standards are identified, motivate the agency to be more assertive in enforcing their use.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

All of HUD's 25 conformity assessment (CA) programs, under the HUD Building-Products Standards & Certification Programs, are in compliance with the ISO guidelines & procedures. These are the same standards used by ANSI and other nationally recognized third-party certification agencies.

*9. Please provide any examples or case studies of standards successes:*

Based on a recent Office of Policy Development & Research (PD&R) assessment of HUD's own Minimum Property Standards (MPS) and Technical Suitability of Products (TSP) program, active discussions are underway to determine the future of the MPS and TSP program. This major study recommends that the Department extend its reliance on voluntary standard in two ways. First, the study recommends that HUD totally abandon the MPS for single-family housing in all aspects totally relying on the model codes, especially the ICC & IRC codes and remove all remaining references to the MPS in HUD regulations. This would clarify the reality of HUD not using its own standards in any way, shape or form. Second the study recommends that HUD abandon its own "Technical Suitability of Products" program relying instead on the National Evaluation Service to review all innovative or other products that do not meet the prescriptive standards of the model codes. This major study is now under review by the assistant Secretary for Housing. If adopted this major reform will further strengthen our reliance on the voluntary and private consensus process in lieu of HUD developed standards and criteria.

Second, HUD's Partnership for Advancing Technology in Housing (PATH) is continuing to encourage private industry to develop standard XML definitions for use in Internet based home construction commercial transactions. These will be used amongst specific

home construction entities. One of the group's objectives is to improve the speed of construction in order to make houses more affordable. Sharing the same technical language and being able to speak quickly and accurately is a big challenge. Applying Information Technology (IT) seemed to be one solution. However, the group didn't know how to implement it.

The first industry based group from the timber manufacturing industry approached PATH to assist them in convening hearings and task groups to develop such a common language (in this case, through XML tag sets) so that it would become an industry de facto "standard". PATH is now working with the window industry to develop similar XML tags for window industry tags will be used internally by the window industry and down through the distribution chain by wholesalers and homebuilders for the just in time ordering of products through web-based tools

These efforts have stimulated the first industry-based attempts to posit these standard definitions (most attempts have been top-down and unsuccessful). Also, because government served only in a facilitation capacity: industry did all the work! We plan to continue this work under PATH with different groups in the construction industry; we currently have three lined up.

*10. Please provide any other comments you would like to share on behalf of your agency:*

## Department of the Interior

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

788

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

269

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

19

### **Voluntary Consensus Standards Body**

### **Acronym**

American Concrete Institute	ACI
American Institute of Steel Construction	AISC
American National Standards Institute	ANSI
American Petroleum Institute	API
American Society of Civil Engineers	ASCE
American Society of Mechanical Engineers	ASME
American Society of Photogrammetry and Remote Sensing	ASPRS
American Water Works Association	AWWA
American Welding Society	AWS
Federal Geographic Data Committee	FGDC
Ground Water Protection Council	GWPC
Institute of Electrical and Electronic Engineers	IEEE
International Committee for Information Technology Standards	INCITS
International Organization for Standardization	ISO
International Organization for Standardization/International Electrotechnical Commission	ISO/IEC

National Association of Corrosion Engineers International	NACE
National Weeds Management Association	NAWMA
Petrotechnical Open Standards Consortium, Inc	POSC
The American Society for Testing and Materials	ASTM

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

n/a

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:

USGS: Since its issuance, Circular A-119 has worked in a straightforward manner to encourage the use of voluntary consensus standards. Circular A-119 allows exemptions where existing voluntary consensus standards are inconsistent with law or otherwise impractical and if each exemption is reported to OMB. The nature of the scientific research the USGS performs makes the use of national voluntary consensus standards a

required tool. The USGS has not requested any exemptions, nor is the USGS contemplating making such a request. We have no recommendations for changes to the Circular.

BLM: The BLM has attempted to enlist support for the development of its data standards both from other agencies, from cooperating State and local governments, and from the public. The BLM believes that these interagency in promoting standards should be highlighted in relation to the spirit of OMB Circular A-119. To that end, it would help if this report also addressed attempts by agencies, on their own initiative, to get agreements on adopting standards that can be adopted for private use as well.

MMS: As a result of A-119 MMS has increased its participation in voluntary standards groups, both domestic and international.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

BLM: The BLM is participating in a number of efforts to gain consensus on standard data exchange information and data sharing. Major efforts to include other federal and state partners are included below:

1) The Federal Geographic Data Committee (FGDC):

The BLM is a member with representation on the FGDC steering committee, its Standards Working Group, and subcommittees developing standards for geospatial data. The BLM maintains a node on the World Wide Web to document the FGDC metadata used to support its Land Use Plans and other land management activities. Conformance with the FGDC Metadata standards is a requirement for using this node. The BLM monitors its information placed on the node to ensure that it meets FGDC requirements. While the FGDC establishes standards are only mandated for Federal agencies, some of the FGDC standards have been submitted for adoption as American National Standards Institute (ANSI) standard and even International Standards Organization (ISO) standards.

2) Inter-Organizational Resource Information Coordinating Council (IRICC):

The Oregon State Office of the Bureau of Land Management participates in voluntary standards that are developed by IRICC, an outgrowth of the North West Forest Plan, which include the Bureau of Land Management, the U.S. Forest Service, and state natural resource partners, particularly in the area of hydrology, fisheries, and related categories. These are being adopted and used by the national land management agencies in cooperative forest management initiative.

FWS: Active FWS participation in the FGDC Coordination Work Group and the Geospatial One-Stop (GOS) Initiative:

- A subgroup of the FGDC's Standards Work Group was formed to develop a process for

approving/endorsing voluntary consensus standards consistent with the OMB Circular A-119 directives.

- One major GOS objective is to develop geographic information standards and services for multiple applications through identification of common data requirements and use of structures from voluntary consensus standards.

*9. Please provide any examples or case studies of standards successes:*

**BLM: Adoption of Standards for Weeds Treatment Areas:**

The BLM has adopted and approved standards for Weeds Treatment areas that will be incorporated into a redesign of its Weeds database. Those standards reflect the adoption of NAWMA standards mentioned above. It is expected that the redesign of the Weeds Data base will be completed in FY 2005.

**Cultural Resources Standards with State Historic Preservation Offices (SHPO):**

BLM has been cooperating with State Historic Preservation Offices and other agencies to standardize its cultural resource data with the States and has secured agreements with the SHPO contacts in the Western States on which standards to use for data sharing.

**Interagency Trails Data Standards:**

The BLM is one of three major national land management agencies that have established data standards for trails information. The membership in this standards working group included the National Park Service (NPS), the BLM, the US Forest Service (USFS), and representatives from trails organizations. Over 150 participants have furnished comments on the Trails standards and the final standards are ready for publication. The standards will be used in the Recreation.gov effort, which is one of the President's E-Government initiatives.

**GEOMAC:**

The data elements for fire perimeter information began to be developed in the summer of 2000 and have gained widespread acceptance in the wildland fire community. The data was developed through the cooperation of Interior Department agencies and is available on the national websites <http://geomac.usgs.gov>

**Hydrologic Unit Boundaries:**

The BLM, the Natural Resources Conservation Service, and the Bureau of Reclamation have used the Federal Standards for delineation of Hydrologic Unit Boundaries to perform detailed Geographic Information System (GIS) mapping. The standard has been submitted to the FGDC for approval as a federal standard.

**National Digital Elevation Program (NDEP)**

The NDEP was established to promote the exchange of accurate digital land elevation data among government, private, and nonprofit sectors and the academic community and to establish standards and guidance that will benefit all users. The NDEP is composed of agencies from the Department of Interior, Commerce, and Agriculture, as well as the

National Imagery and Mapping Agency, National Aeronautics and Space Administration, US Army Corp of Engineers, and the Federal Emergency Management Agency, and representation from state governments through the National States Geographic Information Council.

The National Digital Orthophoto Program

The National Digital Orthophoto Program (NDOP) was established to promote the cooperative production of digital orthophoto quads (DOQ) among participating Federal agencies. Over the years the focus has broadened to include orthophotography acquired by State and local governments. Members include BLM participants as well as the following agencies; (USDA) Farm Service Agency, Natural Resources Conservation Service, U.S. Forest Service, (DOI) U.S. Geological Survey, Bureau of Land Management Federal Emergency Management Agency, Environmental Protection Agency, Bureau of Census and the National States Geographic Information Council.

*10. Please provide any other comments you would like to share on behalf of your agency:*

BLM point of contact: Mr. Jim Horan, 202-452-5023

Department of Justice

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

1

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

5

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

1

**Voluntary Consensus Standards Body**

Global Justice Information Sharing Initiative

**Acronym**

GLOBAL

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

B

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

A

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

A-119 provides effective and unambiguous guidance for the use of voluntary consensus standards through its specific definitions, assessment activities, and usage directives.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

none

*9. Please provide any examples or case studies of standards successes:*

The Department continues to participate in activities that standardize the format and content of law enforcement and public safety data in support of information sharing among state, local, and federal organizations. DOJ is building on collaborative standards advanced through the Law Enforcement Information Sharing Program.

*10. Please provide any other comments you would like to share on behalf of your agency:*

none

Department of Labor

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

5

**1) Government 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.

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**2) Government 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.

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**3) Government 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

**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

NFPA 33-2003 Standard for Spray Application Using Flammable or Combustible Materials

and its negotiated rulemaking committee determined that there was no, one consensus standard available that covered all the topics in the rule.

---

**4) Government 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.

---

**5) Government 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.

---

*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

165

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

19

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
Acoustical Society of America	ASA
American Conference of Governmental Industrial Hygienists	ACGIH
American Industrial Hygiene Association	AIHA
American National Standards Institute	ANSI
American Society for Testing and Materials	ASTM
American Society of Mechanical Engineers	ASME
American Society of Safety Engineers	ASSE
American Welding Society	AWS
Canadian Standards Association	CSA
Commercial Motor Vehicle Safety Alliance	CMVSA
Federal Laboratory Consortium	FLC
Institute of Electrical and Electronic Engineers	IEEE
International Electrotechnical Commission	IEC
International Organization for Standardization	ISO
International Society for Measurement and Control	ISA
National Fire Protection Association	NFPA
Society for Mining, Metallurgy, and Exploration	SME
Society of Automotive Engineers	SAE
Underwriters Laboratories	UL

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

No comments

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

A

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

B

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

No comment

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

None

*9. Please provide any examples or case studies of standards successes:*

N/A

*10. Please provide any other comments you would like to share on behalf of your agency:*

Please make the following changes to the rationale column of Appendix C of the 2003 Report.

Item No. 8 Sanitary Toilets in Coal Mines, change the first sentence to read: ANSI Z4.3-1987 (Reaffirmed 1995) was used as a basis for this rule but 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.

Item No. 9 for Steel Erection Standards, change the rationale to read: There was no one consensus standard available that covered all the topics covered by OSHA's final rule.

Department of State

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

0

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

7

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

1

**Voluntary Consensus Standards Body**

**Acronym**

International Telecommunication Union

ITU

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

Department of State exercises the USA membership in the International Telecommunication Union.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

D

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

D

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

D

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

C

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

A

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

Not applicable.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

None.

*9. Please provide any examples or case studies of standards successes:*

None.

*10. Please provide any other comments you would like to share on behalf of your agency:*

Department of Transportation

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

3

**1) Government Standard: 63 FR 17976; April 13, 1998 - Product Safety Signs and Labels [Incorporated: 1998]**

**Voluntary Standard**

ANSI Z535.4 - ANSI Requirements for Color Coded Header Messages for the Different Levels of Hazard

**Rationale**

NHTSA explained in the NPRM that the American National Standard Institute (ANSI) has a standard<sup>4</sup> for product safety signs and labels (ANSI Z535.4) that identifies a hierarchy of hazard levels ranging from extremely serious to moderately serious and specifies corresponding hierarchies of signal words, i.e., “danger,” “warning,” and “caution,” and of colors. For the header, the ANSI standard specifies a red background with white text for “danger,” an orange background with black text for “warning,” and a yellow background with black text for caution.”

The ANSI standard specifies that pictograms should be black on white, with occasional uses of color for emphasis, and that message text should be black on white. The agency noted in the NPRM that when it earlier updated the requirements for air bag warning labels to require the addition of color and pictograms, it had chosen not to adopt the colors specified in the ANSI standard. NHTSA chose to use yellow instead of orange in the background of the heading for the air bag warning label, even though the word “warning” was used, because of overwhelming focus group preference for yellow. Only two of the 53 participants preferred orange. Participants generally stated that yellow was more eye-catching than orange. Participants also noted that red (stop) and yellow (caution) had meaning to them, but not orange.

NHTSA asked for comment on three color options for the revised utility vehicle rollover warning label. Proposed label 1 used the ANSI color format with the heading background in orange with the words in black. The remainder of the label had a white

background with black text and drawings. Proposed label 2 used a color scheme like the air bag warning labels, which is the same as the ANSI color format except that the background color for the heading in the label is yellow. Proposed label 3 employed the color scheme used in the focus groups - the heading area had a red background with white text. The graphic areas had a yellow background with black and white drawings. The text area had a black background with yellow text.

