

FOURTH ANNUAL REPORT ON
FEDERAL AGENCY USE OF
VOLUNTARY CONSENSUS STANDARDS

IMPLEMENTATION OF
PUBLIC LAW 104-113 AND OMB CIRCULAR A-119
FOR THE PERIOD
OCTOBER 1, 1999, THROUGH SEPTEMBER 30, 2000

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Table of Contents

| | |
|--|----|
| <i>EXECUTIVE SUMMARY</i> | vi |
| 1. SCOPE | 1 |
| FEDERAL STATUTES..... | 1 |
| 2.1 National Technology Transfer and Advancement Act (NTTAA) | 1 |
| 2.2 OMB Circular A-119 and P.L. 104-113 | 1 |
| 2.2.1 Agencies use of voluntary consensus standards versus government-unique standards..... | 1 |
| 2.2.2 Guidance to agencies | 1 |
| 2.2.3 Other issues covered by the Circular | 2 |
| 2.2.4 Role of Secretary of Commerce and NIST | 2 |
| 2.2.5 Agency Standards Executives..... | 2 |
| INTERAGENCY COMMITTEE ON STANDARDS POLICY (ICSP)..... | 2 |
| 3.1 Purpose..... | 2 |
| 3.2 ICSP chair | 2 |
| 3.3 ICSP membership | 2 |
| HIGHLIGHTS OF ICSP ACTIVITIES..... | 2 |
| 4.1 General | 2 |
| 4.2 Interaction with private-sector standards organizations | 3 |
| 4.3 ICSP working groups..... | 3 |
| HIGHLIGHTS OF FEDERAL AGENCY ACTIVITIES..... | 6 |
| 5.1 Department of Agriculture (USDA) | 6 |
| 5.2 Department of Commerce (DOC)..... | 6 |
| 5.3 Department of Defense (DOD) | 6 |
| 5.4 Department of Education (DOED) | 7 |
| 5.5 Department of Energy (DOE)..... | 7 |
| 5.6 Department of Health and Human Services (HHS), Food and Drug Administration (FDA) | 7 |
| 5.7 Housing and Urban Development (HUD) | 8 |
| 5.8 Department of the Interior (DOI)..... | 8 |
| 5.9 Veterans Affairs (VA)..... | 8 |
| 5.10 Consumer Product Safety Commission (CPSC)..... | 8 |
| 5.11 Environmental Protection Agency (EPA)..... | 9 |
| 5.12 Federal Emergency Management Agency (FEMA) | 9 |
| 5.13 General Services Administration (GSA) | 9 |
| 5.14 National Aeronautics and Space Administration (NASA) | 9 |
| 5.15 National Archives and Records Administration (NARA) | 10 |

| | | |
|---|--|------|
| 5.16 | Nuclear Regulatory Commission (NRC) | 10 |
| 6. | AGENCY USE OF GOVERNMENT-UNIQUE STANDARDS IN LIEU OF VOLUNTARY CONSENSUS STANDARDS | 10 |
| 6.1 | Department of Defense (DOD) | 10 |
| 6.2 | Department of Energy (DOE)..... | 10 |
| 6.3 | Housing and Urban Development (HUD) | 10 |
| 6.4 | Department of the Treasury (TREASURY) | 10 |
| 6.5 | Consumer Product Safety Commission (CPSC)..... | 11 |
| 6.6 | Environmental Protection Agency (EPA)..... | 11 |
| 6.7 | General Services Administration (GSA) | 11 |
| 6.8 | Government Printing Office (GPO)..... | 11 |
| 6.9 | National Aeronautics and Space Administration (NASA) | 11 |
| 6.10 | National Archives and Records Administration (NARA) | 12 |
| 7. | CONCLUSIONS..... | 12 |
| 8. | RECOMMENDATIONS | 17 |
| APPENDIX A: CABINET DEPARTMENT REPORTS | | A-1 |
| | Department of Agriculture (USDA) | A-2 |
| | Department of Commerce (DOC)..... | A-4 |
| | Department of Defense (DOD)..... | A-15 |
| | Department of Defense (DOD) | |
| | National Communication System (NCS)..... | A-30 |
| | Department of Education (DOED) | A-32 |
| | Department of Energy (DOE)..... | A-34 |
| | Department of Health and Human Services (HHS) | |
| | Food and Drug Administration (FDA) | A-42 |
| | Department of Housing and Urban Development (HUD) | A-49 |
| | Department of the Interior (DOI)..... | A-52 |
| | Department of Justice (DOJ) | A-54 |
| | Department of Labor (DOL)..... | A-56 |
| | Department of State (STATE) | A-57 |
| | Department of Transportation (DOT)..... | A-59 |
| | Department of the Treasury (TREASURY) | A-61 |
| | Department of Veterans Affairs (VA) | A-63 |
| APPENDIX B: OTHER AGENCY AND COMMISSION REPORTS | | B-1 |
| | Agency for International Development (USAID)..... | B-2 |
| | Consumer Product Safety Commission (CPSC)..... | B-3 |
| | Environmental Protection Agency (EPA)..... | B-6 |
| | Federal Communications Commission (FCC)..... | B-14 |
| | Federal Emergency Management Agency (FEMA) | B-15 |
| | Federal Trade Commission (FTC)..... | B-16 |
| | General Services Administration (GSA) | B-17 |
| | Government Printing Office (GPO)..... | B-20 |

| | |
|--|------|
| International Trade Commission (ITC) | B-22 |
| National Aeronautics and Space Administration (NASA) | B-23 |
| National Archives and Records Administration (NARA) | B-26 |
| National Science Foundation (NSF) | B-28 |
| Nuclear Regulatory Commission (NRC) | B-29 |
| | |
| APPENDIX C: CHARTER OF THE INTERAGENCY COMMITTEE ON STANDARDS POLICY | C-1 |
| | |
| APPENDIX D: MEMBERSHIP OF THE INTERAGENCY COMMITTEE ON STANDARDS POLICY | D-1 |
| | |
| APPENDIX E: LIST OF NIST PUBLICATIONS RELATED TO P.L. 104-11 | E-1 |

EXECUTIVE SUMMARY

Introduction

Public Law (P.L.) 104-113, the National Technology Transfer and Advancement Act (NTTAA), requires Federal agencies to use voluntary standards to the extent practicable, to report development of agency-unique standards, and to participate in the development of voluntary standards. To implement the legislation, the Office of Management and Budget (OMB) revised Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. Circular A-119 requires the National Institute of Standards and Technology (NIST) to report annually to OMB on the progress that Federal agencies have made toward using voluntary standards rather than agency-unique standards, and participation and interaction with private-sector voluntary standards bodies. NIST relies on the Interagency Committee on Standards Policy (ICSP) as the primary means of fulfilling its responsibilities for coordinating Federal standards-related activities.

On September 11, 2000, NIST, as chair of the ICSP, requested that each agency provide information on the status of its implementation activities: agency use of government-unique standards in lieu of voluntary consensus standards, the use of voluntary consensus standards, the number of voluntary standards substituted for government-unique standards, and the number of individual agency participants in voluntary standards bodies as well as an evaluation of the effectiveness of the policies promulgated in the Circular. Table 1 summarizes this information.

This report covers fiscal year (FY) 2000, from October 1, 1999, through September 30, 2000. It also describes NIST's coordination activities, with special emphasis on implementing the NTTAA, as well as information on ICSP activities and individual agencies' reports on NTTAA implementation efforts, and suggestions for future courses of action.

Conclusions

The FY 2000 report indicates that agencies have made significant progress in implementing the NTTAA, with double the number of standards reported used in FY 2000 as compared with FY 1999. In fact, since 1997, Federal agencies have increased their use of voluntary standards to a total of 8,759. This use is occurring across the Federal government, from the Department of Defense (DOD) to the National Aeronautics and Space Administration for procurement, to the Environmental Protection Agency (EPA) and Department of Energy (DOE) for regulation and procurement, to name only a few agencies.

The remarkable recent increase in private-sector consensus standards used by agencies appears to be due to increased visibility of the A-119 Program and increased agency attention to its implementation. In addition, the number of government-unique standards used in lieu of voluntary consensus standards dropped significantly from FY 1999 to FY 2000. While this is in part driven by the regulatory agenda for each agency, this drop also indicates greater reliance on voluntary consensus standards and compliance with the spirit of the NTTAA. While the decline in number of agency employees participating in standards development observed in all previous years of reporting on the implementation of the NTTAA continued in FY 2000, the rate of

decline has definitely slowed to only 4 percent for FY 2000. However, this may not necessarily reflect a decline in agency effort. The work of some participants may have been added to existing standards participants. The number of standards bodies in which Federal agencies participated actually increased by about 7 percent.

Totals for all Federal agencies are shown in the following table:

| FY 2000 Statistics on Federal Agencies' Participation in Development of and Adoption of Voluntary Consensus Standards | | | | | | |
|---|---|---------------------|--|---------------------|--|--|
| Number of Voluntary Consensus Standards Bodies in Which the Agencies Reported Participation in FY 2000 | Number of Agencies' Employees Participating in Voluntary Consensus Standards Bodies | | Number of Voluntary Consensus Standards Used | | Number of Voluntary Consensus Standards Substituted in FY 2000 for Government-Unique Standards | Number of Government-Unique Standards Used in Lieu of Voluntary Consensus Standards in FY 2000 |
| | FY 2000 | Change from FY 1999 | FY 2000 | Change from FY 1999 | | |
| 885 | 2,723 | -110 | 5,453 | +2,767 | 537 | 16 |

Highlights of FY 2000 include publication by NIST of Guidance on Federal Conformity Assessment Activities (15 CFR Part 287) in August 2000. This guidance was requested in Circular A-119 to provide direction and assistance to Federal agencies on their conformity assessment activities to facilitate coordination and exchange of information. In addition, this report contains examples reported by agencies of their success in using voluntary standards. During the reporting period, agencies continued to institute new procedures for identifying existing voluntary standards when proposing new regulations or in procurement activities. In particular, EPA provided additional guidance on the NTTAA to its rule writers for inclusion in the preamble of the Notices of proposed rulemaking. DoD and DOE continued to move Military Specifications and agency-unique standards into the private sector. Other agencies, notably the Department of Health and Human Services and the Nuclear Regulatory Commission, convened agency-wide workshops with other agencies and invited key stakeholders to educate their standards personnel. Private-sector standards developing organizations instituted briefing sessions with Federal agencies to address the issue of references to out-of-date standards in regulations. This led the Coast Guard to adopt several National Fire Protection Association standards in lieu of its own agency-unique standards.

Individual agency reports can be found in Appendices A and B, which contain the reports from 14 Cabinet Departments and 12 other agencies and commissions.

Annual Report to the Office of Management and Budget (OMB) on Implementation of OMB Circular A-119

1. SCOPE

This report, covering fiscal year (FY) 2000 from October 1, 1999, through September 30, 2000, describes the progress that federal agencies have made in implementing the National Technology Transfer and Advancement Act (NTTAA) through their use of voluntary consensus standards and participation in standardization activities. It highlights some examples of agencies' interactions with private-sector voluntary consensus standards bodies, agencies' use of government-unique standards, and the activities of the Interagency Committee on Standards Policy (ICSP). It discusses the National Institute of Standards and Technology's (NIST's) efforts in coordinating federal agencies' standards-related activities, including interactions with key private-sector organizations. Appendices A and B provide copies of the reports that NIST received from 14 Cabinet Departments as well as 12 other agencies and commissions. Appendices C, D, and E, respectively, provide copies of the ICSP Charter, ICSP membership, and a list of NIST publications related to Public Law (P.L.) 104-113.

2. FEDERAL STATUTES

2.1 NTTAA – P.L. 104-113 – P.L. 104-113, the NTTAA of 1995, codified existing policies of the OMB Circular A-119, established reporting requirements, and authorized NIST to coordinate standards and conformity assessment activities of Federal agencies, and with the private sector.

2.2 OMB Circular A-119 and P.L. 104-113 – On February 19, 1998, OMB issued the revised Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*. The purpose was “to make the terminology of the Circular consistent with P.L. 104-113, to issue guidance to agencies on making their reports to OMB, to direct the Secretary of Commerce to issue policy guidance for conformity assessment, and to make changes for clarity.”

2.2.1 Agencies' use of voluntary consensus standards versus government-unique standards – Consistent with section 12(d) of the NTTAA, the Circular directs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements of the NTTAA. The policies in the Circular are intended to minimize reliance by agencies on government-unique standards. These policies do not create the basis for discrimination in agency procurement or regulatory activities among standards developed in the private sector, whether or not they are developed by voluntary consensus standards bodies.

2.2.2 Guidance to agencies – Consistent with section 12(b) of the NTTAA, the Circular directs the Secretary of Commerce to issue guidance to agencies on ways to coordinate their conformity assessment activities. NIST published guidance on federal conformity assessment activities in the *Federal Register*, August 10, 2000, Volume 65, Number 155. The guidance focused on ways

for Federal agencies to eliminate unnecessary duplication and complexity in their conformity assessment activities.

2.2.3 Other issues covered by the Circular – The Circular also describes policies regarding federal use of standards and federal participation in voluntary consensus standards bodies. It covers the use of standards in regulations and provides procedures for managing and reporting on agency use of standards in procurement and regulations. It also covers reporting requirements, including how an agency is to report on its development and use of standards. The Circular also specifies the responsibilities of the Secretary of Commerce and NIST, agency heads, and Agency Standards Executives.

2.2.4 Role of Secretary of Commerce and NIST – The NTTAA and the Circular assign several policy coordination and implementation tasks to the Secretary of Commerce and specifically to NIST. NIST is responsible for chairing the ICSP and submitting an annual report to OMB on agency implementation activities. Compiling this report requires the full cooperation and assistance of all departments and agencies. In addition, as required by OMB every three years, the Secretary of Commerce re-chartered the ICSP on October 26, 2000, following review and comment by participating agencies.

2.2.5 Agency Standards Executives – The Circular delineates the role of Agency Standards Executives, particularly regarding agency-wide compliance with the NTTAA's legal requirements. The Standards Executive is responsible for coordinating agency-wide standards-related activities, coordinating the implementation of the Circular, and serving on the ICSP.

3. INTERAGENCY COMMITTEE ON STANDARDS POLICY (ICSP)

3.1 Purpose – The ICSP was established in 1968 to encourage coordination and liaison among Federal agencies on matters related to standards. In October 2000, the Secretary of Commerce approved a new Charter, which included requirements of the NTTAA. A copy of the new Charter is provided as Appendix C.

3.2 ICSP chair – The Director of the NIST Office of Standards Services chairs the ICSP on behalf of the NIST Director and the Secretary of Commerce. The ICSP is the primary vehicle for coordinating federal activities under NTTAA and the OMB Circular.

3.3 ICSP membership – The ICSP is currently composed of representatives of 14 Federal Cabinet Departments, 12 other Federal agencies and commissions, and several offices in the Executive Office of the President. The composition of the ICSP is shown in figure 1 on page 6. The ICSP membership is provided as Appendix D.

4. HIGHLIGHTS OF ICSP ACTIVITIES

4.1 General – In FY 2000, the Secretary of Commerce issued the updated ICSP charter. Membership in the ICSP continued to be reaffirmed by agency heads as needed. During FY 2000, the ICSP met four times. The meetings focused on such topics as the NTTAA, agency

implementation of the OMB Circular A-119, the conformity assessment guidance finalization and implementation, the National Standards Strategy, and streamlining the reporting process by using electronic tools for the annual report to OMB. ICSP members also heard presentations from NIST and others regarding the congressional hearings on NTTAA, the National Standards Strategy, International Laboratory Accreditation Cooperation (ILAC), and National Cooperation for Laboratory Accreditation (NACLA) activities.

4.2 Interaction with private-sector standards organizations – Representatives from several private-sector standards developing organizations (SDOs) gave presentations to the ICSP on topics of interest. The speakers represented such organizations as Underwriters Laboratories. In addition, the ICSP coordinated its efforts more closely with the American National Standards Institute (ANSI) Government Member Council.

4.3 ICSP working groups – During 2000, a major overhaul of the ICSP working groups took place. A number of working groups were made into virtual groups, a number were dispensed with and a number were created in order to improve the overall efficacy of the ICSP. The ICSP's working groups are shown in figure 1 on page 6.

Their activities are described as follows:

- **Regulatory Agencies Working Group (RAWG)** – The ICSP RAWG helps to develop and implement standards policies of interest to regulatory entities of the Federal Government. Membership includes representatives from CPSC, DOE, EPA, FCC, FDA, FERC, HUD, NIST, NRC, OSHA, and USDA. The RAWG reports to the ICSP and serves as a forum for interagency information exchange and discussion of issues of mutual interest to regulatory agencies. During 2000, the RAWG focused on issues and activities related to: (a) the OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Standards; (b) conformity assessment and conformity assessment guidance to Federal agencies; (c) a U.S. National Standards Strategy; (d) accreditation of standards developers using “essential requirements,” and (e) referencing voluntary standards in federal regulations.
- **Working Group on Strategic Standards Management** – During 2000, the ICSP's Standards Management Working Group was dissolved.
- **Working Group on Directory Databases** – The ICSP working group on Directory Databases, chaired by NIST, undertook a major project in 2000 to connect agencies' Web-based systems on standards committee participation. Four agencies--NIST, DoD, DOE, and NASA--have their information available on the Web. Three of the four are now connected to one another by a single search mechanism. Users can now search DoD, DOC, and NASA's databases simultaneously and return combined sorted results. Users can also e-mail the Federal standards participants should they wish to contact them directly. In the future, this group will continue to add new agencies to the search mechanism as their information becomes available online.
- **Working Group on Quality Management (International Organization for**

Standardization (ISO) 9000 – As in FY 1999, NIST continued to provide material on the proposed revisions to the ISO 9000 standards to the ICSP in FY 2000. NIST also responded to requests for assistance/information on this topic from individual agencies. However, there were no meetings of this working group in FY 2000. This working group will remain inactive until the ICSP determines that there is a need for reactivation, but NIST will continue to share information related to the revisions of ISO 9000 with ICSP members, thus treating this working group as a virtual group.

- **Interagency Working Group on Environmental Management Systems (EMS) (ISO 14000)** – The Interagency Working Group on EMS/ISO 14000 was merged with the Executive Order 13148 group in FY 2000 to discuss items of mutual interest related to ISO 14000 and EMS.
- **Laboratory Accreditation Work Group** – This working group was subsumed into the Federal Coordination Group of the National Cooperation for Laboratory Accreditation (NACLA) during FY 2000.
- **Standards Working Group of the CIO and of ICSP** – This Working Group's goal is to develop a unified government voice on standards and technology requirements. The Standards Working Group of the Enterprise Interoperability and Emerging Information Technology Committee of the Federal CIO Council provides a forum for Federal agencies to identify and define their common requirements so that they may be transmitted to the appropriate voluntary standards development committees or consortia for action. The intent of the working group, chaired by NIST, is to improve the bargaining power of federal agencies within voluntary standards committees through coordinated requirement statements. In FY 2000, the working group demonstrated the requirements Web site and database capabilities for submitting, reviewing, and tracking Government requirements into formal standards processes. The group also discussed possible requirements stemming from the Electronic Documents Conference held at NIST in March 2000.

Interagency Committee on Standards Policy

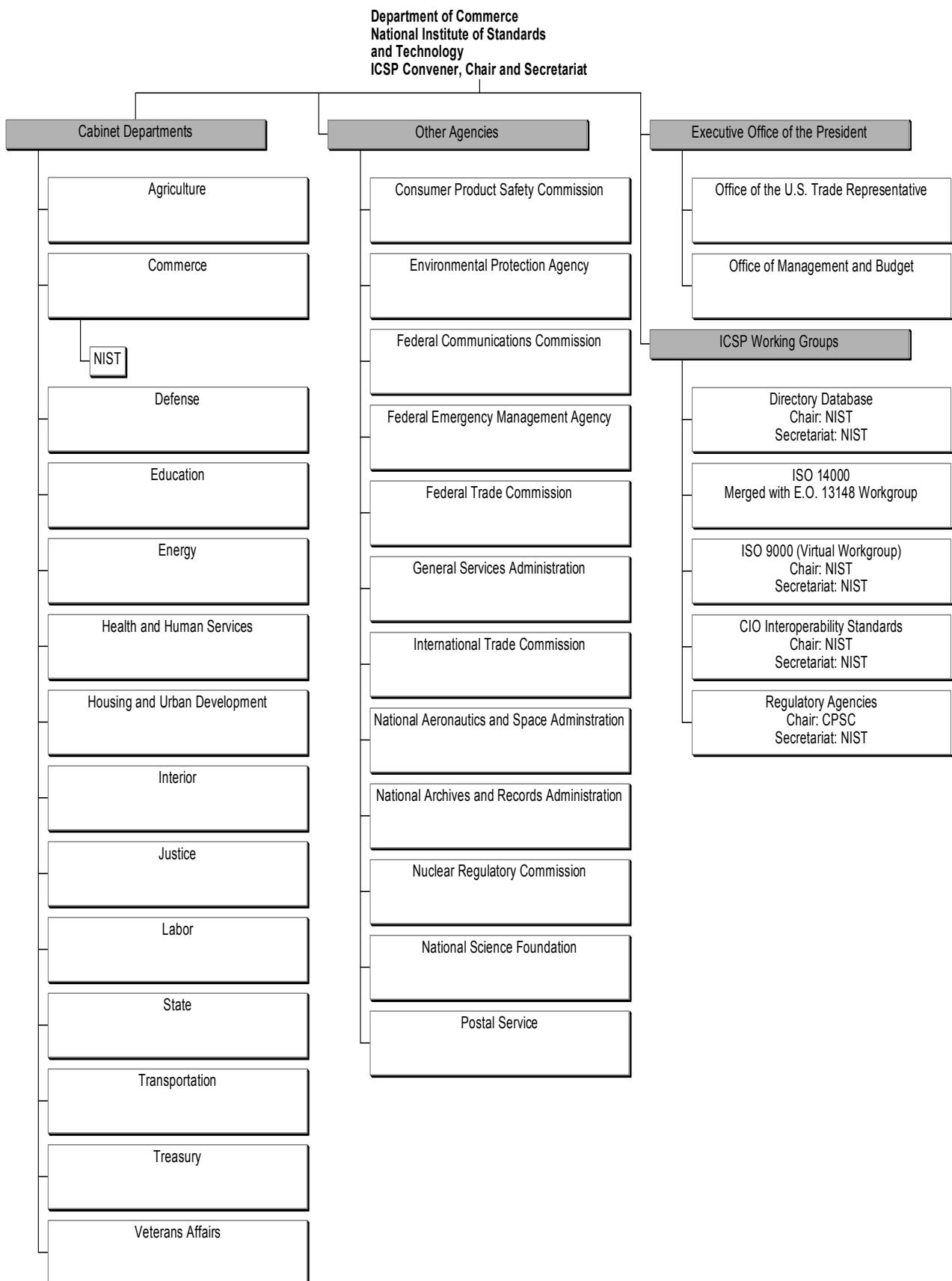


Figure 1

5. HIGHLIGHTS OF AGENCY ACTIVITIES

5.1 Department of Agriculture (USDA) – USDA was involved in a number of standards and conformity assessment activities in FY 2000 including: (a) a United Nations/Economic Commission for Europe Committee meeting that finalized beef cutting and quality standards; (b) a Latin American standards group that initiated development of lamb and chicken cutting and quality standards; (c) International Organization for Standardization (ISO) Technical Committee (TC) 176 for Quality Management and Quality Assurance with regard to livestock and seed quality; (d) ISO TC 34 for Food Products/Subcommittee 6 for Meat and Meat Products, which develops ISO standards in the field of meat and meat product foodstuffs, as well as sampling, methods of testing and analysis, product specifications and requirements for packaging, storage, and transportation of meat and meat products; and (e) NSF International and Underwriters Laboratories working together with USDA to develop their voluntary consensus standards for the hygienic inspection and certification of equipment used to process meat and poultry products.

5.2 Department of Commerce (DOC) – Within DOC, NIST has responsibility for the primary activities for implementing P.L. 104-113 and OMB Circular A-119. This year, the most noteworthy accomplishment was NIST's publication of the Guidance on Federal Conformity Assessment Activities, which was mandated by OMB Circular A-119. Other noteworthy activities included the creation of the online search mechanism for standards participants and the online data entry for the Annual Report to Congress, NIST's cosponsoring and chairing the ILAC 2000 conference at which the ILAC Arrangement was signed, the signing of the NIST-NACLA Memorandum of Understanding (MOU), and the NACLA Mutual Recognition Arrangement by the National Voluntary Laboratory Accreditation Program. During FY 2000, NIST chartered the Commerce Standards Committee, which has participants from six DOC agencies; each reported on its standards-related activities. NIST also continued its work assisting Federal agencies through the ICSP, the NIST Standards Advisory Committee, the Commerce Standards Committee, and through the National Center for Standards and Certification Information.

5.3 Department of Defense (DOD) – The Department's Military Specifications (MilSpecs) Reform initiative resulted in the review of all 40,000 military specifications and standards for potential replacement by voluntary consensus standards. In instances where replacement voluntary consensus standards were available, the Department acted quickly to cancel the military documents and began using voluntary consensus standards. In cases where voluntary consensus replacements were needed but not available, the DoD began working with standards developers to create appropriate standards.

DOD has put into place a very stringent system to review every new requirement for a document to determine if a voluntary consensus document would be more appropriate. A member of the Senior Executive Service must approve every request for a new document. DOD activities are directed to review all available sources to locate an appropriate voluntary consensus document rather than create a military-unique document. The five-year review process identifies documents that did not have a voluntary consensus counterpart at one time, but for which an appropriate document may now have been created. The Department's initial review and correction procedures, coupled with oversight in the creation of new military documents and

periodic review of existing military documents, ensures very little proliferation of DoD government-unique documentation.

5.4 Department of Education (DOED) – DOED continued to work with the American National Standards Institute (ANSI) on developing EDI transaction sets through their Accredited Standards Committee (ASC) X12 committee. This committee is charged with developing uniform standards for electronic interchange of business transactions and standards relating to student personnel and financial aid records. The work of this voluntary consensus building body has helped DOED forge ahead in developing standards and include the appropriate communities to help with transition to and adoption of new standards.

5.5 Department of Energy (DOE) – DOE continues to take a “proactive” approach to standards and standards management. Within DOE, a number of programs and facilities have shifted their focus from production, research, and/or development to environmental remediation and restoration. DOE will literally be breaking new ground in these areas. In the face of a changing mission and a reduced workforce, DOE continues to actively use and support the development of voluntary consensus standards to meet its needs. DOE is also continuing its initiative to better define “candidate” DOE technical standards for conversion to voluntary consensus standards.

DOE has an Integrated Safety Management System through which it implements the OMB Circular A-119 and P.L. 104-113. This system integrates management of DOE's worker, public, and environmental health and safety with its business management, using standards as one of its primary tools. The Directives System policy clearly states DOE's preference to “. . . adopt National Consensus Standards and other commercial and industry standards . . .” in the conduct of DOE's activities. Directives System documents reference appropriate voluntary consensus standards that are acceptable for meeting requirements. This policy also limits the use of mandated government-unique standards in DOE rulemaking, orders, and procurement processes. DOE has designated about 70 individuals to serve as technical standards managers throughout DOE; it also has convened 25 topical committees including several on standards and conformity assessment-related topics.

5.6 Department of Health and Human Services (HHS), Food and Drug Administration (FDA) – 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's development and use of voluntary consensus standards varies within each of the agency's centers, because of differing availability and applicability of such standards in each product area. Voluntary consensus standards are most relevant to medical devices, and consequently the majority of the agency's standards activities addressed by Circular A-119 are centered there.

5.7 Housing and Urban Development (HUD) – HUD had a number of successes in implementing the NTTAA in FY 2000. For example, in July 2000, the Standards Council of the National Fire Protection Association (NFPA) approved the 2000 edition of NFPA 501. This document is the vehicle used by NFPA to process consensus-developed recommended changes to the Federal Manufactured-Home Construction and Safety Standards 24 CFR 3280. HUD, through an MOU with NFPA, is relying upon NFPA to develop and process recommendations for standards changes. While this does not totally replace a federal standard with a consensus one, it has transferred the development to a consensus ANSI-recognized process. HUD intends to review and submit a proposed rule to amend 24 CFR 3280 for public comment shortly. This will include roughly 110 changes. HUD received the recommendations in September 2000.

5.8 Department of the Interior (DOI) – The number of standards reported being used in this year's report has dramatically increased from last year's. This is due to improved reporting on behalf of the agency, particularly, the U.S. Geological Survey's Water Standards Division. Previously, this Division had not reported. In FY 2000, they have now reported using 1,411 standards. In addition to improved reporting, DOI has had a number of other standards successes in FY 2000. For example, the U.S. Geological Survey (USGS) is the lead Federal agency in the National Atmospheric Deposition Program (NADP), with approximately five USGS employees actively participating in the organization. USGS representatives serve on the NADP Executive Committee and Network Operations Committee and a USGS representative serves as chairperson of the NADP Budget Committee. Representatives from approximately 100 federal, state, local, academic, and private-sector organizations participate in the NADP to establish uniform standards for the measurement of chemical constituents deposited to the earth via rain, snow, and sleet. In addition to setting standards, this organization conducts jointly funded monitoring of atmospheric deposition throughout the United States at over 250 locations using the common protocols and standards developed by the organization. Through the use of jointly developed common standards, the data collected is comparable and of known quality from all stations throughout the United States. The use of common standards, procedures, laboratories, instrumentation, and data management criteria enables the participating agencies to collect the information at significantly lower cost and with higher quality.

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

5.10 Consumer Product Safety Commission (CPSC) – The 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.

5.11 Environmental Protection Agency (EPA) – EPA's commitment to the letter and spirit of the NTTAA is evident in regulatory, contracting, and voluntary activities throughout the agency. EPA promulgated 600 final, proposed, and other rules. In the 585 final rule makings during FY 2000, EPA used voluntary consensus standards in 453, or 77 percent, of them. That is a 42 percent increase from 1999. The success of EPA's implementation is largely due to the efforts of the Agency's Standards Program and the Office of General Counsel working cooperatively with the EPA regulatory Policy Steering Committee, the rule writers and standards coordinators throughout the Agency. In addition, a total of 122 EPA contracts, including 6 ADP/IT, 37 construction, and 79 lab contracts included voluntary standards.

5.12 Federal Emergency Management Agency (FEMA) – FEMA has long recognized the value of voluntary consensus organizations, and within the building science community, has been successfully working with these organizations since the early 1980s. By using these organizations for almost 20 years, FEMA has been able to get design and construction provisions that reduce the threat from natural hazards into the hands of the public in an effective and timely manner without the undue burden of additional Federal regulations.

5.13 General Services Administration (GSA) – GSA continues to expand its emphasis on the procurement of commercial off-the-shelf products and services. Since 1994, GSA has replaced 93 government standards with voluntary standards, and has adopted an additional 86 voluntary standards.

5.14 National Aeronautics and Space Administration (NASA) – In FY 2000, the NASA Technical Standards Program initiated three new activities that will enhance its use and support of voluntary consensus standards. The agency-wide Full-Text Technical Standards System will provide full text on-line documents for NASA use for adopted and other non-Government standards products. For those standards products not available electronically, a hard copy will be made available. The Standards Update Notification (Alert) System will provide users with notice of updates to standards products that they have identified for use on their programs. The Lessons Learned/Best Practices/Application Notes system will provide links to internal recommendations for use of individual standards products.

As an acquisition-oriented agency, conformity assessment is a major element of its policies and procedures to ensure the safety and mission success of NASA programs. NASA has a long-standing practice of working with other government agencies and the private sector to integrate best practices into its activities. NASA continues to work with DOD and the aerospace industry to adopt and define consistent quality practices. NASA also cooperates with DOD in the implementation of their Single Process Initiative which is used to identify and apply common standards and criteria at facilities that produce equipment for many end users within both DOD and NASA. The reduction of multiple quality requirements to a single set of quality requirements applicable to all programs eliminates the need for contractors to maintain duplicate or overlapping quality systems and permits more uniform conformity decision process.

5.15 National Archives and Records Administration (NARA) – NARA employees involved in standards-setting activities are cognizant of the importance of using voluntary technical consensus standards. Where possible, NARA has incorporated, by reference in its regulations, voluntary standards rather than government-unique standards. This has been especially important in its revised records storage standards regulation since private companies now have to comply with these standards if they plan to house Federal Government records in their facilities.

5.16 Nuclear Regulatory Commission (NRC) – In FY 2000, NRC took several actions to increase the effectiveness and efficiency of their process for implementing the NTTAA and A-119. NRC Management Directive 6.5, NRC Participation in the Development and Use of Consensus Standards, was issued on November 2, 1999. The Directive provides: (a) direction for implementing P.L. 104-113 and A-119; and (b) organizational responsibilities and guidance for NRC staff participating in the development of consensus standards and for NRC use of consensus standards. The NRC staff met with representatives from the SDOs that provide codes and standards for the nuclear industry twice during this reporting period (December 8, 1999, and July 27, 2000). The NRC has been hosting these meetings on a semiannual basis. The purpose of these meetings is to foster better communication and discuss standards under development, current needs, and priorities. These exchanges have proved to be very beneficial.

6. AGENCY USE OF GOVERNMENT-UNIQUE STANDARDS IN LIEU OF VOLUNTARY CONSENSUS STANDARDS

6.1 Department of Defense (DoD) – The Department relies on MilSpecs and standards in lieu of voluntary consensus documents when the requirement can be justified as truly military-unique, when a voluntary standard does not exist and development is not imminent, or when there is no industry interest to develop an appropriate voluntary standard. Since the Department has a massive number of procurements, DoD has chosen to use the categorical basis as the means of conveying information on its voluntary consensus standards use.

6.2 Department of Energy (DOE) – DOE uses categorical reporting and, therefore, is not required to report on the exact number of instances that a government-unique standard is used in lieu of an existing, appropriate voluntary consensus standard.

6.3 Housing and Urban Development Agency (HUD) – HUD used two government unique standards in lieu of voluntary consensus standards. HUD used 28 CFR 3280 in lieu of ANSI A119.1 and NFPA 501C (circa) 1975 and various state standards and mobile-homes standards circa 1976. These standards encompass HUD-Unique Manufactured-Home Construction and Safety Standards. CFR 200.93 5 was also used in lieu of ANSI A119.1 and NFPA 501C (circa) 1975 and various state standards and mobile-homes standards circa 1976. These standards are HUD Building-Product Standards and Certification Programs.

6.4 Department of the Treasury (TREASURY) – Treasury used two government-unique standards in lieu of voluntary consensus standards. The Customs and Trade Automated Interface Requirements (CATAIR) is used by the customs brokerage industry. The Customs Automated Manifest Interface Requirements (CAMIR) is used by some parties in the transportation sector. The maintenance of the government-unique standards within Customs applications, the CATAIR

and CAMIR formats, are at the request of the participating industry groups that use those standards.

6.5 Consumer Product Safety Commission (CPSC) – In FY 2000, CPSC one government-unique standard, its rule, CFR Parts 1213, 1500, and 1513, in lieu of American Society for Testing and Materials (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.

6.6 Environmental Protection Agency (EPA) – In FY 2000, EPA used two existing government standards, 40 CFR 89 & 92 and 40 CFR 90 in lieu of the voluntary consensus standard, ISO 8178, citing that procedures in 8178 would be impractical because they rely too heavily on reference testing conditions. The Agency decided instead to continue to rely on procedures outlined in 40 CFR Part 90.

6.7 General Services Administration (GSA) – GSA used four government standards in lieu of voluntary consensus standards. Standard AA-D-600B, Door, Vault, Security, and AA-V-2737, Modular Vault Systems were used in lieu of UL 608. FF-L-2740, Locks, Combination, was used in lieu of UL 768. These government specifications cover products used for the protection of national security information. The standards were developed after government review and testing determined that the commercial standards did not provide the required level of protection, or those commercial products that did provide the level of protection significantly exceeded the price of products meeting the government standards. KKK-A-1822D, Ambulance, Emergency Medical Care Surface Vehicle, was used in lieu of ASTM F2020-00. This federal specification is referenced in an existing contract. The ASTM standard is currently being reviewed for possible use in future contracts.

6.8 Government Printing Office (GPO) – GPO used four government-unique standards in lieu of voluntary consensus standards. FED-STD 209 was used in lieu of ISO 14644-1 and ISO 14644-2. The reason cited was that the second ISO standard was not issued until the end of FY 2000. Three MIL standards were used, all with the same explanation: they were cited in a small number of contracts due to editing errors. These are being corrected. They were: MIL-STD 105 for ANSI/ASQC Z1.4; MIL-STD 1189 for ANSI/AIM X5-2 & ANSI X3.182; and MIL-STD 498 for IEEE/EIA 12207.0, IEEE/EIA 12207.1, & IEEE/EIA 12207.2.

6.9 National Aeronautics and Space Administration (NASA) – Because NASA uses the “categorical” method of reporting, “use” of government-unique standards is reported in terms of additions to the NASA Technical Standards Management System, as opposed to tracking individual procurement transactions. During 1999, NASA developed 11 NASA-unique technical standards in three categories, namely: information technology, engineering, and safety and mission assurance. There are four engineering standards, two of which are internal procedures for the application of voluntary consensus standards and two are unique applications based on spacecraft experiences with no current external interest. There are three safety and mission assurance standards, with two being internal procedures and one based on aerospace applications. The last four standards are from the information technology area and are all procedural documents for the application of commercial software.