Despite focus group preference for the signal word “danger,” the agency proposed the use of the word “warning” as more appropriate to the level of risk. The agency also noted that the word “warning” is used in the air bag warning label.

Recognizing that it might encounter additional conflicts between focus group preferences and the ANSI standard in future rulemakings, NHTSA requested comments in the NPRM on the extent to which any final choice regarding colors and signal words should be guided by the focus group preferences instead of the ANSI standard. NHTSA also requested comments on the broader issue of the circumstances in which it would be appropriate for agency rulemaking decisions to be guided by focus group results or other information when such information is contrary to a voluntary consensus standard such as the ANSI standard.

At this time (February 22, 1999), a final decision is still pending regarding its proposal to upgrade the rollover warning label. As to the general questions it posed in the NPRM, NHTSA recognizes that ANSI’s mission differs somewhat from that of the agency’s focus groups with respect to the labeling of hazardous situations. ANSI’s mission is to develop and maintain a standard for communicating information about a comprehensive hierarchy of hazards, while the focus groups’ mission is to design an effective label for a specific hazard. The agency recognizes further that, given the difference in their missions, their conclusions about the appropriate manner of communication might differ on occasion.

Since agency labeling decisions are highly dependent on the facts regarding the specific hazard being addressed, NHTSA anticipates making case-by-case determinations of the extent to which it should follow voluntary standards versus information from focus groups and other sources. NHTSA will rely on its own expertise and judgement in making determinations under the NTTAA and the statutory provisions regarding vehicle safety standards.

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**2) Government Standard: Air Bag Warning Label (1997) [Incorporated: 1997]**

**Voluntary Standard**  
ANSI ISO

**Rationale**

The Air Bag Warning Label uses yellow as the background color, instead of orange, in accordance with an ANSI standard and uses a graphic developed by Chrysler Corporation to depict the hazards of being too close to an air bag, instead of the graphic recommended by the ISO. These decisions were based on focus group testing sponsored by the agency which strongly indicated that these unique requirements would be far more effective with respect to safety than the industry standards.

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**3) Government 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.

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*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

343

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

167

*5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?*

41

**Voluntary Consensus Standards Body**

**Acronym**

Aerospace Industries Association of America

AIA

American Association of Motor Vehicle Administrators

AAMVA

American Association of State Highway and Transportation Officials

AASHTO

American Gas Association

AGA

American Institute of Aeronautics and Astronautics

AIAA

American National Standards Institute

ANSI

American Petroleum Institute

API

American Public Transportation Association	APTA
American Railway Engineering & Maintenance-of-Way Association	AREMA
American Society for Testing and Materials	ASTM
American Society of Civil Engineers	ASCE
American Society of Mechanical Engineers	ASME
American Trucking Associations	ATA
Association of American Railroads	AAR
Canadian General Standards Board	CGSB
Canadian Standards Association	CSA
Commercial Vehicle Safety Alliance	CVSA
Compressed Gas Association	CGA
Gas Technology Institute	GTI
Institute of Electrical and Electronic Engineers	IEEE
Institute of Transportation Engineers	ITE
Intelligent Transportation Society of America	ITS America
International Atomic Energy Agency	IAEA
International Civil Aviation Organization	ICAO
International Commission on Occupational Health	ICOH
International Maritime Organization	IMO
International Organization for Standardization	ISO
Manufacturers Standardization Society of the Valve and Fittings Industry	MSS
NAFTA Land Transportation Standards Subcommittee	NAFTA
National Association of Corrosion Engineers International	NACE
National Board of Boiler and Pressure Vessel Inspectors	NBBPVI
National Committee on Uniform Traffic Control Devices	NCUTCP
National Electrical Manufacturers Association	NEMA
National Fire Protection Association	NFPA
North American Transport of Dangerous Goods Standards	NATDGS
Organization for Economic Cooperation and Development	OECD
Rehabilitation Engineering and Assistive Technology Society of North America	RESNA
Society of Automotive Engineers	SAE
Transportation Research Board	TRB
United Nations Committee on the Transport of Dangerous Goods	UNTDG
United Nations Economic Commission for Europe WP .29/GRSP	UNECE

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

No N/As.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

No

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

DOT believes that Circular A-119 is working effectively and that the use of voluntary standards can save both time and money for regulatory agencies. We have no recommendation to change the Circular at this time.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

The Federal Railroad Administration's (FRA) conformity assessment activities are visible internationally through expanded efforts in the area of safe, uniform international transport of hazardous materials by participation in the Canadian General Standards Board Tank Car Committee and the ASME Transportation Pressure Vessel Committee, as well as continuing to participate in the NATDGS Working Group and the AAR Tank Car Committee.

Participation in voluntary consensus standards bodies as well as in numerous committees and sub-committees of those bodies gives FRA access to the developmental stages of private sector conformity assessment standards to make sure the agency viewpoint is considered in the development of their standards.

*9. Please provide any examples or case studies of standards successes:*

Federal Highway Administration – Intelligent Transportation Systems (ITS) Standards Program: The National Transportation Communications for ITS Protocol (NTCIP) has the following case studies of standards successes available for the ITS Standards community on their web site at: [www.ntcip.org](http://www.ntcip.org).

- NTCIP 9002 – Virginia State DOT Statewide DMS Project
- NTCIP 9003 - Washington State DOT NTCIP VMS Software Upgrade
- NTCIP 9004 - City of Phoenix, Arizona - Phoenix Advanced Transportation Management System
- NTCIP 9005 - Texas Department of Transportation Statewide Center-to-Center Software and Systems Integration
- NTCIP 9006 - City of Lakewood, Colorado - Lakewood Advanced Traffic Management System
- NTCIP 9007 - City of Mesa, Arizona - Signal System Upgrade
- NTCIP 9008 – Minnesota DOT Statewide R/WIS Project
- NTCIP 9009 - Washington State Department of Transportation - Statewide ESS Procurement

*10. Please provide any other comments you would like to share on behalf of your agency:*

The DOT operating administrations offer no additional comments.

Department of the Treasury

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

5

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

5

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

5

**Voluntary Consensus Standards Body**

**Acronym**

American National Standards Institute

ANSI

Federal Public Key Infrastructure Technical Working group

PKIWG

Federal Public Key Steering Committee

FPKISC

Organization for the advancement of structured Information Standards

OASIS

United Nations Centre for Trade Facilitation and Electronic Business

UNI/CEFACT

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

o no further comment

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

B

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

D

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

We believe the guidelines prescribed in Circular 119 are effective. Circular A-119 has placed the focus on using voluntary standards as opposed to the development of government-unique standards. Wide use of voluntary standards promotes the development of an increased use of standards compliant products facilitating the use of new technology and increased flexibility to meet new requirements.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

None

*9. Please provide any examples or case studies of standards successes:*

None

*10. Please provide any other comments you would like to share on behalf of your agency:*

No additional comments

Department of Veterans Affairs

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

0

*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

0

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

4

*5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?*

18

**Voluntary Consensus Standards Body**

**Acronym**

American Industrial Hygiene Association	AIHA
American Institute of Timber Construction	AITC
American National Metric Council	ANMC
American National Standards Institute	ANSI
American Society for Testing and Materials	ASTM
American Society of Heating, Refrigerating, and Air-Conditioning Engineers	ASHRAE
American Society of Hospital Engineers	ASHE
American Society of Mechanical Engineers	ASME
American Society of Safety Engineers	ASSE
Builders Hardware Manufacturers Association	BHMA
Federal Facilities Council	FFC
Government Electronics & Information Technology	GEITA

Association Interagency Committee on Seismic Safety in Construction	ICSS
Joint Commission on Accreditation of Healthcare Organizations	JCAHO
National Fire Protection Association	NFPA
National Institute for Occupational Safety and Health	NIOSH
National Institute of Building Sciences	NIBS
Uniform Building Code	UBC

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

The Veterans Health Administration accepts and conforms to standards developed by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) for Veterans Affairs (VA) health care facilities. Voluntary consensus standard requirements are utilized in the regulatory, contractual and grants determinations executed by the Veterans Health Administration.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

B

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

A

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

The Department of Veterans Affairs, has no comments or recommendations for changes at this time.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

The VA does not engage in conformity assessments activities. VA strives to use industry based standards and commercial off-the-shelf products.

*9. Please provide any examples or case studies of standards successes:*

No comment

*10. Please provide any other comments you would like to share on behalf of your agency:*

Federal regulations prescribe standards that must be used (e.g., OSHA monitoring sampling standards and EPA laboratory standards). Regardless of what may be developed by conformity assessment, VA is not relieved of its obligation to use standards prescribed by regulations. When not obligated to use prescribed regulatory or other (e.g., JCAHO) standard, VA organizations must retain the flexibility to use the standard that best meets its programmatic needs.

## Appendix E – Individual, Unabridged Commission and other Agency Reports

Note: This appendix contains the unabridged Commission and other agency reports as they were submitted to NIST.

### Agency for International Development

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

0

*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

0

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

0

*5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?*

0

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

Our agency does not participate in work that requires use of standards from non-ANSI accredited standards developers, industry consortia, or groups.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

B

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

B

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

No

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

E

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

USAID has no recommendations for changing Circular A-119.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

USAID participates in the Contractor Performance Reporting system developed and managed by the National Institutes for Health, including participating as a member of the committee that determines information requirements. This may be considered a conformity assessment activity since it is standardizing the way that the participating agencies assess contractors' performance.

*9. Please provide any examples or case studies of standards successes:*

Nothing to report for FY 2004.

*10. Please provide any other comments you would like to share on behalf of your agency:*

No general comments about this reporting tool.

Consumer Product Safety Commission

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

2

**1) Government Standard: CPSC CFR Parts 1213, 1500, and 1513 [Incorporated: 2000]**

<b>Voluntary Standard</b>	<b>Rationale</b>
ASTM F1427-96	The CPSC rule goes beyond the provisions of the ASTM voluntary standard to provide increased protection to children from the risk of death and serious injury from entrapment.

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**2) Government Standard: FR/Vol. 68, No. 75/Friday, April 18, 2003, pp. 19142-19147, Metal-Cored Candlewicks Containing Lead and Candles With Such Wicks [Incorporated: 2003]**

<b>Voluntary Standard</b>	<b>Rationale</b>
Voices of Safety International (VOSI) standard on lead in candle wicks	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 FR/Vol. 68, No. 75/Friday, April 18, 2003, pp. 19145-19146, paragraph H2, Voluntary Standards for further information on this finding.

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2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

0

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

30

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

8

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
American National Standards Institute	ANSI
American Society for Testing and Materials International	ASTMI
American Society of Mechanical Engineers	ASME
Canadian Standards Association	CSA
National Fire Protection Association	NFPA
Specialty Vehicle Institute of America	SVIA
Underwriters Laboratories	UL
Window Covering Manufacturers Association	WCMA

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

No comment

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

A

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

No

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

A

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

During FY 2004, the Commission's efforts to enhance voluntary safety standards development was complemented by the overall Federal policy set forth in the Circular. There are no recommendations for changes in the Circular at this time.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

None

*9. Please provide any examples or case studies of standards successes:*

The CPSC staff provided technical support to the development of 28 new, revised, or reaffirmed voluntary consumer product safety standards which were completed in FY 2004. The Commission staff participated in 69 voluntary standards development projects during FY 2004.

*10. Please provide any other comments you would like to share on behalf of your agency:*

The U.S. Consumer Product Safety Act (CPSA), as amended, requires the Commission to defer to issued voluntary standards, rather than promulgate mandatory standards, when the voluntary standards will eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with the voluntary standards. In addition, the Commission is required, after any notice or advance notice of proposed rulemaking, to provide technical and administrative assistance to persons or groups who propose to develop or modify an appropriate voluntary standard. Additionally, the Commission is encouraged to provide technical and administrative assistance to groups developing product safety standards and test methods, taking into account Commission resources and priorities.

Since its inception in 1973, the Commission has promoted the development of voluntary product safety standards. Policy statements in support of voluntary standards were published by the CPSC in 1975 and 1978. These policy statements were updated in 1988 (16 U.S.C. 1031), and a staff directive on implementation of portions of these policy statements was promulgated in 1989 and updated in October 2001. Since the principles set forth in the OMB Circular A-119 Rev. were published, the Commission has consistently supported them.

Environmental Protection Agency

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

50

**1) Government Standard: 40 CFR 89 - Control of Emissions from New and In-Use Non-Road Compression Ignition Engines [Incorporated: 1999]**

**Voluntary Standard**

ISO 8178 - Reciprocating Internal Combustion Engines, Exhaust Emission Measurement

**Rationale**

Procedures would be impractical because they rely too heavily on reference testing conditions. Agency decides instead to continue to rely on procedures outlined in 40 CFR Part 90.

---

**2) Government Standard: 40 CFR 90 - Control of Emission from Non-Road Spark Ignition Engines at or below 19KV [Incorporated: 1999]**

**Voluntary Standard**

ISO 8178 - Reciprocating Internal Combustion Engines, Exhaust Emission Measurement

**Rationale**

Procedures would be impractical because they rely too heavily on reference testing conditions. Agency decides instead to continue to rely on procedures outlined in 40 CFR Part 90.