6.10 National Archives and Records Administration (NARA) – NARA used a number of its own data standards because MARC, EAD, APPM, ISAD (G), and ISAAR (CPF) did not meet their needs. NARA did not use MARC or EAD as the underlying structure of their database because doing so would be too limiting. Both Machine Readable Cataloguing (MARC) and Encoded Archival Description (EAD) feature a "denormalized" data model that would make it impossible to use data captured in that format for other purposes, such as a lifecycle system (box label, bar coding, online ordering, etc.). In addition, because MARC and EAD are implemented nationally, the result is hard-wired outputs. NARA prefers a normalized database approach because the other approach would be too limiting.

7. CONCLUSIONS

In FY 2000, Federal agencies continued to implement P.L. 104-113 and the OMB Circular A-119. Overall, agencies are improving their procedures to track use of standards in both their regulatory and procurement activities.

This past year, NIST took steps to assist agencies with electronic submission of their annual reports. NIST created a Web-based data entry system that allows agencies to track how far along they and other agencies are in entering their data into the system. Sixty percent of agencies had all of their information in the system as of the November 30, 2000, deadline -- a significant increase over last year. NIST is also publishing the annual report both in hard copy and on the Web at <<http://ts.nist.gov/icsp>> so that agencies and the public have ready access. NIST will continue its efforts in this area.

During FY 2000, agencies made significant progress in implementing the NTTAA, with double the number of standards being reported used in FY 2000 -- with an increase in the number of standards reported as used from 2,669 in FY 1999 to 5,453 in FY 2000, as shown in Table 1 and Chart 1. In fact, since 1997 Federal agencies have increased their use of voluntary standards by a total of 8,759 (see Chart 4). If one considers the base of standards used/adopted by DOD prior to 1997, that brings the total of voluntary consensus standards used/adopted by the Government to just over 16,000. This use is occurring across the Federal government, from DOD to NASA for procurement, to EPA and DOE for regulation and procurement, to name only a few agencies. NIST ascribes the improved use of standards to greater use of agency electronic information systems for collecting and reporting the data. The trend reflected in the data in Table 1 shows clearly that the intent of the NTTAA is being fulfilled. The Federal government is using more and more voluntary consensus standards.

During FY 2000, voluntary consensus standards substituted for government-unique standards remained high at 537 (a slight decline from last year's total of 542). Of importance, the number of government-unique standards used in lieu of voluntary consensus standards dropped significantly from FY 1999 to FY 2000. While this is in part driven by the regulatory agenda for each agency, this drop also indicates greater reliance on voluntary consensus standards and compliance with the spirit of the NTTAA. While the decline in standards participation observed in all previous years of reporting on the implementation of the NTTAA continued in FY 2000, the rate of decline has definitely slowed from the 12 percent reported for FY 1999 to 4 percent

for FY 2000 (see Chart 2). As has been conjectured in the past, this is most likely due to staff attrition, budget cuts, and streamlining of agency standards programs. The decline should level off even more in the next year as standards programs reach their steady state and reporting anomalies are reduced. On the positive side, agencies are reporting being involved in many more standards bodies, up 7 percent, over the FY 1999 data (See Chart 3).

More details about individual agency activities can be found in Appendices A and B, which contain the reports from 14 Cabinet Departments and 12 other agencies and commissions. They are provided with minimal or no editing and reformatting. This report also contains copies of the ICSP Charter, the FY 2000 ICSP membership list, and a list of NIST publications related to P.L. 104-113 in Appendices C, D, and E, respectively.

Table 1. FISCAL YEAR (FY) 2000 STATISTICS ON FEDERAL AGENCIES' PARTICIPATION IN DEVELOPMENT OF AND ADOPTION OF VOLUNTARY CONSENSUS STANDARDS¹

| Agency | Number of Voluntary Consensus Standards Bodies in Which the Agency Participates ² | Number of Agency Employees Participating | Change From FY 1999 | Number of Voluntary Consensus Standards Used in FY 2000 | Change From FY 1999 | Number of Voluntary Consensus Standards Substituted for Government-Unique Standards | Number of Government-Unique Standards Used in Lieu of Voluntary Consensus Standards |
|--------------|--|--|---------------------|---|---------------------|---|---|
| USDA | 39 | 59 | 20 | 95 | +95 | 0 | 0 |
| DOC | 176 | 444 | 62 | 5 | +5 | 0 | 0 |
| DoD | 71 | 446 | 26 | 347 | -280 ¹ | 509 | - |
| NCS (DoD) | 18 | 10 | -5 | 0 | 0 | 0 | 0 |
| DOED | 1 | 1 | -6 | 17 | 0 | 0 | 0 |
| DOE | 59 | 676 | 8 | 1,012 | +96 | 1 | - |
| FDA (HHS) | 46 | 241 | -14 | 501 | +411 | 1 | 0 |
| HUD | 6 | 8 | 2 | 300 | +298 | 1 | 2 |
| DOI | 29 | 81 | -3 | 1,569 | +1,425 | 0 | 0 |
| DOJ | 3 | 5 | -3 | 59 | 0 | 0 | 0 |
| DOL | 81 | 89 | 24 | 118 | +103 | 0 | 0 |
| STATE | 1 | 8 | 2 | 0 | 0 | 0 | 0 |
| DOT | 146 | 211 | -18 | 153 | -85 | 11 | 0 |
| TREASURY | 6 | 10 | -9 | 8 | +2 | 2 | 2 |
| VA | 26 | 12 | 0 | 0 | -36 | 0 | 0 |
| USAID | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CPSC | 8 | 28 | 3 | 1 | -3 | 0 | 1 |
| EPA | 15 | 23 | -174 | 229 | +195 | 0 | 2 |
| FCC | 1 | 5 | -45 | 0 | 0 | 0 | 0 |
| FEMA | 4 | 7 | +7 | 0 | -1 | 0 | 0 |
| FTC | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| GSA | 81 | 47 | -2 | 10 | +10 | 10 | 4 |
| GPO | 3 | 2 | 2 | 108 | +108 | 0 | 4 |
| USITC | 1 | 1 | 1 | 0 | 0 | 0 | 0 |
| NASA | 38 | 156 | 11 | 860 | +430 | 0 | - |
| NARA | 5 | 9 | 1 | 25 | +3 | 2 | 1 |
| NSF | 3 | 3 | 0 | 0 | 0 | 0 | 0 |
| NRC | 18 | 141 | 0 | 36 | -9 | 0 | 0 |
| TOTAL | 885 | 2,723 | -110 | 5,453 | +2,767 | 537 | 16 |

¹ Not reflected in the chart are the total number of voluntary consensus standards adopted by Federal agencies and those in the process of being adopted. For example, DoD reported that by FY 2000, it had adopted a total number of 8,965 voluntary consensus standards, an increase of 347 since FY 1999.

² Each agency counts the number of voluntary consensus standards bodies in which it participates. Many of these bodies are reported by several agencies; e.g., EPA, DoD, DOC, etc., participate in ASTM. Thus, by simply adding up the number of bodies, some standards bodies in which several Federal agencies participate may be double counted.

Chart 1: Number of Voluntary Consensus Standards Substituted for Government-Unique Standards

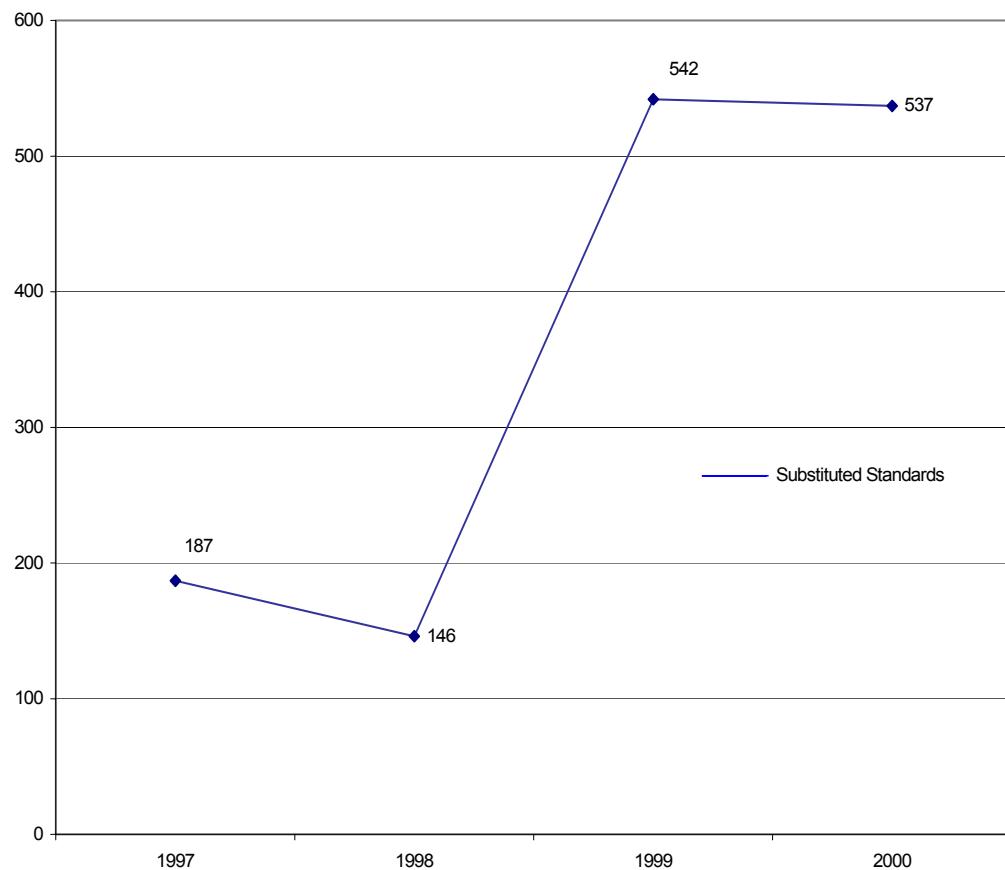


Chart 2: Number of Agency Employees Participating

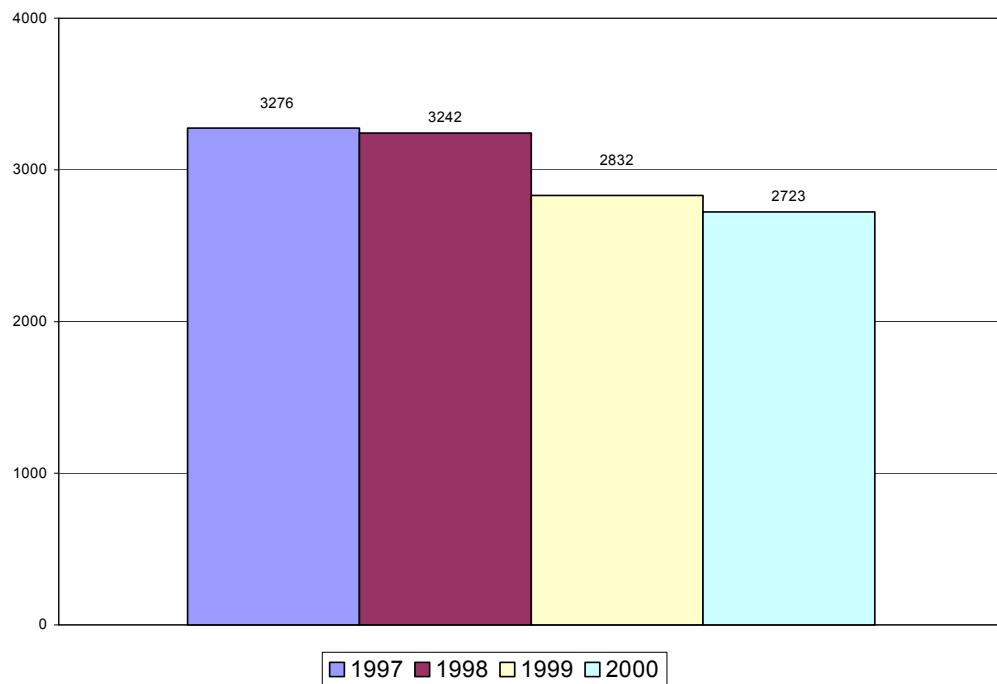


Chart 3: Number of Voluntary Consensus Standards Bodies in Which Agencies Participate

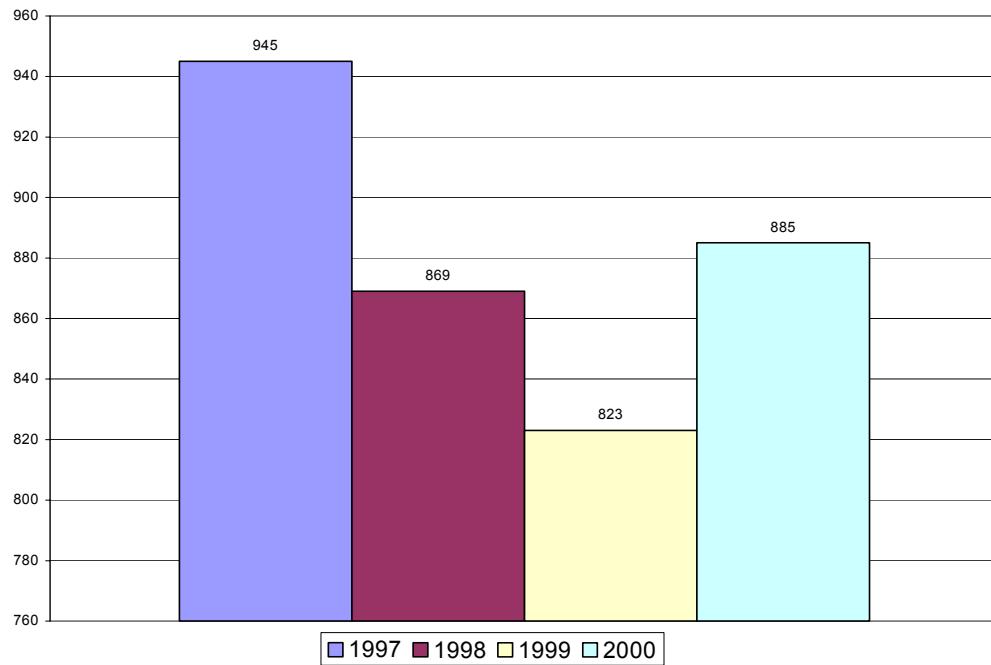
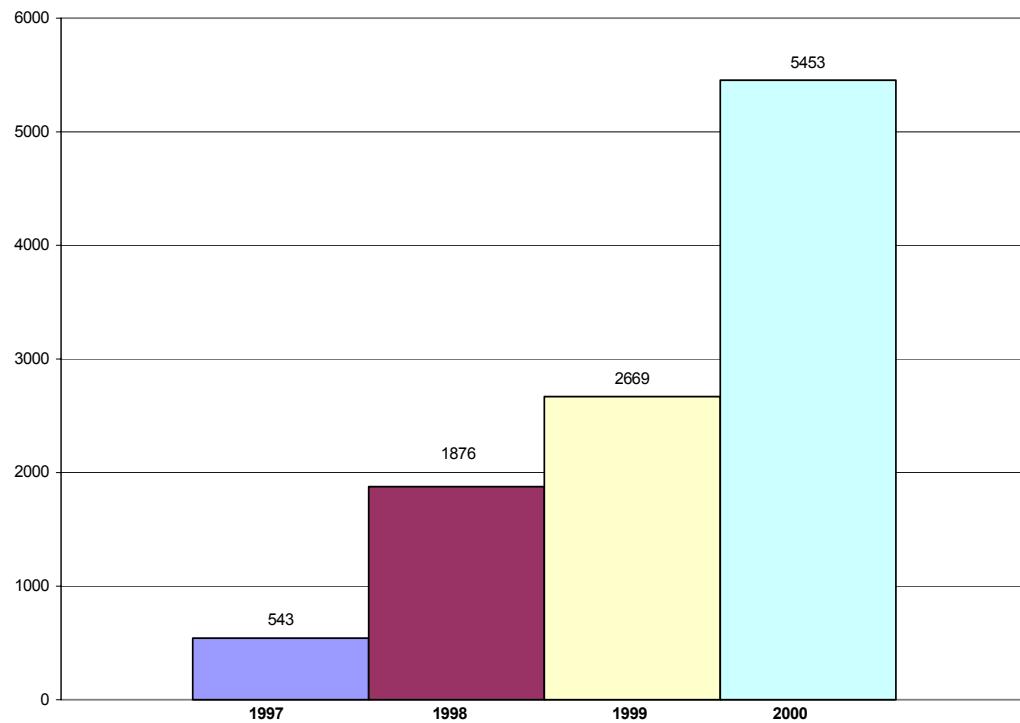


Chart 4: Number of Voluntary Standards "Used" by Federal Agencies



8. RECOMMENDATIONS

Most Federal agencies have continued to progress in their use of voluntary consensus standards for agency programs and missions for both procurement and regulatory activities. Increased use of appropriate strategic alliances and teaming arrangements between Federal agencies and SDOs may be beneficial in ensuring that this trend continues.

All Federal agencies should continue to strengthen their efforts to plan and allocate resources and staff for participation in appropriate voluntary consensus standard activities that support agency missions and strategic plans.

Federal agencies should continue to develop additional policies and systems needed for the most effective implementation of the NTTAA and OMB Circular A-119. Actions that should be considered include: (a) the establishment of an agency standards policy, (b) procedures for improving reporting, agency-wide coordination, and program effectiveness, and (c) monitoring standards activity participation and resource allocation.

Changes in Federal resources and staff can lower the priorities for standards and conformity assessment activities within a department or agency. Some agencies are finding it difficult to participate actively in the ICSP or its working groups. As a result, NIST is making much greater use of virtual working groups and electronic means for sharing information. Changing resources for participation in standards activities also appear to be making it difficult for agencies to ensure adequate representation on appropriate standards committees. Federal agencies should make more effective use of today's technology for coordinating standards participation across government, in positions on standards committee ballots, and in preparing reports on the status of standards activities including the annual report for OMB.

Since the 1998 revision of the Circular, a number of reporting issues have arisen. In particular, agencies are having some difficulties categorizing standards that are not "new" adoptions but are in continued usage. The reporting system spelled out in the Circular is still somewhat confusing to agencies. The issue of intellectual property rights continues to be a concern for Federal agencies. Finally, how to report on standards that are adopted with significant technical modifications is a concern.

These are just a few of the problems that agencies have reported in their implementation efforts. While most agencies are diligently trying to comply with both the law and circular, some are not. NIST plans to work with all agencies during FY 2001 to ensure that implementation of the NTTAA continues to increase. This includes development of means for assisting the Standards Executives in coordinating standards-related activities across federal agencies, improved electronic information and reporting tools, and greater use of ICSP working groups.

In closing, over the past four years there has been a continued increase in the use of voluntary standards by federal agencies in both regulation and procurement, and conformity assessment activities are now receiving greater attention than before passage of the law.

Appendix A:

Cabinet Department Reports

DEPARTMENT OF AGRICULTURE (USDA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

39

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

59

3. Number of Voluntary Consensus Standards Used in FY 2000:

95

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

USDA concurs that 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.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

N/A

8. Provide Any Examples or Case Studies of Standards Successes:

- a. United Nations/Economic Commission for Europe Committee for Trade Industry and Enterprise Development, Meeting of Experts for the Standardization of Meat, March 27-29, 2000, Geneva, Switzerland (finalized beef cutting and quality standard).
- b. Meeting of Rapportuers for the Standardization of Meat, September 25-27, 2000, Campinas and Sao Paulo, Brazil (initiated development of lamb and chicken cutting and quality standards).
- c. International Organization for Standardization (ISO) Technical Committee 176 for Quality Management and Quality Assurance. Livestock and Seed voted on numerous

draft standards before the committee related to standardization in the field of generic quality management, quality systems, quality assurance, generic supporting technologies, and the applied use of these standards.

- d. ISO Technical Committee 34 for Food Products/Subcommittee 6 for Meat and Meat Products. This committee is administered by the U.S. Technical Advisory Group to TC34/SC6, which develops ISO standards in the field of meat and meat product foodstuffs, as well as sampling, methods of test and analysis, product specifications and requirements for packaging, storage, and transportation of meat and meat products.
- e. Worked with NSF International and Underwriters Laboratories to develop their voluntary consensus standards for the hygienic inspection and certification of equipment used to process meat and poultry products. This work was cited along with OMB Circular A-119 in the Livestock and Seed Program's proposed rule for the equipment certification program that adopts the NSF standards as USDA standards.
- f. Participated in an International Seed Testing Association (ISTA) study to determine if large lots of grass seeds are sufficiently homogenous to be shipped in international trade. USDA served as a technical assessor for an ISTA accreditation audit of a government seed laboratory in the United Kingdom.

- a. Comments:

None.

DEPARTMENT OF COMMERCE (DOC)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

176

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

444

3. Number of Voluntary Consensus Standards Used in FY 2000:

5

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

Overall Circular A-119 is a very effective policy document. However, improvements should be made to clarify the reporting system. For example, the "transactional" versus "categorical" reporting typologies are not clearly understood by many agencies.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

- a. Conformity Assessment Guidance – Office of Management and Budget (OMB) Circular A-119, revised February 19, 1998, recognized the conformity assessment requirements and obligations defined in the Act and the role of DOC in this area. The Circular directed the Secretary of Commerce to issue guidance to agencies to ensure effective coordination of Federal conformity assessment activities. On November 3, 1999, NIST published proposed guidance on federal conformity assessment activities in the *Federal Register*. The proposed guidance focuses on ways for federal agencies to eliminate unnecessary duplication and complexity in their conformity assessment activities. The comment period on the proposed guidance ended January 18, 2000, and

comments, including recommendations appearing in a recent Government Accounting Office report, were reviewed. The Final Guidance was published in the *Federal Register*, August 10, 2000, Volume 65, Number 155.

- b. Interagency Committee on Standards Policy (ICSP) Chair and Activities – The National Institute of Standards and Technology (NIST) chairs the ICSP and continues to work with federal agencies to assist them in implementing the Conformity Assessment Guidance by providing them with information and one-on-one assistance.
- c. Conformity Assessment Activities -- National Cooperation for Laboratory Accreditation (NACLA) – Section 12b of the National Technology Transfer and Advancement Act (NTTAA) of 1995 directed NIST to coordinate conformity assessment activities of Federal, state, and local entities to eliminate any unnecessary duplication of conformity assessment activities. In response, NIST has been a driving force behind the creation of NACLA. NACLA is composed of organizations in the United States, with observers from Mexico and Canada, that actively support development of a system for recognizing the competence of testing and calibration laboratories leading to worldwide acceptance of test and calibration reports from those laboratories. Concerned with costly, multiple, duplicate assessments, and the lack of domestic or international recognition of laboratory accreditations, the group has explored solutions that could lead the United States, and perhaps eventually its North American Free Trade Agreement (NAFTA) partners, toward the goal of having only one assessment of a laboratory in a given field of testing, based on internationally accepted procedures. The NACLA vision is for a U.S. laboratory accreditation system that achieves the following goals:
 - (1) for the testing laboratory, a single accreditation in a given field of testing, with worldwide recognition of the laboratory's competence.
 - (2) for the manufacturer/supplier, a test performed once, with worldwide acceptance.
 - (3) for the acceptance body (that is a government agency or an industry specifier), an accreditation based on uniform criteria and intended to ensure that a laboratory is qualified to provide data of consistent quality.

During FY 2000, NIST entered into a Memorandum of Understanding (MOU) with NACLA that recognizes its program for recognizing the competence of laboratory accreditation bodies. Terms of the MOU call for NIST to encourage government agencies to use NACLA-recognized accreditation bodies and to encourage laboratory accrediting bodies to seek NACLA recognition. In addition, NIST will treat NACLA recognition as a suitable alternative to its own laboratory-accreditor recognition program, which NIST established to support its role as a designating authority under international, government-to-government trade agreements. Signing of the NIST-NACLA MOU came

after a public workshop on June 23, 2000, in which public feedback was overwhelmingly supportive. Three laboratory accreditation bodies have now signed a mutual recognition arrangement under NACLA thus supporting the goal of providing a U.S. system for recognizing laboratory accrediting bodies as competent under national and international guidelines. These same bodies are also members of the International Laboratory Accreditation Cooperation (ILAC) Arrangement.

- d. Conformity Assessment Activities – ILAC - In FY 2000, NIST Technology Services/Office of Standards Services (OSS) chaired and hosted ILAC's biennial conference in Washington, D.C. ILAC continues working to help develop and promote the use of international standards and guides and to establish mutual confidence among national and regional organizations and among participating accreditation bodies. Established in 1977, ILAC is the premier international forum for the harmonization of laboratory accreditation procedures and policies as a means of reducing technical barriers to trade and the promotion of laboratory accreditation as a mechanism to enhance confidence in testing and calibration facilities, both domestically and internationally.
- e. Mutual Recognition Arrangements (MRAs) - The NIST National Voluntary Laboratory Accreditation Program (NVLAP) and 36 other laboratory accreditation bodies from 28 economies on five continents signed the ILAC MRA on Thursday, November 2, 2000, in Washington, D.C., which was one of the highlights of the ILAC Conference. The text of the ILAC MRA can be found at <http://www.ilac.org/downloads/ilacmra.pdf>.

When the MRA takes effect on January 31, 2001, test and calibration reports produced by NVLAP-accredited laboratories will be accepted by all of the other signatories (and vice versa). This also means that products tested in one economy by a laboratory that is accredited by a signatory to the MRA will be more readily accepted in the economy of other signatories. This is a major step towards reducing or eliminating the need for retesting of products in the importing economy.

A cornerstone of the new MRA is the utilization of existing or developing regional arrangements established in the Americas {Interamerican Accreditation Cooperation (IAAC) and NACLA}, the Asia Pacific region {Asia-Pacific Laboratory Accreditation Cooperation (APLAC)}, and European Cooperation for Accreditation (EA). The regional arrangement bodies are responsible for maintaining the necessary confidence in accreditation bodies from their region that are signatories to the new ILAC MRA. ILAC and each of the regional bodies use the same international standards, including International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 58 and ISO/IEC 17025.

f. International Accreditation Forum (IAF) and Other Conformity Assessment Committees
NIST serves on the IAF, an organization committed to assisting in the development of Multilateral MRAs among accreditation bodies. NIST is also represented on the ISO Council Committee on Conformity Assessment (CASCO), and has served on working groups involved in the development of international (ISO) guides/standards on conformity assessment. NIST participates in other ISO committees concerned with conformity assessment-related standards, such as ISO Technical Committee (TC) 176. NIST also participates on U.S. subcommittees of the IEC System for Conformity Testing to Standards for Safety of Electrical Equipment (IECEE) (CB Scheme). Finally, NIST's NVLAP is updating its documents to make them consistent with ISO/IEC 17025. A notice of NVLAP's intent can be found in the *Federal Register* 65, FR 66659, November 7, 2000.

g. Conformity Assessment Activities – Other - During 2000, NIST published Special Publication (SP) 831, Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs. This directory is a guide to laboratory accreditation and similar types of programs conducted by professional and trade organizations. These programs accredit or designate laboratories or other entities to assist private sector professional societies, trade associations, related certification bodies, their membership, as well as Government agencies, in carrying out their responsibilities. This accreditation or designation is based on an assessment of the capability of the laboratory to conduct the testing. However, the nature of the assessment varies considerably by organization and program. NIST also published SP 951, Guide to EU Standards and Conformity Assessment, which is an introductory reference on the general principles and concepts behind the European Union's (EU's) "New Approach" laws and directives. It provides information on the EU's approach. In addition to these two publications, NIST maintains an extensive Conformity Assessment Web site to provide more information on this topic.

8. Provide Any Examples or Case Studies of Standards Successes:

- a. Within the International Trade Administration's (ITA's) Office of Consumer Goods, in collaboration with Toy Manufacturers of America, organized a U.S.-sponsored Asia Pacific Economic Cooperation (APEC) ECOTECH seminar titled, "APEC Implementation of ISO 8124," which was held in Hong Kong from March 20-22, 2000.
 - (1) The seminar's purpose was to inform attendees about the technical aspects of, and to encourage APEC economies to align their toy safety standards with, ISO's new standard titled, "ISO 8124-1: The Safety of Toys Part 1: Safety Aspects Related to Mechanical and Physical Properties."
 - (2) The APEC seminar attracted 254 participants from 14 economies. Seminar topics included a detailed discussion of the ISO standard and its relationship to the current U.S. and EU voluntary standards (ASTM F963a and EN 71-1: 1998) and the role of governments in ensuring toy safety.

- (3) Hands-on testing demonstrations highlighted technical methods of ensuring compliance with the ISO standard. Most economies expressed the desire and willingness to work toward toy standards harmonization. In those economies that currently lack a toy standard, full adoption of ISO 8124 was mentioned. However, global harmonization relies on current U.S. and EU efforts to align their standards with ISO 8124.
- b. Another success story in FY 2000 from the ITA occurred in the Office of Aerospace. This office worked with the International Civil Aviation Organization (ICAO) on its Volume 1, Annex 16, Chapter 3, standard on civil aircraft noise. The standard was adopted in 1977 by all ICAO members and, with further work in FY 2000, the standard has been successfully implemented worldwide for manufacture of new aircraft.
- c. NIST has played a strong role in National Committee for Information Technology Standards (NCITS) Technical Committee T4, Security Techniques, since 1991. NIST has been the principal motivating force behind the successful development of the recently approved, three-part, ISO/IEC 15408, Common Criteria for Information Technology Security Evaluation, in both NCITS and ISO/IEC JTC 1. The three-part ISO/IEC 15408 is arguably one of the largest and most complex of all ISO/IEC JTC 1 standards developed to date.

During the development of ISO/IEC 15408, NIST was a Category "C" Liaison Officer between ISO/IEC JTC 1 SC 27 and the Common Criteria Editorial and Implementation Boards. Those boards were composed of representatives from six European and North American governments, gathered together specifically to develop standard language for expressing detailed information technology security requirements that could serve as a basis for evaluating and testing products asserted to be conformant to them. NIST's representative was one of the governmental founders and major technical contributors to that groundbreaking intergovernmental project.

ISO/IEC 15408, which was published in December 1999, has already been formally implemented by 15 national governments, a number that is rapidly growing. Even during the final stages of development, it had become the de-facto standard for the global information technology security community. ISO/IEC 15408 has already shown its ability to help global security in a very important way by providing a common basis for understanding, expressing and testing the security capabilities of computer and communications products.

9. Comments:

DOC

The DOC encourages its staff to participate in standards committee activities relating to the mission of the Department, subject to resource availability. Agency employees participate in the standards development activities of: (1) U.S. private sector standardization bodies;

(2) local, state, and federal governments; and (3) both private and governmental (treaty and nontreaty) international standardization organizations. Standards of interest to the Department cover a broad range of technical areas including: (1) energy conservation, (2) information and computer technology, (3) telecommunications, (4) environmental safety and health, (5) meteorological work, and (6) a variety of other product sectors and fields of technology.

The Commerce Standards Committee (CSC) was formed in FY 2000 to improve communication and coordination on standards-related activities among DOC agencies. Representatives from each of the major units within Commerce were appointed by the Secretary of Commerce. At its first meeting, the Chair and Secretariat of the Committee, both from NIST's OSS, disseminated information about the NTTAA, OMB A-119, strategic standards management, as well as other standards activities both national and international in nature. The reporting guidelines for the OMB Circular A-119 report to Congress were also distributed and discussed. The committee subsequently approved its charter.

The Standards Assistance and Management Information (SAMI) project in OSS, NIST, collects and disseminates information on DOC staff participation in standards development activities. NIST publishes an annual directory containing statistics on all DOC standards committee participation, alphabetical listings of staff participants and standards organizations and committees, and a list of acronyms and abbreviations. This year a new feature was added, which connects the data in the SAMI database with data from other federal agencies' databases such as DOD and NASA. Other agencies will continue to be added to the system in the future, thereby increasing the ability of Federal agencies to share information on technical and other standards activities.

The DOC standards participant information contained in the SAMI database is divided into two parts -- NIST and other (non-NIST) DOC agencies. During FY 2000, 444 DOC staff participated in the standards writing activities of 176 (120 national and 55 international) standards developing organizations. NIST had 391 participants in the activities of 141 standards organizations (98 national and 43 international). NIST participated on 446 committees and held 1,330 memberships on these committees. Fourteen of the standards organizations in which NIST staff members participated had 20 or more NIST memberships. Fifty-three staff members of other DOC agencies participated in 55 committees of 28 standards organizations (23 national and 12 international). They held 103 memberships on those committees. Seven of those standards organizations had five or more other DOC participants.

The following organizations/agencies accounted for 59 percent (61) of the 103 other DOC committee memberships:

| <u>Organizations with Other DOC Members</u> | <u>No. of Committee Memberships</u> |
|---|-------------------------------------|
| Department of State | 15 |
| American National Standards Institute | 10 |
| International Organization for Standardization | 8 |
| NCITS (National Committee for Information Technology Standards) | 8 |
| Federal Committee for Meteorological Service and Supporting Research | 7 |
| International Telecommunication Union - Telegraph | 7 |
| Department of Defense/Federal Aviation Administration/Department of Commerce | <u>6</u> |
| Total | <u>61</u> |

Listed below are 12 standards organizations and the American National Standards Institute (ANSI) in which NIST holds at least 20 committee memberships along with the exact number of committee memberships. The organizations/agencies accounted for 74 percent (983) of the 1,330 other DOC committee memberships:

| <u>Organizations with NIST Members</u> | <u>No. of Committee Memberships</u> |
|--|-------------------------------------|
| American Society for Testing and Materials | 539 |
| American National Standards Institute | 103 |
| International Organization for Standardization | 65 |
| Institute of Electrical and Electronic Engineers | 46 |
| American Society of Mechanical Engineers | 42 |
| International Electrotechnical Commission | 37 |
| CIE (International Commission on Illumination) | 30 |
| NCITS (National Committee for Information Technology Standards) | 27 |
| CGPM (Conférence Générale des Poids et Mesures) | 24 |
| International Organization of Legal Metrology | 24 |
| Telecommunications Industry Association | 23 |
| American Concrete Institute | 23 |
| Telecommunications Industries of America | <u>23</u> |
| Total | <u>983</u> |

DOC AGENCIES (EXCLUDING NIST): SUMMARY OF STANDARDS-RELATED ACTIVITIES

- a. International Trade Administration (ITA) -- The ITA participates in 4 CODEX committees, 1 ICAO committee and one Committee of the U.S.-Russia Working Group Standards for Chemicals. This year, ITA's work in standards furthered toy safety standardization and international civil aviation standards adoption and acceptance worldwide.
- b. National Oceanic and Atmospheric Administration (NOAA) -- Standardization of data acquisition and data management practices is 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) 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.
- c. 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.
- d. Patent and Trademark Office (PTO) -- The PTO participates and contributes to the resolution of identified requirements for international standards, primarily through the Permanent Committee on Industrial Property Information of the World Intellectual Property Organization. PTO staff also participates in standardization activities of the International Patent Classification Union and the ANSI-Accredited Committee on Patent Standards.
- e. 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 metaoata documenting the characteristics of those data; and (2) the definitions of statistical, economic, and geographic terms. The Census Bureau participated in the following groups in FY2000: 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).

NIST: SUMMARY OF STANDARDS RELATED ACTIVITIES

This year, the most noteworthy accomplishment for NIST's NTTAA work was the publication of the Guidance on Federal Conformity Assessment Activities, which was mandated by OMB Circular A-119. Other noteworthy activities included the ILAC 2000 conference, the signing of the NIST-NACLA MOU and the ILAC MRA, the creation of the online search mechanism for standards participants and the online data entry for the Annual Report to Congress. NIST continued its work assisting Federal agencies through the ICSP, NIST Standards Advisory Committee, CSC, and National Center for Standards and Certification Information (NCSCI). See the Conformity Assessment Activities Section for more information on NIST's conformity assessment activities. See the section on Activities of the ICSP for more information on the NIST's ICSP work.

On an ongoing basis, NIST operates a number of standards-related programs and services to assist business, industry, and government in using and understanding standards, technical regulations, and conformity assessment procedures affecting trade in the global marketplace.

NATIONAL CENTER FOR STANDARDS AND CERTIFICATION INFORMATION (NCSCI)

NCSCI is the U.S. focal point for standards-related information at home and abroad; it provides information on U.S., foreign, regional, and international voluntary standards bodies, mandatory government regulations, and conformity assessment procedures for nonagricultural products. NCSCI is the U.S. member of the ISO Information Network, and serves as the U.S. inquiry point under the World Trade Organization Agreement on Technical Barriers to Trade, the NAFTA, and the APEC Subcommittee on Standards and Conformance. NCSCI maintains 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.

- a. Staff members respond to requests for specialized standards information, arrange for translations of foreign standards and regulations, and disseminate information to U.S. industry concerning proposed foreign regulations and general standards issues.
- b. Two telephone hotlines provide weekly updates on draft European standards and on proposed foreign technical regulations that might significantly affect trade.