---

**3) Government Standard: 40 CFR 92 - Control of Air Pollution from Locomotives and Locomotive Engines [Incorporated: 1999]**

**Voluntary Standard**

ISO 8178 - Reciprocating Internal Combustion Engines, Exhaust Emission Measurement

**Rationale**

Procedures would be impractical because they rely too heavily on reference testing conditions. Agency decides instead to continue to rely on procedures outlined in 40 CFR Part 90.

---

**4) Government 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.

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

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

---

**5) Government Standard: EPA Method 10 - Carbon Monoxide, NDIR [Incorporated: 1999]****Voluntary Standard**

ASTM D3162 (1994) Standard Test Method for Carbon Monoxide in the Atmosphere (Continuous Measurement by Non-dispersive Infrared Spectrometry)

**Rationale**

This ASTM standard, which is stated to be applicable in the range of 0.5-100 ppm CO, does not cover the range of EPA Method 10 (20-1,000 ppm CO) at the upper end (but states that it has a lower limit of sensitivity). Also, ASTM D3162 does not provide a procedure to remove carbon dioxide interference. Therefore, this ASTM standard is not appropriate for combustion source conditions. In terms of non-dispersive infrared instrument performance specifications, ASTM D3162 has much higher maximum allowable rise and fall times (5 minutes) than EPA Method 10 (which has 30 seconds).

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

1. This standard 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 CO<sub>2</sub> 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 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.

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**7) Government Standard: EPA Method 101a - Mercury Emissions Sewer/Sludge Incinerator [Incorporated: 2001]**

**Voluntary Standard**

ASTM D6216-98 - Standard Practice for Opacity Monitor Manufacturers to

**Rationale**

The EPA is incorporating ASTM D6216 (manufacturers certification) by

Certify Conformance with Design and Performance Specifications.

reference into EPA Performance Specification 1, Sect. 5 & 6 in another rulemaking. ASTM D6216 does not address all the requirements specified in PS-1.

---

**8) Government 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 CO<sub>2</sub> 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.

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**9) Government 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.

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

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.

ASTM E1979-98 (1998), Standard Practice for Ultrasonic Extraction of Paint, Dust, Soil, and Air Samples for Subsequent Determination of Lead

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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**10) Government Standard: EPA Method 15 - Hydrogen Sulfide/Carbon Disulfide/Carbon Sulfide [Incorporated: 1999]**

**Voluntary Standard**

ASME C00031 or PTC 19-10-1981 - Part 10 Flue and Exhaust Gas Analyses

**Rationale**

Too broad to be useful in regulatory sense. Covers Methods 3, 6, 7, and 15 with variants.

ASTM D4323-84 (1997) - Standard Test Method for Hydrogen Sulfide in the Atmosphere by Rate of Change of Reflectance

ASTM D4323 only applies to concentrations of H<sub>2</sub>S from 1 ppb to 3 ppm without dilution. Many QC items are missing, such as calibration drift and sample line losses. The calibration curve is determined with only one point.

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**11) Government Standard: EPA Method 1650 - Organic Halides, Absorbable (AOX) [Incorporated: 1998]**

**Voluntary Standard**

ISO, DIN, SCAN, and Standard Methods (SM 5320)

**Rationale**

EPA decided to use EPA Method 1650. This Method was developed by drawing on various procedures contained in the methods of voluntary consensus standards bodies and other standards developers, such as ISO,

DIN, SCAN, and Standard Methods (SM 5320). However, none of these more narrowly focused voluntary consensus standards contained the standardized quality control and quality control compliance criteria that EPA requires for data verification and validation in its water programs. Therefore, EPA found none of these VCS standing alone to meet EPA's needs.

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**12) Government 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.

ASTM D3685/3685M-95 - Standard Test method for Sampling and Determination of Particle Matter in Stack Gases

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.

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**13) Government Standard: EPA Method 18 - VOC/GC [Incorporated: 1999]**

**Voluntary Standard**

ASTM D6060-96 (in review 2000) - Practice for Sampling of Process Vents with a Portable Gas Chromatography

**Rationale**

This standard lacks key quality control and assurance that is required for EPA Method 18. For example: lacks acceptance criteria for calibration, details on using other collection media (e.g. solid sorbents), and reporting/documentation requirements.

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**14) Government Standard: EPA Method 180.1 - Turbidity Nephelometric [Incorporated: 1999]**

**Voluntary Standard**

ISO 7027 - Water Quality Determination of Turbidity

**Rationale**

EPA has no data upon which to evaluate whether the separate 90 degrees scattered or transmitted light measurement evaluations according to the ISO 7027 method would produce results that are equivalent to results produced by the other methods.

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**15) Government Standard: EPA Method 2 – Velocity and S-type Pitot [Incorporated: 1999]**

**Voluntary Standard**

ASTM 3796-90 (1998), Standard Practice for Calibration of Type S Pitot Tubes

**Rationale**

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

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

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.

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

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

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.

ISO 10780:1994, Stationary Source Emissions-- Measurement of Velocity and Volume Flowrate of Gas Streams in Ducts

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.

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**16) Government 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.

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**17) Government Standard: EPA Method 23 – Dioxin and Furan (PCDD and PCDF) [Incorporated: 1999]**

**Voluntary Standard**

European Committee for Standardization (CEN) EN 1948-3 (1997), Determination of the Mass Concentration of PCDD'S/PCDF'S-- Part 3: Identification and Quantification

**Rationale**

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

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**18) Government Standard: EPA Method 24 – Surface Coatings, Volatile Matter Content [Incorporated: 1998]**

**Voluntary Standard**

ISO 11890-1 (2000) part 1, Paints and Varnishes--Determination of Volatile Organic Compound (VOC) Content-Difference Method

**Rationale**

Measured nonvolatile matter content can vary with experimental factors such as temperature, length of heating period, size of weighing dish, and size of sample. The standard ISO 11890-1 allows for different dish weights and sample sizes than the one size (58 millimeters in diameter and sample size of 0.5 gram) of EPA Method 24. The standard 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 110 degrees Celcius at all times. Because the EPA Method 24 test conditions and procedures define volatile matter, ISO 11890-1 is unacceptable as an alternative because of its different test conditions.

ISO 11890-2 (2000) Part 2, Paints and Varnishes--Determination of Volatile Organic Compound (VOC) Content-Gas Chromatographic Method

ISO 11890-2 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 this EPA method.

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**19) Government Standard: EPA Method 25 – Gaseous Nonmethane Organic Emissions [Incorporated: 2001]****Voluntary Standard**

EN 12619:1999 Stationary Source Emissions--Determination of the Mass Concentration of Total Gaseous Organic Carbon at Low Concentrations in Flue Gases--Continuous Flame Ionization Detector Method

**Rationale**

The standards do not apply to solvent process vapors in concentrations greater than 40 ppm (EN 12619) and 10 ppm carbon (ISO 14965). Methods whose upper limits are this low are too limited to be useful in measuring source emissions, which are expected to be much higher.

ISO 14965:2000(E) Air Quality--  
Determination of Total Nonmethane  
Organic Compounds--Cryogenic  
Preconcentration and Direct Flame  
Ionization Method

The standards do not apply to solvent  
process vapors in concentrations  
greater than 40 ppm (EN 12619) and  
10 ppm carbon (ISO 14965). Methods  
whose upper limits are this low are too  
limited to be useful in measuring  
source emissions, which are expected  
to be much higher.

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**20) Government Standard: EPA Method 25A – Gaseous Organic  
Concentration, Flame Ionization [Incorporated: 2001]**

**Voluntary Standard**

EN 12619:1999 Stationary Source  
Emissions--Determination of the Mass  
Concentration of Total Gaseous  
Organic Carbon at Low Concentrations  
in Flue Gases--Continuous Flame  
Ionization Detector Method

**Rationale**

The standards do not apply to solvent  
process vapors in concentrations  
greater than 40 ppm (EN 12619) and  
10 ppm carbon (ISO 14965). Methods  
whose upper limits are this low are too  
limited to be useful in measuring  
source emissions, which are expected  
to be much higher.

ISO 14965:2000(E) Air Quality--  
Determination of Total Nonmethane  
Organic Compounds--Cryogenic  
Preconcentration and Direct Flame  
Ionization Method

The standards do not apply to solvent  
process vapors in concentrations  
greater than 40 ppm (EN 12619) and  
10 ppm carbon (ISO 14965). Methods  
whose upper limits are this low are too  
limited to be useful in measuring  
source emissions, which are expected  
to be much higher.

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**21) Government Standard: EPA Method 26 – Hydrogen Chloride, Halides,  
Halogens Emissions [Incorporated: 1999]**

**Voluntary Standard**

EN 1911-1,2,3 (1998), Stationary  
Source Emissions-- Manual Method of  
Determination of HCl--Part 1: Sampling  
of Gases Ratified European Text--Part  
2: Gaseous Compounds Absorption  
Ratified European Text-- Part 3:  
Adsorption Solutions Analysis and  
Calculatio

**Rationale**

Part 3 of this standard cannot be  
considered equivalent to EPA Method  
26 or 26A because the sample  
absorbing solution (water) would be  
expected to capture both HCl and Cl<sub>2</sub>  
gas, if present, without the ability to  
distinguish between the two. The EPA  
Methods 26 and 26A use an acidified  
absorbing solution to first separate HCl

and Cl<sub>2</sub> gas so that they can be selectively absorbed, analyzed, and reported separately. In addition, in EN 1911 the absorption efficiency for Cl<sub>2</sub> gas would be expected to vary as the pH of the water changed during sampling.

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**22) Government Standard: EPA Method 26A – Hydrogen Halide and Halogen, Isokinetic [Incorporated: 1999]**

**Voluntary Standard**

EN 1911-1,2,3 (1998), Stationary Source Emissions-- Manual Method of Determination of HCl--Part 1: Sampling of Gases Ratified European Text--Part 2: Gaseous Compounds Absorption Ratified European Text-- Part 3: Adsorption Solutions Analysis and Calculation

**Rationale**

Part 3 of this standard cannot be considered equivalent to EPA Method 26 or 26A because the sample absorbing solution (water) would be expected to capture both HCl and Cl<sub>2</sub> gas, if present, without the ability to distinguish between the two. The EPA Methods 26 and 26A use an acidified absorbing solution to first separate HCl and Cl<sub>2</sub> gas so that they can be selectively absorbed, analyzed, and reported separately. In addition, in EN 1911 the absorption efficiency for Cl<sub>2</sub> gas would be expected to vary as the pH of the water changed during sampling.

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**23) Government 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.

ASTM E319-85 (Reapproved 1997), Standard Practice for the Evaluation of Single-Pan Mechanical Balances

This standard is not a complete weighing procedure because it does not include a pretest procedure.

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**24) Government 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.

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

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.

ASTM E1979-98 (1998), Standard Practice for Ultrasonic Extraction of Paint, Dust, Soil, and Air Samples for Subsequent Determination of Lead

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.

CAN/CSA Z223.26-M1987, Measurement of Total Mercury in Air Cold Vapour Atomic Absorption Spectrophotometric Method

It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.

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**25) Government Standard: EPA Method 2C – Velocity and Flow Rate, Standard Pitot [Incorporated: 1999]**

**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.

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**26) Government Standard: EPA Method 3 – Molecular Weight Carbon Dioxide, Oxygen [Incorporated: 1999]**

**Voluntary Standard**

ASME C00031 or PTC 19-10-1981-- part 10, "Flue and Exhaust Gas Analyses"

**Rationale**

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

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

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.

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**27) Government 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).

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**28) Government 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).

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**29) Government Standard: EPA Method 320 – Vapor Phase Organic and Inorganic Emissions, FTIR [Incorporated: 1999]**

**Voluntary Standard**

ASTM D6348-98, Determination of Gaseous Compounds by Extractive

**Rationale**

Suggested revisions to ASTM D6348-98 were sent to ASTM by the EPA

Direct Interface Fourier Transform  
(FTIR) Spectroscopy

that, would allow the EPA to accept ASTM D6348-98 as an acceptable alternative. The ASTM Subcommittee D22-03 is currently undertaking a revision of ASTM D6348- 98. Because of this, we are not citing this standard as a acceptable alternative for EPA Method 320 in the final rule today. However, upon successful ASTM balloting and demonstration of technical equivalency with the EPA FTIR methods, the revised ASTM standard could be incorporated by reference for EPA regulatory applicability. In the interim, facilities have the option to request ASTM D6348-98 as an alternative test method under 40 CFR 63.7(f) and 63.8(f) on a case-by-case basis.

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**30) Government Standard: EPA Method 3A – Carbon Dioxide and Oxygen Concentrations, IAP [Incorporated: 1999]**

**Voluntary Standard**

ASTM D5835-95, Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration

**Rationale**

1. They lack in detail and quality assurance/quality control requirements. Specifically, these two standards do 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; and (7) specifications for data recorders, in terms of resolution (all types) and recording intervals (digital and analog recorders, only). 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA

CAN/CSA Z223.2-M86(1986), Method for the Continuous Measurement of Oxygen, Carbon Dioxide, Carbon Monoxide, Sulphur Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Stream

regulatory requirements.