NIST STANDARDS ADVISORY COMMITTEE (SAC)

To coordinate internal standards activities, NIST established the SAC. The SAC continued to work on the implementation of the NIST Voluntary Standards Policy, which was approved by NIST management in 1999. This policy directs NIST organizational units to review their standards-related activities to ensure that they are in-line with the agency's mission and goals so that resources and participation are targeted most effectively. NIST currently has 391 employees participating in many standards committee activities. The policy is expected to assist in aligning this participation as closely as possible with applicable NIST and industry needs. Because NIST also coordinates standards activities within DOC, including publishing the Annual Directory and providing DOC input for the Annual Report, NIST chaired and staffed the CSC in 2000 to improve communication and coordination on standards-related activities among DOC agencies.

FEDERAL INFORMATION PROCESSING STANDARDS (FIPS)

Under the Information Technology Management Reform Act (Public Law (P.L.) 104-106), the Secretary of Commerce approves standards and guidelines that are developed by NIST for Federal computer systems. Under section 513 of the Information Technology Management Reform Act of 1996 and the Computer Security Act of 1987, P.L. 104-106, NIST develops standards, guidelines, and associated methods and techniques for federal computer systems, including those needed to ensure the cost-effective security and privacy of sensitive information in federal computer systems, when there are compelling federal requirements and there are no existing voluntary industry standards. These standards and guidelines are issued by NIST as FIPS for use Government-wide. FIPS address federal requirements for the interoperability of different systems, for the portability of data and software, and for computer security. When FIPS are considered necessary, NIST announces proposed FIPS in the *Federal Register* for public review and comment. No new FIPS were published in FY 2000, which required justification.

Federal Register notices published in 2000 regarding FIPS are:

- a. *Federal Register*: February 25, 2000 (Volume 65, Number 38) -- This notice announced the approval of the withdrawal of 33 Federal Information Processing Standards (FIPS) Publications. These FIPS were withdrawn because the technical specifications that they adopted were obsolete and were no longer supported by industry.
- b. *Federal Register*: February 15, 2000, (Volume 65, Number 31) -- This notice announced the approval of Federal Information Processing Standard 186-2, Digital Signature Standard. This FIPS adopts three techniques for the generation and verification of digital signatures. These are the Digital Signature Algorithm (DSA) and two techniques specified in industry standards (ANSI X9.31-1998,

Digital Signatures Using Reversible Public Key Cryptography for the Financial Services Industry and ANSI 9.62, 1998, Public Key Cryptography for the Financial Services Industry: Elliptical Curve Digital Signature Algorithm).

DEPARTMENT OF DEFENSE (DOD)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

71

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

446

3. Number of Voluntary Consensus Standards Used in FY 2000:

347

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

509

| <u>Voluntary Standard</u> | <u>Government Standard</u> |
|---------------------------|----------------------------|
| UL32 | A-A-1674 |
| SAE-AS9529 | MS9529 |
| SAE-AMS-STD-2175 | MIL-STD-2175 |
| SAE-AS91691 | MS91691 |
| SAE-AS9467 | MS9467 |
| SAE-AS9482 | MS9482 |
| SAE-AS9480 | MS9480 |
| SAE-AS9492 | MS9492 |
| SAE-AS9494 | MS9494 |
| SAE-AS9501 | MS9501 |
| SAE-AS9502 | MS9502 |
| SAE-AS9505 | MS9505 |
| SAE-AS9517 | MS9517 |
| SAE-AS9518 | MS9518 |
| SAE-AS9457 | MS9457 |
| SAE-AS9554 | MS9554 |
| SAE-AS9556 | MS9556 |
| SAE-AS9573 | MS9573 |
| SAE-AS9895 | MS9895 |
| SAE-AS9902 | MS9902 |
| SAE-AS9918 | MS9918 |
| SAE-AS9928 | MS9928 |
| SAE-AS9944 | MS9944 |
| SAE-AS0058 | MS9958 |
| SAE-AS9964 | MS9964 |
| NASM 14156 | MS14156 |

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| NASM 14164 | MS14164 |
| NASM 14177 | MS14177 |
| NASM 14181 | MS14181 |
| NASM 14182 | MS14182 |
| NASM 14183 | MS14183 |
| NASM 14200 | MS14200 |
| NASM 14210 | MS14210 |
| ASME-B18.27.1 | MS16524 |
| SAE-AS5173 | MS5173 |
| ASME-B18.24.3 | MS16633 |
| SAE-J1231 | MS21418 |
| ASTM-D3951 | PPP-H-1581 |
| SAE-AS5379 | MIL-V-5379 |
| SAE-AS8581 | MIL-E-8581 |
| NASM 25027 | MIL-DTL-25027 |
| SAE-AS85720 | MIL-F-85720 |
| SAE-AS1442 | MS21441 |
| SAE-AS21900 | MS21900 |
| SAE-AS21904 | MS21904 |
| SAE-AS9385 | MS9385 |
| SAE-AS9466 | MS9466 |
| SAE-AS9468 | MS9468 |
| SAE-AS9489 | MS9489 |
| SAE-AS9491 | MS9491 |
| SAE-AS9493 | MS9493 |
| SAE-AS9496 | MS9496 |
| SAE-AS9403 | MS9403 |
| SAE-AS9503 | MS9503 |
| SAE-AS9516 | MS9516 |
| SAE-AS9523 | MS9523 |
| SAE-AS9520 | MS9520 |
| SAE-AS9521 | MS9521 |
| SAE-AS9522 | MS9522 |
| SAE-AS9524 | MS9524 |
| SAE-AS9525 | MS9525 |
| SAE-AS9526 | MS9526 |
| NASM 21068 | MS21068 |
| SAE-AS9528 | MS9528 |
| SAE-AS9432 | MS9432 |
| SAE-AS9433 | MS9433 |
| SAE-AS9434 | MS9434 |
| SAE-AS9440 | MS9440 |
| SAE-AS9441 | MS9441 |
| SAE-AS9442 | MS9442 |
| SAE-AS9444 | MS9444 |
| SAE-AS9449 | MS9449 |

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| NASM 21070 | MS21070 |
| SAE-AS9452 | MS9452 |
| SAE-AS9453 | MS9453 |
| SAE-AS9454 | MS9454 |
| ASTM-B166 | QQ-W-390 |
| SAE-AMS-S-5000 | MIL-S-5000 |
| SAE-AS54761 | MIL-S-5676 |
| SAE-AMS-DTL-23053 | MIL-DTL-23053 |
| SAE-AS85075 | MIL-T-85075 |
| SAE-AS21441 | MS21441 |
| SAE-AS21446 | MS21446 |
| SAE-AS21902 | MS21902 |
| SAE-AS21906 | MS21906 |
| SAE-AMS-C-27725 | MIL-C-27725 |
| ASTM-D2000 | MIL-R-3065 |
| NASM 85604 | MIL-B-85604 |
| SAE-AS9276 | MS9276 |
| SAE-AS9285 | MS9285 |
| SAE-AS9292 | MS9292 |
| SAE-AS9296 | MS9296 |
| SAE-AS9303 | MS9303 |
| SAE-AS9305 | MS9305 |
| SAE-AS9307 | MS9307 |
| SAE-AS9309 | MS9309 |
| SAE-AS9311 | MS9311 |
| SAE-AS9312 | MS9312 |
| SAE-AS9316 | MS9316 |
| SAE-AS9317 | MS9317 |
| SAE-AS9318 | MS9318 |
| SAE-AS9319 | MS9319 |
| SAE-AS9320 | MS9320 |
| SAE-AS9321 | MS9321 |
| SAE-AS9356 | MS9356 |
| SAE-AS9357 | MS9357 |
| SAE-AS9358 | MS9358 |
| SAE-AS9359 | MS9359 |
| SAE-AS9360 | MS9360 |
| SAE-AS9361 | MS9361 |
| SAE-AS9362 | MS9362 |
| SAE-AS9371 | MS9371 |
| SAE-AS9372 | MS9372 |
| SAE-AS9373 | MS9373 |
| SAE-AS9374 | MS9374 |
| SAE-AS9375 | MS9375 |
| SAE-AS21905 | MS21905 |
| SAE-AS21907 | MS21907 |

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| SAE-AS21908 | MS21908 |
| SAE-AS21909 | MS21909 |
| SAE-AS9398 | MS9398 |
| SAE-AS21910 | MS21910 |
| SAE-AS21911 | MS21911 |
| SAE-AS21912 | MS21912 |
| SAE-AS21913 | MS21913 |
| SAE-AS21914 | MS21914 |
| SAE-AS21915 | MS21915 |
| SAE-AS21916 | MS21916 |
| SAE-AS21921 | MS21921 |
| SAE-AS21922 | MS21922 |
| SAE-AS21923 | MS21923 |
| SAE-AS21925 | MS21925 |
| SAE-AS21924 | MS21924 |
| SAE-AS21926 | MS21926 |
| SAE-AS21937 | MS21937 |
| SAE-AS21939 | MS21939 |
| SAE-AS21940 | MS21940 |
| SAE-AS21941 | MS21941 |
| SAE-AS21942 | MS21942 |
| SAE-AS21943 | MS21943 |
| NASM 21074 | MS21074 |
| SAE-AS25064 | MS25064 |
| SAE-AS25281 | MS25281 |
| SAE-AS33515 | MS33515 |
| SAE-AS33566 | MS33566 |
| SAE-AS33559 | MS33559 |
| SAE-AS1933 | MIL-STD-1523 |
| ASTM-D6254 | PPP-B-587 |
| NASM 85353 | MIL-N-85353 |
| SAE-AS91721 | MS91721 |
| SAE-AS9208 | MS9208 |
| SAE-AS9209 | MS9209 |
| SAE-AS9210 | MS9210 |
| SAE-AS9212 | MS9212 |
| SAE-AS9216 | MS9216 |
| SAE-AS9218 | MS9218 |
| SAE-AMS-STD-183 | FED-STD-183 |
| ANSI-Z26.1 | MIL-G-3787 |
| NASM 559 | MIL-F-559 |
| NASM 5674 | MIL-R-5674 |
| SAE-AS60002 | MIL-M-60002 |
| SAE-AS6439 | MIL-H-6439 |
| NASM 7873 | MIL-N-7873 |
| NASM 7874 | MIL-B-7874 |

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| NASM 8906 | MIL-B-8906 |
| NASM 8907 | MIL-B-8907 |
| NASM 8922 | MIL-N-8922 |
| NASM 8975 | MIL-F-8975 |
| NASM 8984 | MIL-N-8984 |
| NASM 8985 | MIL-N-8985 |
| PIA-W-9049 | MIL-W-9049 |
| ASTM F696 | MIL-G-10849 |
| ASTM 10971 | MIL-P-10971 |
| NASM 16610 | MIL-P-16610 |
| NASM 20652 | MIL-E-20652 |
| NASM 21143 | MIL-P-21143 |
| NASM 23460 | MIL-P-23460 |
| NASM 23964 | MIL-B-23964 |
| NASM 24066 | MIL-C-24066 |
| SAE-AS38386 | MIL-D-38386 |
| SAE-AS38390 | MIL-H-38390 |
| SAE-AS38404 | MIL-C-38404 |
| PIA-T-43618 | MIL-T-43618 |
| ASTM-D1732 | MIL-M-45202 |
| NASM 45595 | MIL-W-45595 |
| SAE-AS5172 | MS24397 |
| NASM 45938 | MIL-N-45938 |
| ASTM-D5213 | MIL-P-46112 |
| ASME-B30.9 | MIL-S-52432 |
| NASM 63540 | MIL-S-63540 |
| ASME-B5.55M | MIL-P-80052 |
| NASM 81177 | MIL-F-81177 |
| NASM 82496 | MIL-S-82496 |
| NASM 35215 | MS35215 |
| NASM 83050 | MIL-B-83050 |
| ASME-18.27.2 | MS16631 |
| NASM 83459 | MIL-R-83459 |
| ASME-B18.27.1 | MS16625 |
| NASM 85730 | MIL-N-85730 |
| ASME-B18.27.2 | MS3215 |
| ASME-B 18.27.2 | MS3217 |
| SAE-AS3582 | MS9068 |
| SAE-AS9110 | MS9110 |
| SAE-AS9111 | MS9111 |
| SAE-AS9158 | MS9158 |
| SAE-AS91601 | MS91601 |
| SAE-AS91641 | MS91641 |
| SAE-AS91701 | MS91701 |
| SAE-AS9219 | MS9219 |
| SAE-AS9283 | MS9283 |

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| SAE-AS9286 | MS9286 |
| SAE-AS9294 | MS9294 |
| SAE-AS9297 | MS9297 |
| SAE-AS9304 | MS9304 |
| SAE-AS9306 | MS9306 |
| SAE-AS9308 | MS9308 |
| SAE-AS9310 | MS9310 |
| SAE-AS9376 | MS9376 |
| SAE-AS9386 | MS9386 |
| SAE-AS9397 | MS9397 |
| SAE AS9398 | MS9398 |
| SAE AS9403 | MS9403 |
| SAE AS9432 | MS9432 |
| ASME-B18.24.3 | MS16626 |
| SAE-AS9440 | MS9440 |
| SAE-AS9441 | MS9441 |
| ASME-B18.24.3 | MS16628 |
| SAE-AS9444 | MS9444 |
| SAE-AS9449 | MS9449 |
| SAE-AS9450 | MS9450 |
| ASME-B18.24.3 | MS16630 |
| SAE-AS933 | MS24487 |
| NASM 24627 | MS24627 |
| SAE-AS9459 | MS9459 |
| SAE-AS9460 | MS9460 |
| NASM 51605 | MS51605 |
| SAE-AS9464 | MS9464 |
| SAE-AS9465 | MS9465 |
| NASM 21060 | MS21060 |
| NASM 21062 | MS21062 |
| SAE-AS9463 | MS9463 |
| ASME-B18.24.1 | MS16624 |
| ASME-B18.24.1 | MS16625 |
| SAE-AS9466 | MS9466 |
| NASM 21063 | MS21063 |
| ASME-B18.24.3 | MS16627 |
| ASME-B18.24.3 | MS16629 |
| SAE-AS9490 | MS9490 |
| SAE-AS9491 | MS9491 |
| SAE-AS9492 | MS9492 |
| ASME-B18.27.4 | MS16631 |
| SAE-AS9494 | MS9494 |
| NASM 21064 | MS21064 |
| SAE-AS9500 | MS9500 |
| NASM 21066 | MS21066 |
| NASM 16535 | MS16535 |

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| NASM 16208 | MS16208 |
| NASM 15795 | MS15795 |
| NASM 14531 | MS14531 |
| NASM 14493 | MS14493 |
| NASM 14491 | MS14491 |
| SAE-AS9519 | MS9519 |
| NASM 14490 | MS14490 |
| SAE-AS14274 | MS14274 |
| NASM 21067 | MS21067 |
| SAE-AS9523 | MS9523 |
| NASM 14222 | MS14222 |
| NASM 14214 | MS14214 |
| NASM 14213 | MS14213 |
| SAE-AS9527 | MS9527 |
| SAE-AS9553 | MS9553 |
| SAE-AS9555 | MS9555 |
| SAE-AS9557 | MS9557 |
| SAE-AS9558 | MS9558 |
| SAE-AS9559 | MS9559 |
| SAE-AS9564 | MS9564 |
| SAE-AS9565 | MS9565 |
| SAE-AS9566 | MS9566 |
| SAE-AS9572 | MS9572 |
| SAE-AS9574 | MS9574 |
| SAE-AS9575 | MS9575 |
| SAE-AS9576 | MS9576 |
| SAE-AS9577 | MS9577 |
| SAE-AS9579 | MS9579 |
| SAE-AS9581 | MS9581 |
| SAE-AS9583 | MS9583 |
| SAE-AS9584 | MS9584 |
| SAE-AS9585 | MS9585 |
| SAE-AS9586 | MS9586 |
| SAE-AS9587 | MS9587 |
| SAE-AS9589 | MS9589 |
| SAE-AS9685 | MS9685 |
| SAE-AS9696 | MS9696 |
| SAE-AS9698 | MS9698 |
| SAE-AS9699 | MS9699 |
| SAE-AS9705 | MS9705 |
| SAE-AS9712 | MS9712 |
| SAE-AS9714 | MS9714 |
| SAE-AS9715 | MS9715 |
| SAE-AS9716 | MS9716 |
| SAE-AS9732 | MS9732 |
| SAE-AS9742 | MS9742 |

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| SAE-AS9750 | MS9750 |
| SAE-AS9751 | MS9751 |
| SAE-AS9759 | MS9759 |
| SAE-AS9760 | MS9760 |
| SAE-AS9761 | MS9761 |
| SAE-AS9770 | MS9770 |
| SAE-AS9783 | MS9783 |
| SAE-AS9784 | MS9784 |
| SAE-AS9785 | MS9785 |
| SAE-AS9786 | MS9786 |
| SAE-AS9788 | MS9788 |
| SAE-AS9790 | MS9790 |
| SAE-AS9841 | MS9841 |
| SAE-AS9844 | MS9844 |
| SAE-AS9880 | MS9880 |
| SAE-AS9887 | MS9887 |
| SAE-AS9894 | MS9894 |
| ASME-B18.24.3 | MS17828 |
| NASM 17829 | MS17829 |
| NASM 17830 | MS17830 |
| NASM 17988 | MS17988 |
| NASM 20002 | MS20002 |
| NASM 20073 | MS20073 |
| NASM 20074 | MS20074 |
| NASM 20230 | MS20230 |
| SAE-AS20253 | MS20253 |
| NASM 20501 | MS20501 |
| NASM 20600 | MS20600 |
| NASM 20601 | MS20601 |
| NASM 20613 | MS20613 |
| SAE-AS5176 | MS20819 |
| NASM 21025 | MS21025 |
| NASM 21043 | MS21043 |
| NASM 21045 | MS21045 |
| NASM 21046 | MS21046 |
| NASM 21049 | MS21049 |
| NASM 21051 | MS21051 |
| NASM 21055 | MS21055 |
| NASM 21058 | MS21058 |
| NASM 21076 | MS21076 |
| NASM 21077 | MS21077 |
| NASM 21081 | MS21081 |
| NASM 21083 | MS21083 |
| NASM 21085 | MS21085 |
| NASM 21090 | MS21090 |
| NASM 21096 | MS21096 |

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| NASM 21097 | MS21097 |
| NASM 21133 | MS21133 |
| NASM 21207 | MS21207 |
| NASM 21224 | MS21224 |
| NASM 21225 | MS21225 |
| NASM 21244 | MS21244 |
| NASM 21245 | MS21245 |
| NASM 21295 | MS21295 |
| NASM 21296 | MS21296 |
| NASM 21297 | MS21297 |
| NASM 21392 | MS21392 |
| SAE-AS5406 | MS24393 |
| NASM 24628 | MS24628 |
| NASM 24674 | MS24674 |
| NASM 24693 | MS24693 |
| NASM 24694 | MS24694 |
| NASM 25087 | MS25087 |
| NASM 27039 | MS27039 |
| SAE-AS4370 | MS27073 |
| NASM 27577 | MS27577 |
| NASM 27953 | MS27953 |
| NASM 27954 | MS27954 |
| SAE-AS28775 | MS28775 |
| NASM 33547 | MS33547 |
| NASM 33557 | MS33557 |
| NASM 33588 | MS33588 |
| NASM 33602 | MS33602 |
| SAE-AS5131 | MS5131 |
| NASM 33737 | MS33737 |
| NASM 33749 | MS33749 |
| NASM 35190 | MS35190 |
| NASM 35191 | MS35191 |
| NASM 35198 | MS35198 |
| NASM 35199 | MS35199 |
| NASM 35202 | MS35202 |
| NASM 35206 | MS35206 |
| NASM 35207 | MS35207 |
| NASM 35214 | MS35214 |
| NASM 35276 | MS35276 |
| NASM 35307 | MS35307 |
| NASM 35308 | MS35308 |
| NASM 35671 | MS35671 |
| NASM 35791 | MS35791 |
| NASM 35793 | MS35793 |
| NASM 51045 | MS51045 |
| NASM 51047 | MS51047 |

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| NASM 51095 | MS51095 |
| NASM 51096 | MS51096 |
| NASM 51105 | MS51105 |
| NASM 51106 | MS51106 |
| NASM 51400 | MS51400 |
| NASM 51474 | MS51474 |
| NASM 51576 | MS51576 |
| NASM 51838 | MS51838 |
| ASTM-B687 | MS51846 |
| NASM 51850 | MS51850 |
| NASM 51851 | MS51851 |
| SAE-AS172236-172270 | AN172236-AN172270 |
| SAE-AS116913-116924 | AN116913-AN116924 |
| SAE-AS123601-123750 | AN123601-AN123750 |
| NASM 51861 | MS51861 |
| NASM 51863 | MS51863 |
| NASM 51870 | MS51870 |
| ASTM-B687 | MS51872 |
| ASTM-A733 | MS51873 |
| NASM 51932 | MS51932 |
| ASTM-A733 | MS51953 |
| NASM 51959 | MS51959 |
| NASM 51965 | MS51965 |
| NASM 51955 | MS51973 |
| NASM 51974 | MS51974 |
| SAE-AS51989 | MS51989 |
| SAE-AS51992 | MS51992 |
| PIA-PS70086 | MS70086 |
| PIA-PS70087 | MS70087 |
| PIA-PS70102 | MS70102 |
| PIA-PS70104 | MS70104 |
| PIA-PS70105 | MS70105 |
| PIA-PS70107 | MS70107 |
| PIA-PS70108 | MS70108 |
| PIA-PS70113 | MS70113 |
| PIA-PS70114 | MS70114 |
| PIA-PS70115 | MS70115 |
| PIA-PS70116 | MS70116 |
| PIA-PS70118 | MS70118 |
| PIA-PS70119 | MS70119 |
| PIA-PS70120 | MS70120 |
| PIA-PS70121 | MS70121 |
| PIA-PS70123 | MS70123 |
| PIA-PS70124 | MS70124 |
| NASM 90353 | MS90353 |
| NASM 90354 | MS90354 |

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| NASM 90415 | MS90415 |
| NASM 90725 | MS90725 |
| NASM 90726 | MS90726 |
| SAE-AS126881-127192 | AN126881-AN127192 |
| SAE-AS122900-122939 | AN122900-AN122939 |
| NASM 171401-171900 | MS171401-MS171900 |
| NASM 124691-124730 | MS124691-MS124730 |
| NASM 124771-124810 | MS124771-MS124810 |
| SAE-AS172201-172235 | AN172201-AN172235 |
| SAE-AS172271-172320 | AN172271-AN172320 |
| SAE-AS172321-172370 | AN172321-AN172370 |
| ASTM-B227 | QQ-W-345 |
| QQ-W-428 | QQ-W-428 |
| SAE-AMS-QQ-S-700 | QQ-S-700 |
| NASM 3-20 | AN3-AN30 |
| NASM 21-37 | AN21-AN37 |
| NASM 386 | AN386 |
| NASM 525 | AN525 |
| NASM 565 | AN565 |
| SAE-AS5162 | AN776 |
| SAE-AS5164 | AN778 |
| SAE-AS5165 | AN779 |
| SAE-AS5194 | AN816 |
| SAE-AS5406 | AN832 |
| SAE-AS5181 | AN838 |
| SAE-AS5182 | AN839 |
| SAE-AS5185 | AN842 |
| SAE-AS5186 | AN844 |
| SAE-AS5187 | AN846 |
| SAE-AS5188 | AN848 |
| SAE-AS5172 | AN893 |
| SAE-AS5173 | AN894 |
| SAE-AS8991 | AN899 |
| SAE-AS5178 | AN924 |
| SAE-AS115451-115500 | AN115451-AN115500 |
| SAE-AS11580-115850 | AN11580-AN11850 |
| SAE-AS11585-115900 | AN11585-AN115900 |
| SAE-AS11650-116100 | AN11650-AN116100 |
| SAE-AS116901-116912 | AN116901-AN116912 |
| SAE-AS117001-117040 | AN117001-AN117040 |
| SAE-AS11704-117080 | AN11704-AN117080 |
| SAE-AS121601-121650 | AN121601-AN121650 |
| SAE-AS12175-121800 | AN12175-AN121800 |
| SAE-AS121801-121850 | AN121801-AN121850 |
| SAE-AS122676-122775 | AN122676-AN122775 |
| SAE-AS12351-123300 | AN12351-AN123300 |

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| SAE-AS123301-123450 | AN123301-AN123450 |
| SAE-AS123460-123600 | AN123460-AN123600 |
| SAE-AS124951-125100 | AN124951-AN125100 |
| SAE-AS125401-125550 | AN125401-AN125550 |
| SAE-AS125551-125700 | AN125551-AN125700 |
| SAE-AS126275-126586 | AN126275-AN126586 |
| SAE-AS126587-126652 | AN126587-AN126652 |
| SAE-AS127193-127492 | AN127193-AN127492 |
| SAE-AS128363-128686 | AN128363-AN128686 |
| SAE-AS129293-129604 | AN129293-AN129604 |
| SAE-AS150201-150300 | AN150201-AN150300 |
| SAE-AS150401-150425 | AN150401-AN150425 |
| SAE-AS150501-150800 | AN150501-AN150800 |
| SAE-AS150801-151100 | AN150801-AN151100 |
| SAE-AS152601-152900 | AN152601-AN152900 |
| SAE-AS152901-153200 | AN152901-AN153200 |
| SAE-AS15500-155300 | AN15500-AN155300 |
| SAE-AS155901-156200 | AN155901-AN156200 |
| SAE-AS158901-159200 | AN158901-AN159200 |
| SAE-AS162501-162800 | AN162501-AN162800 |

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

N/A

| <u>Government Standard</u> | <u>Voluntary Standard</u> | <u>Explanation</u> |
|----------------------------|---------------------------|---|
| | | DoD reports voluntary consensus standards usage on a categorical basis; therefore, this information is not available. |

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

The current OMB Circular A-119 provides clear guidance on using voluntary consensus standards and participating in voluntary consensus standards bodies. As written, this Circular reinforces our DoD policies regarding use of voluntary standards, reliance on performance documents, and encouragement of participation in voluntary standards bodies. We believe the Circular's plain language format greatly enhances its effectiveness. The Department does not believe additional changes are required at this time.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

N/A

8. Provide Any Examples or Case Studies of Standards Successes:

Case Study Purpose: This study addresses the establishing of an alternative to the contractual application of military standard (MIL-STD) 100, Engineering Drawing Practices, for the purpose of the preparation and delivery of drawings that are of a level of maturity and detail of content as necessary to support full scale production. The alternative to the use of MIL-STD-100 for obtaining drawings involved interaction with non-Government Standards Bodies (NGSBs) and close cooperation with industry and other Government agencies in a manner that facilitated the process and the realization of the desired outcome. The replacing of MIL-STD-100 is an example of a very complex conversion process from DoD-unique requirements to non-Government Standards (NGS) involving a number of NGSBs, all of the military services, as well as a number of other Government agencies. In addition, the total conversion effort illustrates the advantages of partnering with industry in the process of seeking a solution as opposed to after the fact coordination and justification.

Background: MIL-STD-100 is the cornerstone document for technical data packages throughout the DOD, as well as large segments of industry. In all cases where the use of commercial drawings or contractor format was not a viable option, MIL-STD-100 was invoked for the preparation of engineering drawings. Those program offices within DoD that required that major end items be supported through the DOD logistics system, required drawing preparation to MIL-STD-100. In order to provide consistent contractual application and insure proper interface with cataloging and logistics needs, the content of MIL-STD-100 was quite detailed, invoking a multitude of somewhat rigid requirements unique to the DOD. The end result of invoking MIL-STD-100 would be the delivery of original drawings, hard copy or digital data, with a DOD activity identified on the drawing as the original design activity (that activity having change control authority over the drawing contents).

Problem: With the advent of acquisition reform, MIL-STD-100 was identified on a number of separate studies, Willoughby 10, Blueprint for change, Coopers and Lybrand, etc., as excessively cost driving and considerably beyond basic commercial practices. Costs associated with the application of MIL-STD-100 involved virtually all major weapons development programs associated with the DOD. Delivery of drawings by other than the invoking of MIL-STD-100 would require a change in mindset DOD-wide including original equipment manufacturer's and parts suppliers. A hearing of the Defense Standardization Improvement Council (DSIC), in February 1995, reviewed the case of MIL-STD-100 and directed the initiation of program of conversion to NGS and subsequent cancellation on a schedule not to exceed 2 years. Fortunately, 3 years prior to the DSIC direction, a group that was chartered as the DOD Industry Drawing Practices Group had undertaken the conversion of MIL-STD-100 to a national standard under the sponsorship of the American Society of Mechanical Engineers (ASME).

Outcomes: The initial result of the conversion effort was an NGS, ASME Y14.100M, replacing approximately 70 percent of MIL-STD-100 and a new MIL-STD-100G that detailed those engineering drawing practices for which there was no commercial equivalent. The two standards were to be used in combination in a manner that was dictated by the contractual or logistics intent. A follow-up effort initiated in November 1998, combined the

two standards by converting the still unique DOD practices to a set of nonmandatory Appendices. The resulting standard is to be identified as ASME Y14.100-2001. The effort to convert MIL-STD-100 to NGS was actually a series of conversions dictated by the diverse subject material of MIL-STD-100. The interaction with NGSBs involved close cooperation and coordination with 16 subject related subcommittees of ASME, and interface with the Institute of Electrical and Electronic Engineers, the Society of Automotive Engineers, and the American Society of Testing and Materials (ASTM). Private industry played a major role in the conversion of MIL-STD-100 to an NGS. The option for membership to the ASME Subcommittee 100 was offered to all industrial entities especially those that do business with the DoD. Although the numbers of individuals (30 plus) that would attend any given meeting often made for a cumbersome standards writing process, a significant return was realized in that those components of industry and Government agencies having the most interest or concerns involving the composition and contractual delivery of drawings had a direct role in composing the new NGS. Attendance in such numbers also facilitated the identification of appropriate numbers of subject matter experts for the purpose of addressing the great variety of subject material, ranging from printed wiring board technology to software issues to dimensioning and tolerancing, that is a basic feature of MIL-STD-100. Therefore, the follow-up coordination and comment resolution process became more of a mere formality rather than the time-consuming obstacle as is often so characteristic of a project of such wide impact and general interest.

Investments and Payoffs: The primary investment associated with this effort was primarily that of the time spent by the various members of ASME Y14/SC100 in composing text, conducting draft reviews, and participating in comment resolution. Although it would be very difficult to make an actual calculation, the collective effort of Government and industry personnel certainly amounted to some number of man-years. Standards such as ASME Y14.100 affect drawing interpretation and content. Therefore, existing programs are discouraged from attempting application retroactively. The cost of drawing conversion would be prohibitive and not to the advantage of the Government. Application of ASME Y14.100 would essentially be restricted to new programs. The default condition for delivery of drawings to ASME Y14.100 will be acceptance of commercial drawings, contractor format. While it is not possible to forecast the manner, extent, or on what schedule new programs will apply the new standard, those programs that elect to accept commercial drawings will realize considerable savings. Programs that invoke the various appendices in lieu of commercial practice will incur essentially the same costs for drawing delivery as that associated with MIL-STD-100. One other benefit definable with the issue of ASME Y14.100 is that associated with the ongoing downsizing within the DOD. In the very near future standardization resources, in terms of both funding and personnel, will very probably not be able to maintain a drawing practices standard unique to the DOD. Therefore, with the exception of the need for at least a few Government representatives at SC100 meetings, document maintenance and the need for subject matter experts is now the responsibility of ASME.

Current Status: Documentation addressing drawing preparation is now exclusively the responsibility of the NGSB ASME, and associated industry supporters. However, the user,

Government or industry, must remember that no NGS is to stand alone on the subject of drawing preparation. The equivalent to MIL-STD-100, especially early issues hereto, is realized with the application of ASME Y14.100, Engineering Drawing Practices, ASME Y14.24, Types and Application of Engineering Drawings, ASME Y14.34M, Associated Lists, and ASME Y14.35M, Revision of Engineering Drawings and Associated Documents in a combination that will be driven by the contractual and logistics intent. Although it can be stated that drawing preparation standards are now totally under the authority of an NGSB, the DOD must not discontinue involvement in ASME subcommittee activities. There remain some practices that, although detailed in the NGS, are specifically applicable to and in direct support of DOD interest. The Government must be a participant, even if on a relatively minor scale, in future NGS maintenance.

Lessons Learned: Allowing industry to become an early and fully active partner in standards preparation can realize enormous advantages. If the industry user is actually allowed to assist in document preparation, time spent on resolving comments resulting from coordination of drafts is drastically reduced. A significant industry presence can also provide a good cross-section of expertise that facilitates text preparation and the inclusion of new technologies.

9. Comments:

A major result of the Department's Military Specifications (Mil-Specs) Reform initiative was the review of 40,000 military specifications and standards for potential replacement by voluntary consensus standards. In instances where replacement voluntary consensus standards were available, the Department acted quickly to cancel the military documents and began using voluntary consensus standards. In cases where voluntary consensus replacements were needed but not available, DOD began working with standards developers to create appropriate standards. The Department has put into place a very stringent system to review every new requirement for a document to determine if a voluntary consensus document would be more appropriate. Every request for a new document must be approved by a member of the Senior Executive Service. DOD activities are directed to review all available sources to locate an appropriate voluntary consensus document rather than create a military-unique document. The five year review process identifies documents that did not have a voluntary consensus counterpart at one time, but for which an appropriate document may now have been created. The Department's initial review and correction procedures, coupled with oversight in the creation of new military documents, and periodic review of existing military documents, ensures very little proliferation of government-unique documentation.

DEPARTMENT OF DEFENSE (DOD)

National Communications System (NCS)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

18

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

10

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

N/A

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

N/A

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

Within the NCS, the Chief, Technology and Programs Division also chairs the Federal Telecommunications Standards Committee (FTSC). As part of these duties, the Chief is the focal point for telecommunications and related information system standards for the Office of the Manager, National Communications System (OMNCS).

The FTSC prepares standards and recommendations on matters affecting national security and emergency preparedness (NS/EP) and in other areas of communications approved by the committee on the basis of requests from members. It also provides advice to members on how to best represent the Government's NS/EP interests in work in industry and international standards committee.

The FTSC and members of the OMNCS work extensively with voluntary standards organizations to ensure that Government requirements are considered as the standards are developed. The OMNCS has 10 employees who participate in industry voluntary standards activities. The following paragraph lists the committees in which they participate.

Staff of the OMNCS participate in the following voluntary standards related committees:

Organizations Accredited by the American National Standards Institute (ANSI):

- Committee T1, Telecommunications, and its technical subcommittees
- Telecommunications Industry Association (TIA) committees TR-41, TR-45, and TR-46
- Institute of Electrical and Electronics Engineers (IEEE)

Commercial and Multi-National Organizations Not Accredited by ANSI:

- ATM Forum
- Internet Engineering Task Force (IETF)
- Network Interconnection Interoperability Forum (NIFF)
- Telecommunications and Internet Protocol Harmonization Over Networks (TIPHON)
- TeleManagement Forum
- Electronic Communications Implementation Committee (ECIC) Federal, State, and Local Committees
- Federal Telecommunication Standards Committee (OMNCS furnishes Chair and Executive Secretary)
- International Telecommunications Advisory Committee and its study groups (Department of State)
- Multiservice Switching Forum (MSF)
- Parlay Group Inc. (for Application Programming Interfaces)
- Mobile Wireless Internet Forum (MWIF)
- International Multimedia Telecommunications Consortium (IMTC)
- Distributed Management Task Force (DMTF)

International Organizations:

- International Telecommunications Union-Telecommunications Sector (ITU-T) (OMNCS heads U.S. delegations to 3 study groups)
- International Telecommunications Union-Radio Sector (ITU-R)

DEPARTMENT OF EDUCATION (DOED)

For the past several years, DOED has been working with the American National Standards Institute (ANSI) on developing EDI transaction sets through their Accredited Standards Committee (ASC) X12 committee. This committee is charged with developing uniform standards for electronic interchange of business transactions. The X12 Committee develops standards to facilitate electronic interchange relating to such business transactions as order placement and processing, shipping and receiving, invoicing, payment, and cash application data associated with the provision of products and services.

DOED's National Center for Education Statistics (NCES) sponsors the work of task groups to attend ANSI ASC X12 meetings. Information about the activities that NCES has been involved in can be obtained at <<http://nces.ed.gov/edi>>. In addition, the Department has been involved in developing EDI transaction sets for Student Financial Assistance.

The work of this voluntary consensus building body has helped DOED forge ahead in developing standards. We include the necessary members of the affected communities to help with transition to and adoption of new standards.

Transaction sets that DOED has promulgated for information about students (both at the elementary/secondary level and at the postsecondary level) and other aspects of education are the following:

Transaction Sets Relating to Individual Student Records

- TS 130 - Student Educational Record (Transcript)
- TS 131 - Student Educational Record (Transcript) Acknowledgment
- TS 138 - Testing Results Request and Report
- TS 146 - Request for Student Educational Record (Transcript)
- TS 147 - Response to Request for Student Educational Record (Transcript)
- TS 189 - Application for Admission to Educational Institutions

Implementation Guides

Transaction Sets Relating to Personnel Records

- TS 132 - Personnel Information

Transaction Sets Relating to Student Financial Aid Records

- TS 135 - Student Loan Application
- TS 139 - Student Loan Guarantee Result
- TS 144 - Student Loan Transfer and Status Verification
- TS 190 - Student Enrollment Verification
- TS 191 - Student Loan Pre-Claims and Claims
- TS 810 - Invoice
- TS 820 - Payment Order/Remittance Advice

Transaction Sets Relating to Institutional Records

- TS 133 - Educational Institutional Profile
- TS 152 - Statistical Government Information used to transmit CCD, IPEDS and Library surveys to NCES
- TS 188 - Educational Course Inventory

Specific reporting questions:

- 1. The number of government-unique standards used in lieu of a voluntary consensus standard and the reason why the agency decided to use the government unique standard. Agencies do not need to report the use of government unique standards if there is not a comparable private sector standard.**

Nothing to report for this period.