1. 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 nonmandatory 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. 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

ISO 10396:1993, Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations

1. They lack in detail and quality assurance/quality control requirements. Specifically, these two standards do 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; and (7) specifications for data recorders, in terms of resolution (all types) and recording intervals (digital and analog recorders, only). 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

ISO 12039:2001, Stationary Source Emissions-- Determination of Carbon Monoxide, Carbon Dioxide, and

This ISO standard is similar to EPA Method 3A, but is missing some key features. In terms of sampling, the

## Oxygen--Automated Methods

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.

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### **31) Government Standard: EPA Method 3B – Oxygen, Carbon Dioxide, Carbon Monoxide, Emission Rate Correction Factor [Incorporated: 1999]**

#### **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.

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

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

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### **32) Government Standard: EPA Method 4 – Moisture Content in Stack Gases [Incorporated: 1999]**

**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.

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

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

ASTM E337-84 (1996), Standard Test Method for Measuring Humidity with a Psychrometer (the Measurement of Wet- and Dry-Bulb Temperatures)

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

**33) Government Standard: EPA Method 5 – Particulate Matter, Stationary Sources [Incorporated: 1999]**

**Voluntary Standard**

ASME PTC-38-80 R85 or C00049, Determination of the Concentration of Particulate Matter in Gas Streams

**Rationale**

It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.

ASTM D3685/D3685M-98, Test Methods for Sampling and Determination of Particulate Matter in Stack Gases

It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.

ISO 9096:1992, Determination of Concentration and Mass Flow Rate of Particulate Matter in Gas Carrying

It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance

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**34) Government Standard: EPA Method 515.1 - Chlorinated Acids in Water by CC/ECD [Incorporated: 1998]**

**Voluntary Standard**

Standard Methods 6640B

**Rationale**

Standard Methods 6640B for acid herbicides was tentatively deemed impractical for EPA's needs because its sample preparation and quality control procedures were not similar enough to EPA Method 515.1 to ensure that there would not be underreporting of acid herbicide contamination. EPA plans to offer to work with the Standard Methods committee to resolve this issue prior to the next publication.

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**35) Government 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.

Standard Method 6640 B for the chlorinated acids

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.

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**36) Government 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.

Standard Method 6610, 20th Supplemental Edition

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.

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**37) Government 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.

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**38) Government Standard: EPA Method 6 - Sulphur Dioxide Emissions [Incorporated: 1999]**

**Voluntary Standard**

ASME C00031 or PTC 19-10-1981 - Part 10 Flue and Exhaust Gas

**Rationale**

Too broad to be useful in regulatory sense. Covers Methods 3, 6, 7, and 15

Analyses	with variants.
ISO 11632:1998 - Stationary Source Emissions - Determination of the Mass Concentration of Sulfur Dioxide - Ion Chromatography	ISO 11632:1998 - Stationary Source Emissions - Determination of the Mass Concentration of Sulfur Dioxide - Ion Chromatography
ISO 7934:1998 - Stationary Source Emissions - Determination of the Mass Concentration of Sulfur Dioxide - Hydrogen Peroxide/Barium Perchlorate/ Thorin Method	This standard is only applicable to sources with 30 mg/m <sup>3</sup> SO <sub>2</sub> or more. In addition, this method does not separate SO <sub>3</sub> from SO <sub>2</sub> as does EPA Method 6; therefore, this method is not valid if more than a negligible amount of SO <sub>3</sub> is present. Also, does not address ammonia interferences.

**39) Government Standard: EPA Method 6c - Sulpher Dioxide Emissions Stationary by IAP [Incorporated: 1999]**

<b>Voluntary Standard</b>	<b>Rationale</b>
ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration	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.
CAN/CSA Z223.2-M86 - (1986) Method for the Continuous Measurement of Oxygen, Carbon Dioxide, Carbon Monoxide, Sulphur Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Streams	Too general. This standard lacks in detail and quality assurance/quality control requirements. Appendices with valid quality control information are not a required part of this method.
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations	Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

**40) Government Standard: EPA Method 7 - Nitrogen Oxide Emissions Stationary Sources [Incorporated: 1999]**

<b>Voluntary Standard</b>	<b>Rationale</b>
ASME C00031 or PTC 19-10-1981 -	Too broad to be useful in regulatory

Part 10 Flue and Exhaust Gas Analyses

sense. Covers Methods 3, 6, 7, and 15 with variants.

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**41) Government Standard: EPA Method 7e - Nitrogen Oxide, Instrumental [Incorporated: 1999]**

**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.

CAN/CSA Z223.2-M86 - (1986) Method for the Continuous Measurement of Oxygen, Carbon Dioxide, Carbon Monoxide, Sulphur Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Streams

Too general. This standard lacks in detail and quality assurance/quality control requirements. Appendices with valid quality control information are not a required part of this method.

ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations

Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

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**42) Government 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.

ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations

Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

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**43) Government Standard: EPA Method CTM 022 [Incorporated: 2002]**

**Voluntary Standard**

**Rationale**

ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration

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.

ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations

Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

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**44) Government Standard: EPA Method GG – (Title not found in index) [Incorporated: 2003]**

**Voluntary Standard**

ASTM D3031-81 – Method of Test for Total Sulfur in Natural Gas (Hydrogenation), Withdrawn

**Rationale**

This method has been deleted from the final rule because it was discontinued by the ASTM in 1990 with no replacement. If the total sulfur content of the fuel being fired in the turbine is less than 0.4 weight percent, we are adding a provision that the following methods may be used to measure the sulfur content of the fuel: ASTM D4084-82 or 94, D5504-01, D6228-98, or the Gas Processors Association Method 2377-86. This provision is consistent with the provision in 40 CFR 60.13(j)(1) allowing alternatives to reference method tests to determine relative accuracy of CEMS for sources with emission rates demonstrated to be less than 50 percent of the applicable standard.

---

**45) Government 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.

---

**46) Government 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.

---

**47) Government Standard: EPA Performance Specifications 11 - Particulate Matter Continuous Monitoring System [Incorporated: 1999]**

**Voluntary Standard**

ISO 10155:1995 - Stationary source emissions. Automated monitoring of mass concentration of particles - Performance characteristics, test methods and specifications.

**Rationale**

This international standard is only applicable on a site specific basis by direct correlation with the manual method ISO 9096 (which does not produce particulate matter measurements like EPA Method 5). This appears to be a PM CEMS performance specification similar to EPA Performance Specification 11, but does not contain detailed RATA procedures. Also, EPA doesn't have a final performance specification to compare this to.

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**48) Government Standard: GLI Method 2 [Incorporated: 1999]**

**Voluntary Standard**

ISO 7027 - Water Quality Determination of Turbidity

**Rationale**

EPA has no data upon which to evaluate whether the separate 90 degrees scattered or transmitted light measurement evaluations according to the ISO 7027 method would produce results that are equivalent to results produced by the other methods.

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**49) Government Standard: Standard Method 2130B [Incorporated: 1999]**

**Voluntary Standard**  
ISO 7027 - Water Quality  
Determination of Turbidity

**Rationale**  
EPA has no data upon which to evaluate whether the separate 90 degrees scattered or transmitted light measurement evaluations according to the ISO 7027 method would produce results that are equivalent to results produced by the other methods.

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**50) Government 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.

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

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.

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*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

67

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

45

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

23

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
Air Conditioning & Refrigeration Institute	ACRI
American Gas Association	AGA
American National Standards Institute	ANSI
American Petroleum Institute	API
American Society For Quality	ASQ
American Society for Testing and Materials	ASTM
American Society of Mechanical Engineers	ASME
American Water Works Association	AWWA
Codex	CODEX
Data Standards Maintenance Organization	DSMO
Electronic Industries Alliance	EIA
International Organization for Standardization	ISO
International Union of Pure and Applied Chemistry	IUPAC
National Conference of Standards Laboratories	NCSL
National Fire Protection Association	NFPA
NSF International	NSFI
Organization for Economic Cooperation and Development	OECD
Society of Automotive Engineers	SAE
Standards Engineering Society	SES
Underwriters Laboratories	UL
United Nations Economic Commission for Europe WP .29/GRSP	UNECE
United States Pharmacopoeia	USP
Water Environment Federation	WEF

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

EPA reports each UNIQUE use of a standard which is different than any of the other categories

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

D

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

B

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

No

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

The Circular assumes that a summary of absolute numbers of standards (used or substituted) tell a uniform story throughout the government. That assumption is false. Until the circular is revised to enable accurate and meaningful reporting, there is little or no way to assess the genuine effectiveness of A-119 across agencies, or as it might tell a picture within any given agency.

Those individuals involved in standards in federal agencies uniformly appreciate the existence of the Circular for drawing attention to the importance that standards play in federal acquisition and regulatory programs and activities. The extent to which standards are incorporated into federal procurements and regulations is due largely to the ability of standards professionals in agencies to leverage the existence of the law and circular in order to promote use of, and participation in the development of voluntary standards. The expertise, and even the process, involved in the development of a VCS is extremely valuable to both the government agencies and to the community effected by the standards.

All of that is certainly good, and in keeping with the spirit of the NTTAA. The specifics of the annual report, however, have degenerated over the years to focus on numbers that unfortunately do not translate uniformly across federal agency missions. Graphs to show "use" of standards or "rejection of standards" are based on numbers that have been so distilled from reality that the summary picture is unhelpful at best and misleading in general.

The best solution at this point may be to eliminate the annual reports altogether with the exception of the number required by the law: namely, the number of times that an Agency uses a GUS instead of a potentially applicable VCS. The most critical change would be to completely eliminate the tables or combined number charts based on federal reporting. A combined table or chart inevitably leads to comparisons across agencies and it is precisely that comparison which is faulty.

For example, one of the intents of the NTTAA was to reduce government time and costs in developing government unique standards. The assumption is that anytime a GUS is used, it's more costly to the government and/or the stakeholders. So a table that shows EPA "rejecting" VCSs can lead to a conclusion that the Agency has expended resources in developing a GUS. Such a conclusion is false, and it would be appropriate for EPA stakeholders to understand this fact.

In all the rules this year where EPA chose to use an existing EPA method instead of a voluntary standard, EPA did not create a new GUS. In other words, there was no expenditure of government time and money to develop a GUS. Quite the contrary. EPA Methods in the CFR are the test methods that the Agency uses, and these have been developed over the years with input from the regulated community. When there is a potentially applicable VCS, the Agency rule writers spend resources to evaluate the applicability of the standard. This year, EPA can report that in 67 separate analyses the Agency determined that an existing VCS was applicable, and as least as useful as the existing EPA method. Whether a VCS is used or not, there is ADDITIONAL cost of resources expended to do the analysis whereas adoption of the EPA method would incur less time/resources because it is already a method accepted by enforcement and the regulated community.

That is not saying that there is no value to VCSs...there is tremendous value and the Agency adopts them into regulations according to the criteria in the OMB Circular. The point is: the annual report may well give an inaccurate impression.

Looking at annual report tables it might appear that EPA runs against the cost-effective thrust in of the NTTAA because the Agency has evaluated and found unsuitable a number of VCS and so continues to use existing EPA methods. The cost-related conclusion would be wrong on two counts: one, wrong to assume that the Agency spent money developing GUSs and wrong that adoption of VCSs would be less costly for the Agency than the GUS.

Cost effective for the Agency and cost effective for the purpose of the regulation are

separate categories. In 2004, the Agency evaluated several hundred VCSs for incorporation into regulations. Most of the VCSs had already been adopted by the Agency in previous rules and so are not reported here as "new uses". Some, though, upon evaluation were determined to be not useful for the purposes of the rule and so were rejected for use. The Agency published proposed rules and cited the VCSs as not applicable. By the time the final rules were published not a single comment was received regarding the use of a GUS vs a VCS. In fact, not a single comment was received relative to standards at all. In other words, the regulated community commented on the substance of the regulation in question but said nothing about the standards. It is hard to conclude, therefore, that the use of GUSs in these instances is a cost problem for the user.

Comparing numbers across Agencies is likewise faulty. Even among regulatory agencies, legal mandates, mission and number of rules per year vary considerably. At least one other regulatory agency issues on the order of two to three major rules per year. EPA issues 600-900 depending on the agenda. For other agencies the potential to use VCSs in any rule may be high or low. If only two rules are done per year and half of them are subject to NTTAA, then numbers for rejection of VCS is going to be a relatively high percentage of the regulatory activities for the year. At EPA, the use or rejection of VCS is going to be a lower percentage because of the increased number of rules. These differences are important but completely hidden if viewing only a table of absolute numbers. If the annual report says that Agency "X" rejected 0 or 1 VCS and Agency "Y" rejected 30, it appears that Agency "Y" is grossly more reluctant to use VCSs than the one rejecting only 1. There is no way to logically conclude that, but the table does not lead one to understand this. In other words, the picture does not tell the real story.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

*9. Please provide any examples or case studies of standards successes:*

*10. Please provide any other comments you would like to share on behalf of your agency:*

Question #1 is misleading. The Agency is not using 50 GUS in lieu of VCSs. There were 50 VCSs last year that did not meet the technical needs of the Agency in the specific rules for which they might have been applicable. We did not develop 50 new GUSs. Although the question does not say that directly, it is worded in a manner that could lead readers to misunderstand.