- 2. The number of voluntary consensus standards bodies the agency participates in, and the number of employees.**

The Department had one representative who participated in one voluntary consensus standards body during this period.

- 3. The number of voluntary consensus standards the agency has used since the last report.**

The Department used 17 voluntary consensus standards during this period.

- 4. Identification of voluntary consensus standards that have been substituted for government unique standards.**

Nothing to report for this period.

DEPARTMENT OF ENERGY (DOE)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

59

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

676

3. Number of Voluntary Consensus Standards Used in FY 2000:

1,012

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

1

| | |
|---------------------------|----------------------------|
| <u>Voluntary Standard</u> | <u>Government Standard</u> |
| ANSI/ISO/ASQ Z1.13-1998 | DOE-ER-STD-6001-92 |

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

N/A

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

The guidance in the Office of Management and Budget (OMB) Circular A-119 appears to be sufficient in terms of outlining the basic functions and responsibilities of Federal agency standards management and standards participation activities. It allows sufficient latitude for each Federal agency to develop its own approach tailored to specific agency needs, and places the emphasis on outcomes rather than processes. Some simplification and clarification of transactional and categorical reporting may be necessary.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

National Voluntary Laboratory Accreditation Program; Department of Energy Laboratory Accreditation Program; National Cooperation for Laboratory Accreditation; DOE Voluntary Protection Program; and assessment, certification, and testing done under DOE Topical Committees (TCs), including the Metrology TC, Accreditation TC, Environmental Management Systems TC, Quality Assurance Special Interest Group/Topical Committee, High Efficiency Particulate Air (HEPA) Filter Qualification Testing/HEPA TC, Biota Dose Assessment Topical Committee, and Meteorology TC.

8. Provide Any Examples or Case Studies of Standards Successes:

Information on voluntary reporting on federal conformity assessment activities for the Department of Energy (DOE) Annual Report -- DOE is involved in several conformity assessment activities, including:

- a. National Voluntary Laboratory Accreditation Program (NVLAP) – DOE facilities, including Sandia National Laboratories, Pacific Northwest National Laboratory, Honeywell Federal Manufacturing and Technologies, Bechtel BWXT Idaho, and Oak Ridge Metrology Center, are accredited under National Institute of Standards and Technology (NIST) NVLAP to perform calibrations in a variety of metrology parameters, including dimensional, radiation, physical, and electrical metrology. The scope of accreditation of each laboratory can be obtained from the NVLAP Web site located at <http://ts.nist.gov/ts/htdocs/210/214/214.htm>.
- b. Department of Energy Laboratory Accreditation Program (DOELAP) – Through DOELAP, DOE establishes specific performance testing requirements and site assessment criteria for accreditation of DOE personnel dosimetry systems and radiobioassay. DOELAP incorporates standards (including International Organization for Standardization (ISO)/International Electrotechnical Commission Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories, Health Physics Society Standards, and DOE Technical Standards), establishes DOE organizational responsibilities and accreditation processes, and establishes procedures for administering DOELAP and for acquiring accreditation. DOELAP evaluates the respective DOE personnel dosimetry or radiobioassay program's laboratory performance, based on performance testing criteria, and their operational competence, based on established "quality system" criteria regarding good laboratory practice. DOELAP is used for worker monitoring and protection at DOE and DOE contractor sites and facilities, as required in 10 CFR Part 835, "Occupational Radiation Protection."
- c. National Cooperation for Laboratory Accreditation (NACLA) – DOE representatives have been active in founding and supporting NACLA, and are currently member organizations of NACLA and participate in managing NACLA activities. NACLA recently recognized its first three competent accreditation bodies and has signed an important Memorandum of Understanding with NIST.
- d. DOE Voluntary Protection Program (VPP) – DOE has established VPP criteria for its facilities' occupational safety and health programs, based on the Occupational Safety and Health Administration's VPP. These criteria establish a baseline that denotes compliance with all occupational safety and health standards, rules, and regulations. DOE conducts onsite evaluations to establish how successful DOE applicants for VPP have exceeded the baseline criteria.
- e. DOE Topical Committees (TCs) – The DOE Technical Standards Program (TSP), within DOE's Office of Environment, Safety and Health, has chartered a number of DOE TCs that directly and indirectly advocate and support conformity assessment activities across

DOE. These TCs are composed of DOE and DOE contractor subject matter experts, and generally include members and observers from other Federal agencies, industry, and standards developing organizations (SDOs). The TCs are chartered to coordinate with these groups on standards activities, including conformity assessment. DOE TCs involved in conformity assessment activities include the following:

- Metrology TC – Comprised of representatives from laboratories across the DOE complex, the Metrology TC coordinates the efforts of many DOE organizations involved in metrology and actively interacts with NIST, NASA, DoD, and other Federal agencies in its activities. The group has developed a Web site (<http://www.sandia.gov/metrology/mchome.html>) that contains information on metrology capabilities at the various DOE laboratories, past meeting minutes, committee members and contacts, white papers on metrology issues, and future meeting announcements. The group is in the process of developing information on calibration uncertainty analysis procedures and supplier certification programs used in the various DOE laboratories.
- Accreditation TC – Comprised of representatives from laboratories across the DOE complex, the Accreditation TC promotes unified laboratory accreditation activities across DOE and actively interacts with NACLA, American National Standards Institute, ISO, and other organizations to promote nationally and internationally recognized accreditation standards. The group has also developed a Web site (<http://www.sandia.gov/accreditation>) that contains information on past committee meetings, committee membership and contacts, and white papers on accreditation issues.
- Environmental Management Systems TC (EMS TC) – The EMS TC provides information and assistance to DOE organizations interested in establishing ISO 14000 certified environmental management programs.
- Quality and Safety Management Special Interest Group/Quality Assurance Topical Committee (QA TC) – The QA TC develops, improves, and provides management information related to quality and safety issues involving the U.S. DOE community, including information and assistance to DOE organizations interested in ISO 9000 criteria or a move from DOE specific standards to industry consensus standards.
- High Efficiency Particulate Air (HEPA) Filter Qualification Testing/HEPA TC – The DOE conducts functional and quality testing of HEPA filters, used in critical applications at DOE facilities, at a designated facility for HEPA filters to ensure conformance with American Society for Testing and Materials standards and to help ensure adequate performance in safety applications.

- Biota Dose Assessment Topical Committee (BDATC) – The BDATC has broad representation from DOE offices, national laboratories, universities, and the private sector. The BDATC brings together the expertise in health physics, radioecology, environmental monitoring, and risk assessment as a resource base for DOE on biota dose assessment. It coordinates these interests to establish common standards and processes for biota dose assessment across DOE, the United States, and internationally. Through its standard, the BDATC provides radiation dose evaluation methods that can be used to meet DOE requirements. The international community, including the International Atomic Energy Agency and the Atomic Energy Control Board of Canada, are interested in broader application of the DOE BDATC standard.
- Meteorology TC – The DOE Meteorology TC (MTC) works across DOE, with other Federal agencies, and with ANS to help promote the use of ANS 3.11 as a replacement for various agency standards. The MTC can also provide onsite evaluations of onsite meteorology programs to support implementation of the new ANS 3.11 standard.

9. Comments:

DOE implements the Federal guidance and requirements of OMB Circular A-119 and the statutory requirements of Public Law (P.L.) 104-113 (15 U.S.C. 272) on the use of voluntary consensus standards through specific Departmental directives (policy, requirements, guides, and technical standards) and supporting management systems.

Foremost is DOE's Integrated Safety Management System (ISMS). ISMS is a system that integrates management of DOE's worker, public, and environmental health and safety with its business management, using standards as one of its primary tools.

DOE policies provide the top tier of requirements that implement standards-related Federal Law and Policy. DOE Policy 251.1, "Directives System," establishes a Directives System for managing DOE requirements and guidance documents. The Directives System focuses on DOE's environment, safety and health requirements, and guidance. Technical standards (i.e., as defined in P.L. 104-113) are a key element of this system. The Directives System Policy clearly states DOE's preference to ". . . adopt National Consensus Standards and other commercial and industry standards . . ." in the conduct of DOE's activities. Directives System documents reference appropriate voluntary consensus standards that are acceptable for meeting requirements. This Policy also limits the use of mandated government-unique standards in DOE rulemaking, Orders, and procurement processes.

Another policy, DOE Policy 410.1A, "Promulgating Nuclear Safety Requirements," requires notice and comment to promulgate new nuclear safety requirements. New nuclear safety requirements developed by DOE are "performance-based" rules and orders that promote the adoption of voluntary consensus standards as acceptable methods to implement requirements.

DOE also specifies responsibilities for managers and organizations in managing and implementing P.L. 104-113 and OMB Circular A-119 requirements in its "Functions and Responsibilities (FAR) Manual."

These DOE policies, requirements, and responsibilities on the use of voluntary consensus standards are implemented at the working level through a DOE-wide management system and infrastructure established through DOE Order 252.1, "Technical Standards Program," an accompanying program Guide, DOE Guide 252.1-1, "Technical Standards Program Guide," and Technical Standards Program Procedures (TSPPs).

DOE Order 252.1 establishes the DOE Technical Standards Program (TSP), which implements most Federal and DOE technical standards requirements, and manages internal standards development activities across DOE. DOE Order 252.1 incorporates references to P.L. 104-113 and the February 1998 revision to OMB Circular A-119. This Order reinforces the Federal requirement for DOE elements to use voluntary consensus standards in preference to Federal and DOE (i.e., government-unique) standards, consistent with P.L. 104-113 and OMB Circular A-119. The TSP further encourages and supports staff participation in the planning, development, and coordination activities of national and international SDOs.

The TSP Guide and TSPPs provide information on the TSP functions and management, program resources and services, and the DOE processes and procedures for selecting, developing, and maintaining DOE Technical Standards and using voluntary consensus standards. The TSP Guide also provides basic information on reporting the use of government-unique standards in both regulation (DOE is nominally self-regulating in key areas such as nuclear safety) and procurement (where most reporting is category-based). The DOE TSP is developing additional reporting procedures to assist program officials conducting procurements. The DOE TSPPs incorporate working level processes that implement the technical standards provisions of P.L. 104-113 and OMB Circular A-119. DOE currently manages its technical standards activities in conformance with Federal policy and requirements.

Another function serving DOE implementation of P.L. 104-113 and OMB Circular A-119 was the Department Standards Program, established to institute "standards" (in this application, "standards" include policy, laws, rules, guides, and technical standards) as the basis for work throughout the Department. Under this program, a DOE-wide process (the "Work Smart Standards" process) that enables DOE contractors to select voluntary consensus standards as the basis for their work was developed and implemented. Under the process, voluntary consensus standards can be selected and used in lieu of DOE-developed or other government-unique standards, when such standards are appropriate for the work and work-related hazards. This "Work Smart Standards" process now enables DOE laboratory and management and operating or integrating contractors, with DOE approval, to identify and apply the set of standards (including voluntary consensus standards) that best fit their activities and adequately address related hazards. This approach focuses on outcomes and

performance, rather than detailing "how" things are to be done within DOE. The process is part of the DOE ISMS and is supported by a major contract reform effort designed to more closely link performance expectations with contractual obligations based on standards.

Key DOE policy and requirements documents define the "Work Smart Standards" approach. These include DOE Policy 450.3, "Authorizing Use of the Necessary and Sufficient Process for Standards-Based Environment, Safety and Health Management," and DOE M 450.3-1, "The Department of Energy Closure Process for Necessary and Sufficient Sets of Standards." The "Work Smart Standards" approach is now applied across a broad range of DOE sites, facilities, and activities. During FY 2000, DOE developed updates of guidance and standards to support the "Work Smart" process.

The DOE Standards Executive, Richard L. Black, Director, Office of Nuclear and Facility Safety, is responsible for developing and implementing the DOE TSP through DOE's Technical Standards Program Manager and the TSP. Through Mr. Black's participation on the Interagency Committee on Standards Policy (ICSP), DOE supports ICSP activities and policy implementation, and provides "lessons-learned" information to other Federal agencies on DOE's approach to establishing a standards-based culture.

As noted above, DOE Order 252.1 emphasizes the use of voluntary consensus standards within the Department. DOE's Technical Standards Program Office (TSPO) operates under this Order to implement program policy, support the conversion of Department standards to voluntary consensus standards, identify voluntary consensus standards that can suit Department needs, develop and maintain databases to support the program and meet reporting requirements, and coordinate day-to-day Department technical standards activities. The TSPO has developed procedures, methods, and training approaches to implement the DOE TSP and communicate the policy to use voluntary consensus standards throughout DOE, and support participation in SDO activities related to DOE missions and functions. The TSPPs establish a five-year standards review cycle to check for continued applicability. The procedures also provide guidance on the conversion of Department standards to voluntary consensus standards.

Information on the TSP and the TSPO can be accessed at the following Internet address (Uniform Resource Locator): <http://tis.eh.doe.gov/techstds/>.

To coordinate consistent implementation of federal and DOE policy and requirements at the working level, DOE senior managers have designated Technical Standards Managers (approximately 70 individuals) representing the various Department headquarters, field, laboratory, and contractor organizations. Established in 1992, the Technical Standards Managers' Committee (comprised of these Technical Standards Managers) operates under the DOE TSP, supports the DOE sites in technical standards activities, facilitates communications on program implementation issues, and participates in establishing program goals and procedures. Databases documenting the voluntary consensus standards adopted by DOE and the personnel participating in the activities of SDOs are maintained by the TSPO. The information in these databases is compiled and provided to OMB annually.

During FY 2000, the TSP continued the recognition of "topical" standards committees within DOE. TCs provide a venue for DOE-wide coordination with national and international SDOs and other federal agencies in such diverse areas as laboratory accreditation, metrology, fire protection, environmental management systems, meteorology, biota dose assessment, chemical safety, emergency management, and nuclear safety training. These committees are composed of subject matter experts from across the DOE community, and serve as a focal point for standards activities in specific technical areas. TCs provide a forum for all interested DOE parties to join and participate in reviewing technical standards produced by counterpart SDOs, address standards application issues within their area of technical expertise, and work to develop DOE and Federal positions on standards issues. As of November 2000, the TSP has recognized 25 DOE TCs. (These committees are listed at the Internet address provided above.)

DOE also has an Information Technology Standards Program (Internet address is <http://www-it.hr.doe.gov/Standards/index.html>) that is conducted in conjunction with the DOE TSP. The DOE Information Technology Standards Program is managed by staff from DOE's Office of the Chief Information Officer, with assistance from over 70 designated DOE and contractor information technology points of contact representing key programs and sites. It coordinates information technology standards activities Department-wide, including the identification, adoption, implementation, and retirement of nongovernment and government information technology standards in support of the DOE Information Architecture. This program has stressed the use of international and voluntary consensus information technology standards over development of internal standards in its adoption processes.

The Department also implements a legislatively mandated, multiyear effort to improve the energy efficiency in the Nation's buildings through energy efficiency standards, codes and guidelines for buildings, building equipment, and appliances through its Office of Energy Efficiency and Renewable Energy (Internet address is <http://www.eren.doe.gov/>). The Department's codes and standards development efforts in these areas are closely coordinated with SDOs and include early involvement of industry and state stakeholders and relevant Federal agencies. During FY 2000, DOE developed and issued new energy efficiency standards as part of an open, negotiated process with the lighting industry and energy efficiency advocates. These included standards for improvements in the energy efficiency of fluorescent lamp ballasts in commercial and industrial applications (to go into effect on April 1, 2005), and energy efficiency standards for residential central air conditioners and heat pumps (proposed October 3, 2000).

DOE continues to take a "proactive" approach to standards and standards management even as its mission continues to evolve in response to the conclusion of the Cold War and shrinking congressional appropriations. Within DOE, a number of programs and facilities have shifted their focus from production, research, and/or development to environmental remediation and restoration, where DOE will literally be breaking new ground and setting standards for others to follow. In addition, Department staffing levels are declining to meet

Congressional budget constraints. Still, in the face of a changing mission and a reduced workforce, DOE continues to actively use and support the development of voluntary consensus standards to meet its needs.

In FY 2000, the number of voluntary consensus standards adopted for use increased to 1,012 (in comparison to 916 in 1999, 840 in 1998, and 809 in 1997). The number of individuals participating in voluntary consensus standards activities also increased to 676 in FY 2000 (in comparison to 668 in 1999, 681 in 1998, and 871 in 1997), and the number of documented participations by those individuals in standards developing groups increased to 1,385 (in comparison to 1,306 in 1999; 1,321 in 1998; and 1,540 in 1997). These increases occurred in spite of continued significant "downsizing" and budget cuts experienced by DOE, and reflects increased interest on the part of DOE organizations.

Also, DOE (through the TSPO) is continuing its initiative with SDOs to convert DOE Technical Standards to voluntary consensus standards.

In accordance with the reporting requirements iterated in OMB Circular A-119, the above information has been developed for the OMB Annual Report and is being submitted to NIST to report use of voluntary consensus standards within DOE and DOE participation in standards development activities. The information includes both mandatory agency reporting requirements and voluntary conformity assessment reporting information.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

46

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

241

3. Number of Voluntary Consensus Standards Used in FY 2000:

501

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

1

| | |
|--|---|
| <u>Voluntary Standard</u> ISO 17025 | <u>Government Standard</u> FDA Laboratory Guidelines |
|--|---|

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

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. The agency participates in 542 standards development committees within the 46 voluntary consensus standards bodies reported in FY 2000.

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. Voluntary consensus standards are less relevant in the areas of human and veterinary pharmaceuticals, biological products, and food, where such standards are generally not available and are not being developed, and where standards of other national or international organizations {U.S. Pharmacopoeia (USP), World Health

Organization (WHO), Food and Agricultural Organization (FAO), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)} as well as regulatory standards predominate.

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 20 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.

FDA's development and use of voluntary consensus standards varies within each of the Agency's centers, because of differing availability and applicability of such standards in each product area. Voluntary consensus standards are most relevant to medical devices, and consequently the majority of the Agency's standards activities addressed by Circular A-119 are centered there.