Secondly, then, to be accurate, the report would have to say that the Agency has a whole slew of EPA test methods that are in the CFR and which are used in hundreds if not thousands of regulations -- sometimes VCSs are adopted for use along with these methods and sometimes the potential VCSs can't, in the final analysis, be used. The final analysis is completely dependent on the regulation not on the existence of the EPA method or the VCS: in other words, a VCS might be an acceptable alternative to an EPA method in one regulation and in another regulation the SAME VCS and GUS would NOT

be mutual alternatives. It's the intent of the rule that determines the outcome not the internal merits of the method or VCS on its own.

It is precisely this relationship that does not get translated by summary tables and which is at the very heart of how EPA implements the NTTAA...and the implementation conforms to the language fo the Circular itself.

Federal Communications Commission

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

0

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

5

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

7

<u>Voluntary Consensus Standards Body</u>	<u>Acronym</u>
American National Standards Institute	ANSI
Cellular Telecommunications and Internet Association	CTIA
Institute of Electrical and Electronic Engineers	IEEE
International Commission on Non-Ionizing Radiation Protection	ICNIRP
National Council of Radiation Protection and Measurements	NCRPM
National Institute of Standards and Technology	NIST
Telecommunications Industry Association	TIA

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

B

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

C

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

The policies of OMB Circular A-119 are clearly stated for application to the activities of the FCC, and the Commission recognizes the benefit of using voluntary consensus standards when applicable.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

None

*9. Please provide any examples or case studies of standards successes:*

*10. Please provide any other comments you would like to share on behalf of your agency:*

This web-based procedure for reporting works intermittingly.

## Federal Trade Commission

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

0

*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

0

*4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?*

0

*5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?*

0

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

Nothing to add

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

C

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

No

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

See response to question 10.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

See response to question 10.

*9. Please provide any examples or case studies of standards successes:*

See response to question 10.

*10. Please provide any other comments you would like to share on behalf of your agency:*

The Federal Trade Commission is an independent agency of the United States Government charged with enforcing competition and consumer protection laws. The Commission's only 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 or practices affecting commerce. The Commission does not promulgate its own standards or engage in other standards activities pertinent to OMB Circular A-119.

General Services Administration

*1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?*

8

**1) Government Standard: Federal Specification A-A-1922 - Shield, Expansion (Caulking Anchors, Single Lead) [Incorporated: 2004]**

**Voluntary Standard**

ASTM E488 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements

**Rationale**

This government-unique standard is prepared & maintained by the Defense Logistics Agency (DLA). Both the GSA & DLA contract for products that reference A-A-1922. In order to maintain product continuity in the Federal marketplace, we must cite the standard as the DLA.

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**2) Government Standard: Federal Specification A-A-1923 - Shield Expansion (Lag, Machine and Externally Threaded Wedge Bolt Anchors) [Incorporated: 2004]**

**Voluntary Standard**

ASTM E488 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements

**Rationale**

This government-unique standard is prepared & maintained by the Defense Logistics Agency (DLA). Both the GSA & DLA contract for products that reference A-A-1923. In order to maintain product continuity in the Federal marketplace, we must cite the standard as the DLA.

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**3) Government Standard: Federal Specification A-A-1924 - Shield, Expansion (Self Drilling Tubular Expansion Shell Bolt Anchors) [Incorporated: 2004]**

**Voluntary Standard**

ASTM E488 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements

**Rationale**

This government-unique standard is prepared & maintained by the Defense Logistics Agency (DLA). Both the GSA & DLA contract for products that reference A-A-1924. In order to maintain product continuity in the Federal marketplace, we must cite the standard as the DLA.

---

**4) Government Standard: Federal Specification A-A-1925 - Shield,**

**Expansion (Nail Anchors) [Incorporated: 2000]**

**Voluntary Standard**

ASTM E488 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements

**Rationale**

This government-unique standard is prepared & maintained by the Defense Logistics Agency (DLA). Both the GSA & DLA contract for products that reference A-A-1925. In order to maintain product continuity in the Federal marketplace, we must cite the standard as the DLA.

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**5) Government Standard: Federal Specification A-A-59486 - Padlock Set (Individually Keyed or Keyed Alike) [Incorporated: 2004]**

**Voluntary Standard**

ASTM F883 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements

**Rationale**

Commercial Item Descriptions A-A-59486 contain military specific requirements that are not present in ASTM F883. Military agencies are a primary customer of our agency and they are mandated to use padlocks procured via conformance to the GUS.

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**6) Government Standard: Federal Specification A-A-59487 - Padlock (Key Operated) [Incorporated: 2004]**

**Voluntary Standard**

ASTM F883 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements

**Rationale**

Commercial Item Descriptions A-A-59487 contain military specific requirements that are not present in ASTM F883. Military agencies are a primary customer of our agency and they are mandated to use padlocks procured via conformance to the GUS.

---

**7) Government 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 burdensome 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 burdensome 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.

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**8) Government 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.

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*2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?*

0

*3. Please provide the number of voluntary consensus standards used during FY 2004?*

305

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

91

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

26

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
Aerospace Industries Association of America	AIA
Ambulance Manufacturers Division, National Truck Association	AMD/NTEA
American Gas Association	AGA
American National Standards Institute	ANSI
American Society For Quality	ASQ
American Society for Testing and Materials	ASTM
American Society of Heating, Refrigerating, and Air-Conditioning Engineers	ASHRAE
American Society of Mechanical Engineers	ASME
American Water Works Association	AWWA
Automotive Lift Institute - ALOIM	ALI
Builders Hardware Manufacturers Association	BHMA
Business and Institutional Furniture Manufactures Association	BIFMA
Gas Appliance Manufacturers Association	GAMA
Green Seal Standards for Adhesives	GSSA
ISO Technical Advisory Group SC 29/TC 10 Hand Tools Committee	ISO TAG
Maintenance Council of American Trucking Associations	TMC/ATA
National Aerospace and Defense Contractors Accreditation Program	NADCAP
National Fire Protection Association	NFPA
National Institute of Building Sciences	NIBS
National Sanitation Foundation	NSF
Performance Review Institute	PRI
Society of Automotive Engineers	SAE
Steel Door Institute	SDI
Technical Association of the Pulp and Paper Industry	TAPPI
The Society for Protective Coatings	SSPC
Underwriters Laboratories	UL

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

C

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

No Comments

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

6FL: 13

ISO SC 10 TC 29

The US Technical Advisory Group (TAG) is responsible for determining the U.S position on IEC/ISO standards pertaining to technical committee or subcommittees in addition to the review of policy matters. The standards include hand tools and accessories for safety requirements relating to the elements of design, use, and selection of; performance, tolerances, and outline configurations of; including but not limited to, wrenches, pliers, screwdrivers, shears, punches, chisels, hammers, and toolboxes. The standards will

include the development of requirements, the consideration of various types and classes of hand tools and accessories required for specified classes of service, and the tests needed to determine conformance with the service classification requirements.

ASME, American Society of Mechanical Engineers, B107 Main Committee

GSA Heartland Global Supply is a member of the ASME B107 main committee relating to hand tools and actively participates in the development of non-government procurement and safety standards. This committee is actively involved in maintaining and improving standards to assure customer requirements are maintained.

Tool Fastener Working Group:

To discuss the standardization and end use relationship between Fasteners and Hand Tools. By active participation from: GSA, FSS Heartland Global Supply, Defense Industrial Center, Philadelphia, NG Standards Activities (AIA, SAE, and ASME), Fasteners and Tool Manufacturers, Designers, and end users. Fastener and Hand Tools are an integrated system where the goal of this group is to improve the performance of Fastener Systems by evaluating at the Tool-Fastener Interface, in addition to creating a review committee to evaluate and improve non-government standards.

Green Seal:

Green Seal is an independent, non-profit “third party certification” organization devoted to the creation of scientific evaluation criteria for environmentally preferred products. This criterion is then used to provide credible objective, and unbiased product review. 6FLE continues to provide suppliers with the option of certifying their products with Green Seal. Also, a list of relevant Green Seal standards and Green Seal recommended products is maintained the GSA Heartland Global Supply web page under “Environmental Issues”.

<http://www.greenseal.org/>

National Institute of Building Sciences (NIBS):

Master Painters Institute:

Scientific Certification Systems (SCS):

6FLE continues to provide suppliers with the option of certifying their products under the SCS Specification for Architectural and Anti-Corrosive Paint. This was a joint effort by the National Institute of Building Sciences (NIBS), Master Painters Institute (MPI), ICI paint, Department of Defense, General Services Administration, Chemical Manufacturers’ Association, and Scientific Certification Systems. This criteria is based on International Organization for Standardization (ISO) Standard 14042, as prepared by Technical Committee ISO/TC 207, Environmental Management, Subcommittee SC 5, Life Cycle Assessment and has been adopted as a standard by Master Painters Institute (MPI). Also, a copy of this standard and a list of SCS Certified products are maintained

on the GSA Heartland Global Supply web page under “Environmental Issues”.  
<http://www.scs1.com>  
<http://www.hvacmall.com/listing/nibs.htm>

Clean Air Act National Emission Standards for Hazardous Air Pollutants (CAA NESHAP) Compliance – for Shipbuilding and Aerospace coatings:

The Clean Air Act (40th Code of Federal Regulations, Subpart 63.741-63.753 and 63.780) designate “Shipbuilding and Ship Repair Facilities” and “Aerospace Manufacturing and Rework Facilities” as a regulated emissions source categories. Clean Air Act rules limit the volatile organic hazardous air pollutant (VOHAP) content of several types of solvents, coatings, strippers and maskants used within these industrial categories. Compliance is based on proper documentation that volatile organic compound (VOC) or VOHAP emissions were within allowable limits. For select items regulated by the NESHAP, the GSA Heartland Global Supply continued to collect brief technical data certificates which provide much of the data that U.S. EPA requires the coating end user to maintain at their location. These certificates were then faxed to the Department of Defense liaison office. Also, GSA provided input to how to structure a new web site that is to offer these documents electronically in the future.

<http://r6.gsa.gov/fss/hac/envirnmt.htm>  
[Select “Shipbuilding” or “Aerospace” NESHAP Data Sheets]

Hazardous Material Information Resource System (HMIS) Functional Working Group:

The HMIS Functional Working Group (FWG) is chartered under the sponsorship of the HMIS Policy Working Group (PWG). Its role is to represent the users of hazardous materials information and management systems, which deal with Material Safety Data Sheets (MSDS) or related/associated technical information, and strive to ensure that the functional needs of those users are met. Also, the FWG prepares recommendations to the PWG on issues pertaining to the functional aspects of improvements to existing or future DOD hazardous materials information and management systems. The core FWG membership consists of voting representatives from the Army, Air Force, Navy, DLA, and GSA.

<http://www.dlis.dla.mil/hmirs/>

Joint Group on Environmental Attribute (JGEnvAtt) meeting – GSA/ Department of Defense/ Other Federal Agency, HQ DLA, Fort Belvoir, VA:

Summarized to attendees were the latest Heartland Global Supply’s efforts in delineating those FSC 8010 products that meet the definition of “Low-VOC.” GSA interfaced with key DOD and EPA personnel in learning of the latest efforts to delineate products with environmental attributes. Gathered and brought back references on the latest, four

approved environmental attributes, of which “Low-Volatile Organic Compound” (Low-VOC) is one.

<http://www.dlis.dla.mil/epp/aboutjgenvatt/group.asp>

National Defense Industrial Association/ Department of Defense:

? Attended the 9th Annual Joint Service Pollution Prevention Symposium and Exhibition – Department of Defense, August 16-19, 2004. Networked with well over 100 customers, and visited well over 200 private companies and government agency exhibits. Attended 25 hours of technical sessions.

? <http://www.jsemconference.com/2004/>

National Aerospace Defense Contractors Accreditation Program (NADCAP)

NADCAP represents major prime contractors, suppliers, and government agencies in aerospace, defense, and related industries throughout the United States and internationally. NADCAP is administered by the Performance review Institute (PRI), and independent for profit trade association affiliated with the Society of Automotive Engineers (SAE). Through NADCAP, PRI accredits subcontractors and suppliers to aerospace and industry consensus standards. Through NADCAP, PRI assures and enhances quality, saves valuable time and efforts, and cuts direct and overhead costs by performing the following functions:

- Compiling audit criteria
- Securing acceptance of these lists as internationally recognized ASE Aerospace Standards
- Auditing suppliers’ technical capabilities and conformance to applicable procedures and/or government agencies
- Focusing the responsibility for quality maintenance on the supplier and subcontractors
- Publishing a qualified manufacturer’s List and making it available to primes
- Promoting the benefits of using accredited suppliers

GSA Heartland Global Supply is a prime member of the Sealants and Coating Groups and is also a member of Qualified Product Management Council (QPMC).

Society of Automotive Engineers (SAE)

GSA Heartland Global Supply is a member of the SAE, G8 - Aerospace Coatings Committee and G9 Aerospace Sealants Committee and actively participates in the development of Aerospace Material Standards. These committees are actively involved in the conversions of Military Specifications and the development of Aerospace Material Standards.

Chairman of the G8 Laboratory Accreditation Sub-Committee, for development of a

laboratory accreditation protocol consistent with ISO and IEC accreditation standards. This standard, AS5505, May 2001, provides interpretation of ISO/IEC 17025 and establishes additional requirements for accreditation of testing laboratories for evaluating organic coatings. This step was necessary for the development of the Qualified Manufacturers List (QML) program for G8 Aerospace Coatings.

Chairman of the EG-1B Aerospace Hand tools subcommittee. This committee is actively involved in the development of aerospace standards for hand, power and pneumatic tools for while partnering with the Department of Defense, Defense Logistic agency Government fastener work group incorporating real world applications for the new generation of hand tools.

USDA, Forestry Service

GSA/FSS Heartland Global Supply representative to the USDA, Forestry Service, and Tree Marking Paint Standard Development Committee provides expert consultation for environmental, health and technical issues leading to development of the FS 2400-400 specification.

Building Products Pre-Approval Program (BPPAP)

GSA/FSS Heartland Global Supply participates through representation to the Building Products Pre-Approval Program (BPPAP) Committee of the National Institute for Building Sciences, Washington, DC. This committee coordinates the development of non-governmental architectural and industrial paint and coatings Standards with the Master Painters Institute. Through this committee, more than 26 Federal Specifications and Commercial Item Descriptions have been replaced with Master Painters Institute Standards.

The BPPAP committee, through Scientific Certifications Systems, a third party, internationally recognized certification organization, is pursuing development of Environmentally Preferred Purchasing, EPP, and certification for products, mandated by Executive Order 13101. The BPPAP reviews and approves the protocol for EPP certification that SCS performs.

USDA Forest Service

Joint meeting (May 2004) with representatives from the USDA Forest Service Missoula and San Dimas Technology & Development Centers. Discussed new requirements for wildland fire suppression equipment and abolishing the practice of allowing third-party certification to NFPA standards for protective clothing and equipment. Discussed procedures for first article testing and acceptance for water-handling fire suppression equipment.

National Fire Protection Association (NFPA) Technical Committee on Wildland Fire Fighting Protective Clothing and Equipment

Committee meeting in Phoenix, Arizona (March 2004) to continue work on revision of NFPA Standard 1977. Meeting to finalize revision and review comments on proposed 2005 edition of NFPA Standard 1977, Wildland Firefighting Protective Equipment and Clothing.

*9. Please provide any examples or case studies of standards successes:*

Development of AS 4986 alternative coatings in lieu of hex chromium

Whenever a voluntary standard is technically adequate, industry is willing and able to comply with the requirements, and the standard is appropriate such as numerous SAE, AMD, ATA and NFPA standards, we will always cite these in our technical documents since it simplifies our engineering processes and results in successfully using voluntary standards. Conversely, if the voluntary standard does not adequately cover the respective area, results in unjustified additional costs without tangible benefits to the Government, can result in litigation, or simply is not “practical” and is not in the Government's interest, we must avoid citing the standard.

*10. Please provide any other comments you would like to share on behalf of your agency:*

Government Printing Office

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

4

**1) Government Standard: FED-STD 209 [Incorporated: 2000]**

**Voluntary Standard**

ISO 14644-1 & ISO 14644-2

**Rationale**

Quality Assurance. Second ISO standard not issued until end of FY 2000. Being phased out.

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**2) Government Standard: MIL-STD 105 [Incorporated: 2000]**

**Voluntary Standard**

ANSI/ASQC Z1.4

**Rationale**

Quality Assurance. Cited in small number of contracts due to editing errors. These are being corrected and phased out.

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**3) Government Standard: MIL-STD 1189 [Incorporated: 2000]**

**Voluntary Standard**

ANSI/AIM X5-2 & ANSI X3.182

**Rationale**

Quality Assurance. Cited in small number of contracts due to editing errors. These are being corrected and phased out.

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**4) Government Standard: MIL-STD 498 [Incorporated: 2000]**

**Voluntary Standard**

IEEE/EIA 12207.0, IEEE/EIA 12207.1, & IEEE/EIA 12207.2

**Rationale**

Quality Assurance. Cited in small number of contracts due to editing errors. These are being corrected and phased out.

---

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

2

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

6

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
American Society for Testing and Materials	ASTM
International Civil Aviation Organization	ICAO
International Organization for Standardization	ISO
Job Definition Format	CIP4
National Committee for Information Technology Standards	NCITS
TAPPI	TAPPI

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

C

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

The Circular provides effective procedures for the transition to use of voluntary consensus standards in Government business. We have no recommendations for changes.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

Some individuals attended a seminar; otherwise there were no assessment activities at our agency.

*9. Please provide any examples or case studies of standards successes:*

Not applicable

*10. Please provide any other comments you would like to share on behalf of your agency:*

This format is easy to use. More definitions would be useful

## National Aeronautics and Space Administration

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

This agency reports voluntary consensus standards usage on a category basis

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

39

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

147

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

30

### **Voluntary Consensus Standards Body**

### **Acronym**

Aerospace Industries Association of America	AIA
American Bearing Manufacturers Association	ABMA
American Institute of Aeronautics and Astronautics	AIAA
American National Standards Institute	ANSI
American Society for Nondestructive Testing	ASNT
American Society For Quality	ASQ
American Society for Testing and Materials	ASTM
American Society of Agricultural Engineers	ASAE
American Society of Mechanical Engineers	ASME
American Society of Metals	ASM
American Welding Society	AWS
Computational Fluid Dynamics (CFD) General Notation System	CGNS
Consultative Committee for Space Data Systems	CCSDS
Electronic Industries Alliance	EIA
Government Electronic Industries Alliance	GEIA
Institute for Interconnecting and Packaging Electronic Circuits	IPEC
Institute of Electrical and Electronic Engineers	IEEE

Institute of Environmental Sciences & Technology	IEST
Interconnection Technology Research Institute	ITRI
International Electrotechnical Commission	IEC
International Organization for Standardization	ISO
International Organization for Standardization/International Electrotechnical Commission	ISO/IEC
National Association of Corrosion Engineers International	NACE
National Conference of Standards Laboratories	NCSL
National Fire Protection Association	NFPA
Radio Technical Commission for Aeronautics	RTCA
Society of Automotive Engineers	SAE
Space Frequency Coordination Group	SFCG
The Internet Society	ISOC
Welding Research Council	WRC

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

A

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

B

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

A

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

NASA's efforts to enhance the use of Voluntary Consensus Standards continues to be stimulated by the guidance and directives provided in OMB Circular A-119. This has enhanced the awareness of Voluntary Consensus Standards within the Agency and participation in Voluntary Consensus Standards Developing Bodies as reflected in items 4 and 5.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

NASA is continuously evaluating and improving its conformity assessment practices and procedures. The Agency has a practice of working with other Government Agencies and the public sector to integrate best practices into its activities. Other Government Agencies assist with Contract Administration Services (CAS), including substantial conformity assessment activities. The Defense Contract and Audit Agency, Defense Contract Management Agency, Office of Naval Research, and other activities continue to provide conformity assessment services for NASA programs. These relationships utilize the expertise and infrastructure within these agencies. They enable NASA to limit internal assessments to areas where external capabilities are not available. Processes established for these activities provide a mechanism to continually exchange ideas and best practices related to conformity assessment. NASA continues to pursue Star Status in the Occupational Safety and Health Administration's (OSHA) Voluntary Protection Program (VPP). The VPP participation provides a mechanism for both improving internal safety practices and for utilizing the services of the OSHA programs to perform oversight inspections. NASA Centers not yet certified are in various stages of preparation for assessment.

*9. Please provide any examples or case studies of standards successes:*

NASA's Agencywide Full-Text Technical Standards System provides one-stop, easy access to technical standards required for use by the Agency's programs and projects. For the top 20 non-NASA standards used by the Agency, in FY03, 34,400 Voluntary Consensus Standards (VCSs) were downloaded by NASA and its onsite support contractor personnel. In FY04, 43,448 VCSs were downloaded. Based on these metrics, downloading of VCSs increased at least 20% from the previous year.

NASA's Standards Update Notification System (SUNS) provides standards users with daily update notification of changes to registered technical standards being utilized by their programs and projects. Update notifications requested in FY04 increased by 36% over FY03 bring the total number of requests to 4493 since the system was implemented in April 2001.

The linking of lessons learned to relevant technical standards continues to enhance and improve engineering practices across the Agency. Since implementation in April 2002, over 8000 accesses have been made by NASA engineering staff to engineering lessons

learned through “hot links” to standards on the NASA Technical Standards Program Website. The results of this effort have afforded NASA programs and projects with greater utility and application, not only of the standards themselves, but of potentially key lessons learned from past programs and are now being passed on and utilized in a new generation of flight and ground hardware and software. In addition, over 300 Application Notes have been identified based on document individual experiences and linked to specific technical standards.

*10. Please provide any other comments you would like to share on behalf of your agency:*

A. During FY2004 a survey was made within the Agency regarding how standards downloaded from the NASA Full-Text Technical Standards System are being used. Of the approximately 6,000 respondents to the questionnaire, the following results were obtained regarding usage:

- a. Development of Program/Project Development Requirements---23.4%
- b. In-house Research and Development Activities--29.8%
- c. Verification of Contractors Design and Development Processes--17.4%
- d. Acquisition of Parts or Materials--8.7%
- e. Evaluation of Proposals--3.2%
- f. Education and Training--11.8%
- g. Other Uses--5.7%

B. System statistics show that downloads of Voluntary Consensus Standards increased by approximately 20% from FY2003 to FY2004.

C. Technical Standards will become the core of NASA’s new Independent Technical Authority (ITA) system being implemented in response to a recommendation from the (Space Shuttle) Columbia Accident Investigation Board report. The ITA will be implemented through a system of “Warrant Holders” who will have NASA-wide responsibility for approving use and exceptions to technical requirements (e.g. standards) for NASA programs in defined discipline and system areas. The resulting coordination of standards decisions across NASA is expected to increase.

National Archives and Records Administration

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

1

**1) Government Standard: NARA data standard [Incorporated: 2000]**

**Voluntary Standard**

Archives, Personal Papers, and Manuscripts (APPM);  
General International Standard Archival Description (ISAD(G));  
International Standard Archival Authority Record for Corporate Bodies, Persons, and Families (ISAAR(CPF));  
Encoded Archival Description (EAD);  
Machine Readable Cataloging (MARC)

**Rationale**

These voluntary standards do not meet the precise needs of the agency.

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2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

2

**Voluntary Standard**

IEEE Std 1540-2001, IEEE Standard for Software Life Cycle Processes - Risk Management  
ISO/IEC 15288:2002(E), Systems Engineering - System life cycle processes

**Government Standard**

NARA 805 Systems Development Lifecycle (SDLC)  
NARA 805 Systems Development Lifecycle (SDLC)

3. Please provide the number of voluntary consensus standards used during FY 2004?

52

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

19

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

<b><u>Voluntary Consensus Standards Body</u></b>	<b><u>Acronym</u></b>
American National Standards Institute	ANSI
Association for Information and Image Management	AIIM
Consultative Committee for Space Data Systems (CCSDS)	CCSDS
Institute of Electrical and Electronic Engineers	IEEE
International Council on Archives (ICA)	ICA
International Organization for Standardization	ISO
National Fire Protection Association	NFPA
National Information Standards Organization	NISO
Research Libraries Group (RLG)	RLG
Society of American Archivists (SAA)	SAA

*6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:*

NARA uses the transaction basis for counting standards. We adhere to this definition of use:

"Use" means incorporation of a standard in whole, in part, or by reference for procurement purposes, and the inclusion of a standard in whole, in part, or by reference in regulation(s).

Therefore, although we cite in this report all uses of voluntary consensus standards substituted for government standards in the FY 2004 reporting period (in our response to question 2), the total number of standards reported in the response to question 3 are only those falling within the "use" definition above.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

C

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

B

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

A

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

We believe the Circular is working effectively and have no recommendations for changes.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

None

*9. Please provide any examples or case studies of standards successes:*

None for 2004.

*10. Please provide any other comments you would like to share on behalf of your agency:*

Government standard: NARA data standards

Voluntary standards:

1. MARC Machine Readable Cataloging
2. EAD Encoded Archival Description
3. APPM Archives, Personal Papers, and Manuscripts
4. ISAD(G) General International Standard Archival Description
5. ISAAR (CPF) International Standard Archival Authority Record for Corporate Bodies, Persons and Families

Explanation:

NARA examined the above standards in depth, and incorporated as many of the standards as possible in our new standards for archival description. However, we did not incorporate the standards fully for several reasons:

1. some of these standards are library standards, not archival standards, and thus were not wholly suitable;
2. some of these standards dictate a physical design solution that NARA does not find technically sound;

3. some of these standards focus on personal papers collections, not government records.

It should also be understood that the archival description standard is a standard that NARA is using for description of its own holdings, not a standard imposed on the external world.

National Science Foundation

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

0

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

5

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

5

**Voluntary Consensus Standards Body**

American Society for Testing and Materials  
IEEE - Bioinformatics Standards Committee  
International Telecommunication Union  
National Spectrum Managers Association  
Trusted Computing Group, Inc.

**Acronym**

ASTM  
BSC/IEEE  
ITU  
NSMA  
TCG

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

B

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

B

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

B

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

D

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

Just fine.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

None.

*9. Please provide any examples or case studies of standards successes:*

None.

*10. Please provide any other comments you would like to share on behalf of your agency:*

None.

## Nuclear Regulatory Commission

1. Please list the government unique standards used in lieu of voluntary standards during FY 2004?

0

2. Please list the voluntary consensus standards substituted for government unique standards during FY 2004?

0

3. Please provide the number of voluntary consensus standards used during FY 2004?

77

4. Please provide the number of agency employees participating in voluntary consensus standards activities during FY 2004?

145

5. Please enter the voluntary consensus standards bodies in which your agency participated in during FY 2004?

13

### **Voluntary Consensus Standards Body**

### **Acronym**

American Concrete Institute	ACI
American Institute of Steel Construction	AISC
American National Standards Institute	ANSI
American Nuclear Society	ANS
American Society for Testing and Materials	ASTM
American Society of Civil Engineers	ASCE
American Society of Mechanical Engineers	ASME
Health Physics Society	HPS
Institute of Electrical and Electronic Engineers	IEEE
Institute of Nuclear Materials Management	INMM
Instrumentation Societ of America	ISA
National Council of Radiation Protection and Measurements	NCRPM
National Fire Protection Association	NFPA

6. Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards:

NRC responses to items 6.1-6.5 are complete and "Not Applicable" has not been selected for any of the responses.

6-1. Does your agency report: (a) Only the first time use of standards; (b) Continued use of standards; (c) Both first-time and continued use of standards; or (d) Not applicable?

A

6-2. Does your agency report: (a) The total number of standards it uses; (b) Each instance where the agency uses (i.e. references) a standard; (c) Both the total number and each instance; or (d) Not applicable?

A

6-3. Does your agency report multiple editions of a single standard as one standard use or as multiple standards used: (a) Single; (b) Multiple; (c) Both; or (d) Not applicable?

A

6-4. Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes): (a) Yes; (b) No; (c) Not applicable?

Yes

6-5. Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both: (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?

D

*7. Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

The NRC believes that the Circular provides appropriate direction and encouragement for federal agencies to develop internal agency-wide guidelines. The circular also provides sufficient and reasonable flexibility for each agency to make an independent determination relative to participation on voluntary consensus bodies and use of developed standards.

*8. Please provide any conformity assessment activities in which your agency was involved in FY 2004 as described in the Federal Register Vol. 65, No. 155, Thursday August 10, 2000 - Guidance on Federal Conformity Assessment Activities:*

No Comment

*9. Please provide any examples or case studies of standards successes:*

No Comment

*10. Please provide any other comments you would like to share on behalf of your agency:*

No Comment

## Appendix F – Federal Agency Activities Related to Use of Private Sector Standards and Conformity Assessment

NOTE: The following table lists the various standards organizations in which Federal agencies or their employees participated. The organizations, their names, and their acronyms are listed as they were reported to NIST by the agencies contributing to this year’s report. There are 476 individual organizations identified by the agencies, some of which may be duplicated due to differences in the names of the organizations caused by reporting errors or by name changes made by the organizations themselves.

<b>FY 2004 Voluntary Consensus Standards Bodies in which Federal Agencies Participated</b>	
<b>Voluntary Consensus Standards Body</b>	<b>Acronym</b>
AACE International	AACE
Accredited Standards Committee X12	ASC X12
Accredited Standards Committee X9	ASCX9
ACI International	ACI
Acoustical Society of America	ASA
Aerospace Industries Association	AIA
Air Conditioning & Refrigeration Institute	ARI
Air Movement and Control Association	AMCA
Air Transport Association	ATA
Alliance for Telecommunications Industry Solutions	ATIS
Almond Board of California	ABC
Aluminum Association	AA
Ambulance Manufacturers Division, National Truck Association	AMD/NTEA
American Society for Photobiology	ASP
American Academy of Pediatrics	AAP
American Architectural Manufacturers Association	AAMA
American Association for Laboratory Accreditation	A2LA
American Association of Blood Banks	AABB
American Association of Cereal Chemists	AACC
American Association of Food Hygiene Veterinarians	AAFHV
American Association of Motor Vehicle Administrators	AAMVA
American Association of Physicists in Medicine	AAPM
American Association of State Highway and Transportation Officials	AASHTO
American Association of Textile Chemists and Colorists	AATCC
American Association of Tissue Banks	AATB
American Bearing Manufacturers Association	ABMA
American Boat and Yacht Council	ABYC
American College of Nuclear Physicists	ACNP
American College of Radiology	ACR

American College of Surgeons	ACOS
American Committee on Immunization Practices	ACIP
American Concrete Institute	ACI
American Conference of Governmental Industrial Hygienists	ACGIH
American Congress on Surveying and Mapping	ACSM
American Dental Association	ADA
American Foundation for the Accreditation of Haematopoietic Cell Therapy	FAHCT
American Gas Association	AGA
American Gear Manufacturers Association	AGMA
American Glovebox Society	AGS
American Hardboard Association	AHA
American Industrial Hygiene Association	AIHA
American Institute of Aeronautics and Astronautics	AIAA
American Institute of Chemical Engineers	AIChE
American Institute of Steel Construction	AISC
American Institute of Timber Construction	AITC
American Institute of Ultrasound Manufacturers	AIUM
American Leather Chemists Association	ALCA
American National Metric Council	ANMC
American National Standards Institute	ANSI
American Nuclear Society	ANS
American Oil Chemists Society	AOCS
American Petroleum Institute	API
American Public Health Association	APHS
American Public Transportation Association	APTA
American Railway Engineering & Maintenance-of-Way Association	AREMA
American Red Cross	ARC
American Society for Blood and Marrow Transplantation	ASBMTT
American Society for Gene Therapy	ASGT
American Society for Nondestructive Testing	ASNT
American Society For Quality	ASQ
American Society for Reproductive Medicine	ASRM
American Society for Testing and Materials	ASTM
American Society of Agricultural Engineers	ASAE
American Society of Cinematographers	ASC
American Society of Civil Engineers	ASCE
American Society of Clinical Oncology	ASCO
American Society of Heating, Refrigerating, and Air-Conditioning Engineers	ASHRAE
American Society of Hospital Engineers	ASHE
American Society of Mechanical Engineers	ASME
American Society of Metals	ASM

American Society of Photogrammetry and Remote Sensing	ASPRS
American Society of Quality Control	ASQC
American Society of Safety Engineers	ASSE
American Society of Sanitary Engineering	ASSE
American Society of Mass Spectrometry	ASMS
American Trucking Associations	ATA
American Vacuum Society	AVS
American Veterinary Medical Association	AVMA
American Water Works Association	AWWA
American Welding Society	AWS
American Wind Energy Association	AWEA
American Wood Preservers Association	AWPA
AOAC	AOAC
APA - The Engineered Wood Association	APA
Architectural Woodwork Institute	AWI
ASME International	ASME
Association for Automatic Identification & Mobility	AIM Global
Association for Information and Image Management	AIIM
Association for the Advancement of Medical Instrumentation	AAMI
Association for the Assessment and Accreditation of Laboratory Animal Care	AAALAC
Association of American Railroads	AAR
Association of Biomolecular Research Facilities	ABRF
Association of Food and Drug Officials	AFDO
Association of Official Analytical Chemists International	AOACI
ASTM International	ASTM
Automotive Lift Institute - ALOIM	ALI
Baking Industry Sanitary Standards Committee	BISSC
Basic Linear Algebra Subprograms Technical Forum	BLAS
Biometrics Application Programming Interface Consortium	BioAPI
BOCA International	BOCA
British Pharmacopeia	BP
British Standards Institute	BSI
Builders Hardware Manufacturers Association	BHMA
Building Seismic Safety Committee	BSSC
Business and Institutional Furniture Manufactures Association	BIFMA
California Strawberry Commission	CSC
Canadian General Standards Board	CGSB
Canadian Standards Association	CSA
Cantaloupe Board of California	CBC
Cast Iron Soil Pipe Institute	CISPI
Cellular Telecommunications and Internet Association	CTIA

Central Laboratory for Blood Transfusion	CCLBT
Chocolate Manufacturers Association	CMA
Clinical Data Interchange Standards Consortium	CDISC
Coalition for Responsible Waste Incineration	CRWI
Codex	CODEX
Codex Ad Hoc Intergovernmental Taskforce on Fruit and Vegetable Juices	CCFVJ
Codex Alimentarius Commission	CODEX
Codex Committee on Milk & Milk Products	CCMMP
Codex Committee on Pesticide Residues	CCPR
Codex Committee on Processed Fruits and Vegetables	CCPFV
Collaborative Committee on the Validation of Alternative Methods	CCVAM
College of American Pathologists	CAP
Commercial Motor Vehicle Safety Alliance	CMVSA
Commercial Refrigerator Manufacturers Association	CRMA
Commercial Vehicle Safety Alliance	CVSA
Committee on Data for Science and Technology	CODATA
Common Criteria Management Committee	CCMC
Compressed Gas Association	CGA
Computational Fluid Dynamics (CFD) General Notation System	CGNS
Conference for Food Protection	CFP
Consortium for Advanced Manufacturing - International	CAMI
Construction Specifications Institute	CSI
Consultative Committee for Space Data Systems	CCSDS
Consumer Electronics Association	CEA
Cooling Tower Institute	CTI
Cordage Institute	CI
Corn Refiners Association	CRA
Cosmetic Ingredient Review	CIR
Cosmetic Toiletry and Fragrance Association	CTFA
Council for International Organizations of Medical Sciences	CIOMS
Council for Optical Radiation Measurements	CORM
Council on Ionizing Radiation Measurements and Standards	CIRMS
Data Interchange Standards Association, Inc.	DISAI
Data Standards Maintenance Organization	DSMO
Deep Foundations Institute	DFI
Designated Standards Maintenance Organizations	DSMO
Deutsches Institut fur Normung - German Institute for Standardization	DIN
Digital Imaging Communications in Medicine	DICOM
Electronic Commerce Code Management Association	ECCMA
Electronic Components Assemblies & Materials Association	ECAMA
Electronic Industries Alliance	EIA

Electrostatic Discharge Association	EDA
Engineering Sciences Data Unit (ESDU) International	ESDU
European Center for Validation of Alternative Methods	ECVAM
European Committee for Standardization	CEN
European Directorate for Quality of Medicines	EDQM
European Pharmacopeia	EP
External RNA Controls Consortium	ERCC
Eye Bank Association of America	EBAA
Federal Facilities Council	FFC
Federal Geographic Data Committee	FGDC
Federal Laboratory Consortium	FLC
Federal Public Key Infrastructure Technical Working group	PKIWG
Federal Public Key Steering Committee	FPKISC
FM Global	FM Global
Food and Agriculture Organization of the United Nations	FAO
Foundation for Accreditation of Cellular Therapies	FACS
Fresh Fruit and Vegetable Association	FFVA
Fresh Produce Association of the Americas	FPAA
Gas Appliance Manufacturers Association	GAMA
Gas Technology Institute	GTI
Gelatin Manufacturers of America	GMA
Global Harmonization Task Force	GHTF
Global Justice Information Sharing Initiative	GLOBAL
Government Electronic Industries Alliance	GEIA
Government Electronics & Information Technology Association	GEITA
Green Seal Standards for Adhesives	GSSA
Ground Water Protection Council	GWPC
Gypsum Association	GA
Hardwood Plywood & Veneer Association	HPVA
Health Physics Society	HPS
Health Protection Branch, Health Canada	HPB
High Frequency Industry Association	HFIA
High Level Seven	HLS
Honey Board	HB
Human Factors and Ergonomics Society, Inc.	HFESI
Human Factors Society	HFS
IBM Global Services Methodology	IBM/GSM
IDE Alliance	IDEA
IEEE - Bioinformatics Standards Committee	BSC/IEEE
Illuminating Engineering Society of North America	IESNA
INCITS	INCITS

Independent Cosmetic Manufacturers and Distributors	ICMAD
Industrial Safety and Equipment Association	ISEA
Industry-wide Cooperative Meat Identification Standards Committee	ICMISC
Information Technology Industry Council	ITI
Institute for Interconnecting and Packaging Electronic Circuits	IPEC
Institute for Reference Materials and Manufacturers	IRMM
Institute of Clean Air Companies	ICAC
Institute of Electrical and Electronic Engineers	IEEE
Institute of Environmental Sciences & Technology	IEST
Institute of Food Technologists	IFT
Institute of Industrial Engineers	IIE
Institute of Nuclear Materials Management	INMM
Institute of Transportation Engineers	ITE
Instrumentation Society of America	ISA
Instrumentation, Systems, and Automation Society	ISA
Insulated Cable Engineers Association	ICEA
Intelligent Transportation Society of America	ITS America
Interagency Committee on Seismic Safety in Construction	ICSS
Interagency coordinating Committee on the Validation of Alternative Methods	ICCVAM
Inter-American Accreditation Cooperation	IAAC
Inter-American Metrology System	SIM
Interconnection Technology Research Institute	ITRI
International Union for the Protection of New Varieties of Plants	IUPOV
International Association for Food Protection	IAFP
International Association for the Properties of Water and Steam	IAPWS
International Association of Cancer Registrars	IACR
International Association of Color Manufacturers	IACM
International Association of Environmental Mutagen Societies	IAEMS
International Association of Plumbing and Mechanical Officials	IAPMO
International Atomic Energy Agency	IAEA
International Blood Group Reference Laboratory	IBRGL
International Bottled Water Association	IBWA
International Building Code	IBC
International Bureau of Weights and Measures	BIPM
International Cartographic Association	ICA
International Center for Diffraction Data	ICDD
International Civil Aviation Organization	ICAO
International Code Council	ICC
International Commission on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Veterinary Use	VICH
International Commission on Illumination	CIE

International Commission on Non-Ionizing Radiation Protection	ICNIRP
International Commission on Occupational Health	ICOH
International Commission on Radiation Protection	ICRP
International Commission on Radiation Units and Measurements, Inc.	ICRU
International Committee for Cosmetic Harmonization and International Cooperation	CHIC
International Committee for Information Technology Standards	ICITS
International Committee for Weights and Measures	CIPM
International Conference of Building Officials	ICBO
International Conference on the Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use	ICH
International Council for Science	ICSU
International Council on Archives (ICA)	ICA
International Crystal foundation	ICF
International Dairy Federation	IDF
International Dairy Foods Association	IDFA
International Electrotechnical Commission	IEC
International Energy Agency	IEA
International Federation of Fruit Juice Producers	IFFJP
International Federation on Information Processing	IFIP
International Fragrance Association	IFRA
International Fresh-cut Produce Association	IFPA
International Hydrographic Organization	IHO
International Imaging Industry Association	IIIA
International Life Sciences Institute	ILSI
International Maritime Organization	IMO
International Natural Sausage Casing Association	INSCA
International Nomenclature Committee	INC
International Organization for Standardization	ISO
International Organization for Standardization in Microbiology	ISOB
International Organization for Standardization/International Electrotechnical Commission	ISO/IEC
International Organization for Standardization/International Electrotechnical Commission	ISO/IEC
International Organization of Legal Metrology	OIML
International Pharmaceutical Excipients Council	IPEC
International Seed Testing Association	ISTA
International Society for Analytical Cytology	ISAC
International Society for Blood Transfusion	ISBT
International Society for Cardiovascular Surgery	ISCVS
International Society for Cell Therapy	ISCT
International Society for Measurement and Control	ISA
International Society on Thrombosis and Homeostasis	ISTH
International Sprout Growers Association	ISGA

International Telecommunication Union	ITU
International Testing Services	ITSETL
International Union Against Cancer	UICC
International Union of Crystallography	IUCR
International Union of Laboratories and Experts in Materials, Systems and Structures	RILEM
International Union of Pure and Applied Chemistry	IUPAC
International Union of Pure and Applied Physics	IUPAP
International Workshop on Genetic Toxicology	IWGT
International Regulatory Alternatives Group	IRAG
Internet Engineering Task Force	IETF
Internet Software Consortium	ISC
Interstate Shellfish Sanitation Conference	ISSC
IPC - Association Connecting Electronics Industries	IPC
ISO Technical Advisory Group SC 29/TC 10 Hand Tools Committee	ISO TAG
J2EE National Consortium	J2EE/NC
JANNAF - Interagency Propulsion Committee	JANNAF
Java Grande Forum	JGF
JEDEC - Solid State Technology Association	JEDEC
Job Definition Format	CIP4
Joint Commission on Accreditation of Healthcare Organizations	JCAHO
Joint Electron Device Engineering Council	JEDEC
Joint FAO/WHO Expert Committee on Food Additives	JECFA
Joint Financial Managers Improvement Program	JFMIP
Lead Industries Association	LIA
Life Sciences Research Organization	LSRO
Logical Observation Identifier Name Codes	LOINC
Magnetic Materials Producers Association	MMPA
Maintenance Council of American Trucking Associations	TMC/ATA
Manufacturers Standardization Society of the Valve and Fittings Industry	MSSVFI
Master Painters Institute	MPI
Meat and Poultry Business to Business Data Standards Organization	MPXML
Meat and Poultry Equipment Standards	MPES
NACE International	NACE
NAFTA Land Transportation Standards Subcommittee	NAFTA
National Academy of Sciences	NAS
National Advisory Committee for Acute Exposure to Hazardous Substances	NACAEHS
National Aerospace and Defense Contractors Accreditation Program	NADCAP
National Association of Architectural Metal Manufacturers	NAAMM
National Association of Chain Manufacturers	NACM
National Association of Corrosion Engineers International	NACE
National Association of Photographic Manufacturers	NAPM

National Association of Relay Manufacturers	NARM
National Automatic Merchandising Association	NAMA
National Bison Association	NBA
National Board of Boiler and Pressure Vessel Inspectors	NBBPVI
National Cancer Registrars Association	NCRA
National Committee for Clinical Laboratory Standards	NCCLS
National Committee for Information Technology Standards	NCITS
National Committee on Uniform Traffic Control Devices	NCUTCP
National Committee on Vital and Health Statistics	NCVHS
National Computer Security Center	NCSC
National Conference of Standards Laboratories	NCSL
National Conference on Interstate Milk Shipments	NCIMS
National Conference on Weights and Measures	NCWM
National Cooperation for Laboratory Accreditation	NACLA
National Coordinating Council for Cancer Surveillance	NCCCS
National Council of Prescription Drug Programs	NCPDP
National Council of Radiation Protection and Measurements	NCRPM
National Dialog on Cancer	NDC
National Egg Regulators Association	NERA
National Electrical Manufacturers Association	NEMA
National Environmental Health Association	NEHA
National Fire Protection Association	NFPA
National Fluid Power Association	NFPA
National Food Processors Association	NFPA
National Hardwood Lumber Association	NHLA
National Hydrogen Association	NHA
National Information Standards Organization	NISO
National Institute for Biological Sciences and Controls	NIBSC
National Institute for Occupational Safety and Health	NIOSH
National Institute of Building Sciences	NIBS
National Institute of Standards and Technology	NIST
National Marrow Donor Program	NMDP
National Oilseed Processors Association	NOPA
National Organic Program	NOP
National Petroleum Management Association	NPMA
National Safety Council	NSC
National Sanitary Foundation	NSF
National Sanitation Foundation	NSF
National Skill Standards Board	NSSB
National Spectrum Managers Association	NSMA
National Toxicology Program	NTP

National Uniform Billing Committee	NUBC
National Uniform Claim Committee	NUCC
National Weeds Management Association	NAWMA
NCSL International	NCSLI
North American Association of Central Cancer Registries	NAACCR
North American Deer Association	NADA
North American Elk Breeders Association	NAEBA
North American Millers Association	NAMA
North American Open Math Initiative	NAOMI
North American Transport of Dangerous Goods Standards	NATDGS
North Atlantic Treaty Organization	NATO
Northwest Horticulture Council	NHC
NSF International	NSFI
Nuclear Information and Records Management Association, Inc.	NIRMAI
Object Management Group	OMG
Optical Internetworking Forum	OIF
Optical Society of America	OSA
Optical Storage Technology Association	OSTA
Optics and Electro-Optics Standards Council	OEOSC
Organization for Economic Cooperation and Development	OECD
Organization for the Advancement of Structured Information Standards	OASIS
Pan American Network for Drug Regulatory Harmonization	PANDRH
Pan-American Standards Commission	COPANT
Parachute Industry Association	PIA
Parallel Tools Consortium	PTOOLS
Parenteral Drug Association	PDA
Performance Review Institute	PRI
Petrotechnical Open Standards Consortium, Inc	POSC
Pipe Fabrication Institute	PFI
Plastics Pipe Institute	PPI
Plumbing and Draining Institute	PDI
Plumbing-Heating-Cooling Contractors Association	PHCCA
Produce Marketing Association	PMA
Product Quality Research Institute	PQRI
Project Management Institute	PMI
Quarter-Inch Cartridge Drive Standards, Inc.	QCDS
Rack Manufacturer Institute	RMI
Radio Technical Commission for Aeronautics	RTCA
Rational Unified Process	RUP
Research Institute for Fragrance Materials	RIFM
Reference Architecture and Common Application Framework	RACAF

Rehabilitation Engineering and Assistive Technology Society of North America	RESNA
Research Libraries Group (RLG)	RLG
Resistance Welders Manufacturers Association	RWMA
Robotics Industries Association	RIA
Rubber Manufacturers Association	RMA
Sanitary Standards Program	SSP
Scientific Apparatus Makers Association	SAMA
Security Industry Association	SIA
Semiconductor Equipment and Materials International	SEMI
Service Access and Delivery	SAD
Service Interface and Integration	SII
Service Platform and Infrastructure	SPI
Sheet Metal & Air Conditioning Contractors National Association	SHACCNA
Simulation Interoperability Standards Organization	SISO
Single Ply Roofing Institute	SPRI
Society for Biomaterials	SFB
Society for Glassware and Ceramic Decorations	SGCD
Society for Mining, Metallurgy, and Exploration	SME
Society for Protective Coatings	SPC
Society of Allied Weight Engineers	SAWE
Society of American Archivists	SAA
Society of American Value Engineers	SAVE
Society of Automotive Engineers	SAE
Society of Cosmetic Chemists	SCC
Society of Motion Picture and Television Engineers	SMPTE
Society of Toxicological Pathologists	STP
Society of Toxicology	SOT
Space Frequency Coordination Group	SFCG
Specialty Vehicle Institute of America	SVIA
Standard for Exchange of Non-clinical Data	SEND
Standards Engineering Society	SES
Steel Door Institute	SDI
Steel Founders Society of America	SFSA
Steel Window Institute	SWI
Strategic National Implementation Process Subgroups for HIPPA Standards Implementation	SNIP
TAPPI	TAPPI
Tea Association of America	TAA
Technical Association of the Pulp and Paper Industry	TAPPI
Technical Committee for Juice and Juice products	TCJJP
Telecommunications Industry Association	TIA
The American Society for Testing and Materials	ASTM

The Instrumentation, Systems, and Automation Society	ISA
The Internet Society	ISOC
The Open Group	TOG
The Soap and Detergent Association	SDA
The Society for Protective Coatings	SSPC
The Tire and Rim Association, Inc.	TRA
TIA	TIA
Transportation Research Board	TRB
Truck Trailer Manufacturers Association	TTMA
Trusted Computing Group, Inc.	TCG
Tuft's Conference on Modified Fats	CMF
U.S. Adopted Names Council	USANC
U.S. Product Data Association	US PRO
UML National Consortium	UML/NC
UN Centre for Trade Facilitation & Electronic Business	UNCTFEB
Underwriters Laboratories	UL
Uniform Building Code	UBC
United Egg Producers	UEP
United Fresh Fruit and Vegetable Association	UFFVA
United Nations Centre for Trade Facilitation and Electronic Business	UNI/CEFACT
United Nations Committee on the Transport of Dangerous Goods	UNTDG
United Nations Economic Commission for Europe WP .29/GRSP	UNECE
United States Pharmacopoeia	USP
US Animal Health Association	USAHA
US Egg and Poultry Association	USEPA
Versailles Project on Advanced Materials and Standards	VAMAS
Video Electronics Standards Association	VESA
Water Environment Federation	WEF
Welding Research Council	WRC
Western Growers Association	WGA
Western Wood Products Association	WWPA
Window and Door Manufacturers Association	WDMA
Window Covering Manufacturers Association	WCMA
Workgroup for Electronic Data Interchange	WEDI
World Health Organization	WHO
World Intellectual Property Organization	WIPO
World Meteorological Organization	WMO
World Trade Organization	WTO
World Wide Web Consortium	W3C

## **Appendix G – The Interagency Committee on Standards Policy (ICSP)**

The Interagency Committee on Standards Policy, also known as the ICSP, is the primary body responsible for coordinating standards use among agencies of the Federal government. The ICSP seeks to promote effective and consistent standards policies plus foster cooperation between government, industry, and other private organizations involved in standards activities. The Committee reports to the Secretary of the Department of Commerce (DOC) through the Director of the National Institute of Standards and Technology (NIST).

To review the current charter of the ICSP, click here:

<http://standards.gov/icsp/query/index.cfm?do=Home.ICSPCharter>

To see a list of the current ICSP membership, click here:

<http://standards.gov/icsp/query/index.cfm?do=Home.ICSPExecutives>

**Appendix H – Publications Related to the National Technology Transfer and Advancement Act (NTTAA) and Office of Management and Budget (OMB) Circular A-119**

To review a list of publications and reference documents related to Federal agency implementation of the NTTAA as well as OMB Circular A-119, visit the NTTAA Library online at <http://ts.nist.gov/ts/hdocs/210/nttaa/pubs.htm>.

These documents can be obtained in hardcopy form by sending a written request to:

Standards Coordination and Conformity Group (or, SCCG)  
Standards Services Division  
National Institute of Standards and Technology  
Gaithersburg, Maryland 20899-2150  
301-975-2490

When making requests, please identify specific documents by title, author, and date wherever possible.