It is the intent of FDA's standards policy to: (1) enable the agency to participate in international standards activities that will assist it in implementing statutory provisions for safeguarding the public health; (2) increase its efforts to harmonize its regulatory requirements with those of foreign governments, including setting new standards that better serve the public health; and (3) respond to laws and policies that encourage agencies to use voluntary standards that provide the desired degree of protection. FDA conducts a comprehensive review of its existing regulations on an ongoing basis. As part of this review, the Agency considers the appropriateness of existing regulations and policies, as specified in Circular A-119.

Center for Devices and Radiological Health (CDRH)

Section 204 of the FDAMA of 1997 (P.L 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d), allowing the Agency to recognize voluntary consensus standards established by international and national standards developing organizations that may be used to satisfy identified portions of device

premarket review submissions or other requirements. In a *Federal Register* notice published on February 25, 1998, the Agency announced the availability of a guidance document entitled "Recognition and Use of Consensus Standards" describing how FDA planned to implement that part of FDAMA, and providing an initial list of recognized standards. CDRH has more recently made available two standards relevant documents on their Web site. The first, "Use of Standards in Substantial Equivalence Determinations," is intended to clarify for industry and Agency reviewers the ways in which standards may be used in demonstrating substantial equivalence in premarket notification (510(k)) submissions. Previous guidance discussed the use of declarations of conformity to standards recognized by FDA under the newly created Section 514(c) (Recognition of a Standard) of the Federal Food, Drug, and Cosmetic Act. This document expands upon that guidance by discussing the use of FDA-recognized standards in 510(k)s that do not contain a declaration of conformity, and the use of nonrecognized standards. The second 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 calendar year 1999, a CDRH official served as GHTF Chair. The GHTF has a Memorandum of Understanding with Technical Committee 210, the International Organization for Standardization (ISO) committee responsible for many aspects of device standards.

Center for Drugs Evaluation and Research (CDER)/Center for Biologics Evaluation and Research (CBER)

Voluntary consensus standards are less applicable to pharmaceutical and biological products. CDER and CBER, therefore, have limited involvement in such activities, but do participate on relevant committees of four voluntary consensus standards bodies. While the Agency's involvement with voluntary consensus standards development is limited in these particular areas (mostly because such standards are not available and are not under development in these areas), it should be noted that the Centers do participate in many other types of standards development activities that are excluded from Circular A-119 reporting requirements.

Numerous employees are involved in the standards development activities of the USP, a private, voluntary, not-for-profit national standards setting body of more than 1,500 health care professionals, recognized authorities in medicine, pharmacy, and allied sciences. USP publishes and revises the United States Pharmacopoeia and the National Formulary (NF), the legally recognized compendia of drug standards in the United States.

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 United States 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 and implemented in ICH, that is aimed at standardizing the safety-related terminology used in adverse experience reporting.

FDA actively participates with WHO in developing international standards for ensuring the quality of pharmaceutical and biological products, and the Organization for Economic Cooperation and Development (OECD) on good laboratory practices for animal studies. In 1997, a new hemispheric initiative was launched on pharmaceutical harmonization in the Americas, with emphasis on relevant ICH and WHO standards. Work with this initiative is continuing.

Although FDA's work with USP is specifically excluded from reporting under Circular A-119, and ICH, OECD, and WHO do not meet the definition of voluntary consensus standard bodies under the Circular, 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.

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, the WHO, and 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, AOAC International (formerly the Association of Official Analytical Chemists), and IDF/FIL (International Dairy Federation). CFSAN has provided the U.S. Delegate or Alternate Delegate to 80 percent (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. 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, 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 and the International Organization of Vines and Wines.

CVM is very 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.

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 Sanitary and Phytosanitary (SPS) Measures; with the implementation and the counterpart committees of the North American Free Trade Agreement; 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. This is done to ensure that FDA'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 forum. FDA topics have included food safety, food labeling, bulk drugs, standards for latex gloves and condoms, and medical device regulation.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

The CDRH has liaison with the American National Standards Institute (ANSI) Accreditation Committee, ANSI International Conformity Assessment Committee, ANSI Board Committee on Conformity Assessment, and American Society for Testing and Materials Committee E-36 on Conformity Assessment. The Center uses suppliers' declaration of conformity as described in ISO/International Electrotechnical Commission (IEC) Guide 22 in its standards recognition program and has developed an Mutual Recognition Agreement with the EU on mutual recognition of each other's conformity assessment procedures related to manufacture and marketing of medical devices.

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. FDA officials are also involved with Codex Alimentarius activities, especially in the area of pesticide and industrial 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/IEC17025 standard is the foundation in this coordination effort.

As part of the Presidential Food Safety Initiative, FDA proposed regulations to establish requirements pertaining to sample collection and private laboratories. Consequently, ORA and CFSAN held two public meetings to gather comments concerning standards for private laboratories. FDA has drafted new regulations for public comment, which will be issued by the end of the calendar year for persons who use sampling services (services that collect samples for another party) and private laboratories used in connection with imported food. The proposal identifies standards for samples to be properly collected and maintained. Additionally, the proposal would require laboratories to use validated or recognized analytical methods. This proposal will help to ensure the integrity and scientific validity of data and results submitted to FDA. The draft proposed regulation will conform to both ISO/IEC and AOAC standards.

Within ORA, the field laboratories are in the beginning phase to become ISO/IEC 17025 accredited. The ORA has started its first series of staff training to conform to the ISO/IEC 17025 standard and quality assurance managers have been hired to coordinate the changeover to an ISO 17025-based quality system.

CDER 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, they coordinate with other Centers in the development of "Guidance to Industry" documents. They also coordinate activities with other agencies, such as the Environmental Protection Agency, the U.S. Fish and Wildlife Service, the Consumer Product Safety Commission, the Drug Enforcement Agency, and the National Institute of Standards and Technology (NIST). Finally, a majority of standards-setting activities are focused on interactions with national and international standards-setting bodies such as USP, ICH, OECD, WHO, and the Pan American Health Organization (PAHO). An innovative approach to harmonizing international standards is being undertaken with PAHO. PAHO participating countries with whom FDA is working do not have established standards related to drug regulation. Therefore, FDA is providing them with training based on our current standards in hopes that they will elect to adopt our standards.

CFSAN coordinated and compiled over 100 foreign WTO notifications regarding food safety and trade. CFSAN comments are part of the interagency process creating the United States' position on particular TBT and SPS issues through the WTO notification system.

8. Provide Any Examples or Case Studies of Standards Successes:

None.

9. Comments:

The number of voluntary consensus standards used in FY 2000 is reported as 501 with the type designation of "Not Applicable." For a regulatory agency such as FDA, neither a "categorical" nor a "transactional" designation correctly describes how we use these standards.

Five hundred and one is the total number of voluntary consensus standards available as of the end of the current reporting period for market approval applicants to reference in their applications. Applicants can reference these standards in lieu of submitting data to meet approval requirements. At the end of FY 1999, FDA had a total of 460 voluntary consensus standards available for use but reported in the FY 1999 report only the net increase of 90 from the FY 1998 report. This year the Agency is reporting the cumulative total because we believe this number more accurately reflects FDA's use of voluntary consensus standards in our regulatory processes. This number reflects a net increase of 41 (460 to 501) from FY 1999.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

6

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

8

3. Number of Voluntary Consensus Standards Used in FY 2000:

300

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

1

Voluntary Standard
NFPA 501

Government Standard
45 CFR 3280

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

2

Government Standard
28 CFR 3280

Voluntary Standard
ANSI A119.1 &
NFPA 501C

Explanation
HUD-Unique Manufactured
Home Construction & Safety
Standards.

CFR 200.93 5

ANSI A119.1 &
NFPA 501C

HUD Building-Product
Standards & Certification
Programs.

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

This policy has been effective in replacing federal standards with public domain standards. This has resulted in more timely, up-to-date, and technically accurate standards.

7. Provide the Conformity Assessment Activities in which the Agency has been Involved:

All of HUD's 25 conformity assessment programs, under the HUD Building-Products Standards & Certification Programs, are in compliance with the International Organization

for Standardization (ISO) guidelines and procedures. These are the same standards used by American National Standards Institute (ANSI) and other nationally recognized third-party certification agencies.

8. Provide Any Examples or Case Studies of Standards Successes:

- a. In July 2000, the Standards Council of the National Fire Protection Association (NFPA) approved the 2000 edition of NFPA 501. This document is the vehicle used by NFPA to process consensus-developed recommended changes to the Federal Manufactured-Home Construction and Safety Standards 24 CFR 3280. HUD, through a Memorandum of Understanding with NFPA, is relying upon NFPA to develop and process recommendations for standards changes. While this does not totally replace a Federal standard with a consensus one, it has transferred the development to a consensus ANSI-recognized one. HUD intends to review and submit a proposed rule to amend 24 CFR 3280 for public comment shortly. This will include roughly 110 plus changes. HUD received the recommendations in September 2000.
- b. HUD's already considerable GIS resources are benefiting greatly from, and will continue to improve, thanks to standards. HUD is developing a GIS system that will consolidate HUD's and some (of the Departments of the United States) census data and make it available to state and local governments and to other agencies.

Some standards links that make this possible are: Association of Computing Machinery, European Committee for Electrotechnical Standardization Technical Committee (TC) 287 Geographic Information (GI), Digital Geographic Information Working Group (NATO), European Commission--GI 2000-GIS Standards Page, Federal Geographic Data Committee, Institute of Electrical and Electronics Engineers, International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) TC 211, Geographic Information/Geomatics, The Internet Engineering Task Force, ISO/IEC Joint TC 1, International Telecommunication Union, Information Technology Institute Council, National Committee on Information Technology Standards (NCITS) TCs L1 (GIS) and K5 (Information Technology (IT) Vocabulary (see Millennial American National Standards Dictionary of IT {ANSGIT} below), National Institute of Standards and Technology, The Object Management Group, The Open Group, and World Wide Web Consortium.

9. Comments:

HUD's eight participants in standards developing organizations (SDOs) are from HUD's:

Office of Policy, Research, and Development(R); Office of Healthy Homes & Lead-Hazard Control (L); Office of Administration Operations (AO); Office of Housing-Federal Housing Commissioner (H); and the Office of the Chief Information Officer (Q).

SDOs in which they participate:

American Society of Civil Engineers, American Society for Testing and Materials, Council of American Building Officials, Federal Geographic Data Committee, NCITS, and Underwriters Laboratories.

Questions regarding HUD's standards may be directed to Roy P. Mullinax, CCP at (202) 708-0614, ext. 6075, or e-mail: Roy_P._Mullinax@hud.gov. IT terms/acronyms may be referenced by seeing ANSI's Millennium ANSDIT on the Web via <http://www.ncits.org>.

DEPARTMENT OF THE INTERIOR (DOI)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

29

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

81

3. Number of Voluntary Consensus Standards Used in FY 2000:

1,569

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

As a result of A-119, the Minerals Management Service (MMS) has increased its participation in voluntary standards groups, both domestic and international.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

Metadata standards development by the consensus standards committee under the American Society for Testing and Materials (ASTM) Section D 18.05, "Remote Sensing and GIS," chaired by a U.S. Geological Survey (USGS) Water Resources Division worker. To develop a consistent and uniform metadata standard for information about digital geospatial data so all agencies can facilitate data sharing.

Currently, the MMS is working with the American Petroleum Institute (API) developing a series of best cementing practices standards.

MMS is also evaluating several existing API standards addressing the design and use of floating production systems in deepwater areas of the Gulf of Mexico, in lieu of developing unique MMS standards.

8. Provide Any Examples or Case Studies of Standards Successes:

In 1998, the USGS Office of Water Quality (OWQ) published a Technical Memorandum entitled "Policy for the Approval of (USGS) Water Quality Analytical Methods." In addition to establishing procedures for the approval of new water quality analytical methods, this memorandum established that ASTM methods and methods published in "Standard Methods," both voluntary- and consensus-based standard methods, are also approved for use as water quality analytical methods. This memorandum also establishes that all methods published by the U.S. Environmental Protection Agency are approved. The relevant ASTM standards are published in volumes 11.01 to 11.05, "Water and Environmental Technology." They contain 922 different standards. The 1995 edition of "Standard Methods," published by the American Public Health Association, the American Water Works Association, and the Water Environment Federation, contains 489 consensus-based standards, for a total of 1,411 consensus-based standards adopted by OWQ in this technical memorandum. All of these methods are approved for use in water quality programs and do not have to be developed and validated by the USGS.

The USGS is the lead federal agency in the National Atmospheric Deposition Program (NADP) with approximately five USGS employees actively participating in the organization. USGS representatives serve on the NADP Executive Committee and Network Operations Committee and a USGS representative serves as chairperson of the NADP Budget Committee. Representatives from approximately 100 federal, state, local, academic, and private sector organizations participate in the NADP to establish uniform standards for the measurement of chemical constituents deposited to the earth via rain, snow, and sleet. In addition to setting standards, this organization conducts jointly funded monitoring of atmospheric deposition throughout the United States at over 250 locations using the common protocols and standards developed by the organization. Through the use of jointly developed common standards, the data collected is comparable and of known quality from all stations throughout the United States. The use of common standards, procedures, laboratories, instrumentation, and data management criteria enables the participating agencies to collect the information at significantly lower cost and with higher quality.

9. Comments:

We believe that the use of voluntary standards is effective. To provide you with the highest quality data possible, it would be of value for you to explain the purpose and use of some of the data collected, specifically numbers one, two, and three on the Web page. (Explanatory Note: FY 2000 was the first year agencies entered their data via the Web for NIST's use in compiling this report.) Interior manages a diverse set of assets and applications that include (but are not limited to) geologic, geographic, hydrometric, flora, fauna, land, mining, and mapping. With over 2,000 field locations across the country, it is impossible to know for sure exactly how many voluntary consensus standards organizations that we participate in.

DEPARTMENT OF JUSTICE (DOJ)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

3

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

5

3. Number of Voluntary Consensus Standards Used in FY 2000:

59

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

Circular A-119 policy is appropriate and has increased the awareness, value, and usage of voluntary consensus standards.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

The Office of Science and Technology of the National Institute of Justice (NIJ) sponsors the Office of Law Enforcement Standards (OLES) in collaboration with the National Institute of Standards and Technology (NIST). The mission of OLES is to apply science and technology to the needs of the criminal justice community, including law enforcement, corrections, forensic science, and the fire service.

To accomplish this mission, OLES (a) develops methods for testing equipment performance and for examining evidentiary materials, (b) develops standards for equipment and operating procedures, (c) develops standard reference materials, and (d) performs other scientific and engineering research as required by external sponsors. This interagency cooperative effort results in improvement in the quality and consistency of various conformity assessment requirements and processes at the federal and state levels.

The areas of research investigated by this office include clothing, communication systems, emergency equipment, investigative aids, protective equipment, security systems, vehicles,

speed measuring equipment, weapons, and analytical techniques and standard reference materials used by the public safety community. The exact projects that comprise OLES' program are based upon the most recent recommendations of the Law Enforcement and Corrections Technology Advisory Council and vary depending upon the priorities of the criminal justice community. The results of this research are used to improve the ability of the law enforcement community to specify appropriate product/equipment requirements and to effectively test for conformance to those requirements.

OLES ensures that the results of its work will be readily available to all interested parties by providing standards, technical reports, and nontechnical guides to NIJ (and its Law Enforcement and Corrections Standards and Testing Program) for dissemination to federal, state, and local law enforcement agencies, and in most cases, the general public. The majority of OLES/NIJ documents are announced through the National Criminal Justice Reference Service.

8. Provide Any Examples or Case Studies of Standards Successes:

In collaboration with the Federal Bureau of Investigation (FBI), NIST has completed and published American National Standards Institute (ANSI)/NIST-ITL 1-2000 Data Format for the Interchange of Fingerprint, Facial, & Scar Mark & Tattoo (SMT) Information as an American National Standard. This is a revision, re-designation, and consolidation of ANSI/NIST-CSL 1-1993 and ANSI/NIST-ITL 1a-1997.

This standard specifies a common format to be used to exchange fingerprint, facial, and SMT identification data effectively across jurisdictional lines or between dissimilar systems made by different manufacturers. It is the tool that establishes interoperability between federal, state, local, and international users of Automated Fingerprint Identification Systems (AFIS). Nearly 200 Federal, State, local, and international law enforcement agencies; criminal justice administrations; vendors; and other organizations participated in the standards development.

NIST, in conjunction with the FBI, has created a publicly available database of latent fingerprints from crime scenes and their matching rolled fingerprint mates. Software and utilities are also provided to manipulate these files. This database can be used by researchers and commercial developers to create and test new fingerprint identification algorithms, test commercial and research AFIS systems, and assist in the training of latent fingerprint examiners.

9. Comments:

None.

DEPARTMENT OF LABOR (DOL)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:
81
2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:
89
3. Number of Voluntary Consensus Standards Used in FY 2000:
118
4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:
0
5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:
0
6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:
None.
7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:
N/A
8. Provide Any Examples or Case Studies of Standards Successes:
N/A
9. Comments:
None.

DEPARTMENT OF STATE (STATE)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

1

2. Number of Agency Employees Participating In Voluntary Consensus Standards Activities:

8

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

Department of State (DoS) does not write standards within the meaning of Circular A-119.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

None.

8. Provide Any Examples or Case Studies of Standards Successes:

See comments below.

9. Comments:

The DoS is not involved in the actual development of technical standards. The DoS has a major policy role in radiocommunication and telecommunication standardization as obligated by international treaty, and coordination roles in other areas. The Bureau of Economic and Business Affairs (EB) represents the DoS on the Interagency Committee on Standards Policy, the Government Member Council, as well as the Information Infrastructure Standardization Panel and its steering committee at the American National Standards Institute (ANSI). The Department represents the United States administration under the treaty obligations found in the Convention of the International Telecommunications Union

(ITU), Minneapolis, 1998. The DoS, through the EB Communications and Information Policy Deputate, provides the forum for development of positions and contributions for presentation at ITU Radiocommunication and Telecommunication Standardization study group meetings where international recommendations (voluntary standards) and standardization policies are written. The DoS coordinates, leads, and/or accredits U.S. delegations to ITU technical and policy meetings. The Department sponsors the International Telecommunication Advisory Committee, a public committee chartered under the Federal Advisory Committee Act, where advice on standardization and policy issues is offered by the private sector telecommunications industry and private sector standards developing organizations (SDOs) such as ANSI-accredited Committee T1, the Telecommunications Industry Association, and the Society of Cable Television Engineers. The Department also bases its decisions on advice from, and in coordination with, other public sector Agencies (Department of Defense, National Communications System, National Institute of Standards and Technology {NIST}, National Telecommunications and Information Administration, National Aeronautics and Space Administration, and the Federal Communications Commission). More than 100 U.S. corporations are participating members of the ITU, under the sponsorship of the DoS. Those companies and interested government agencies participate and play major roles in the ITU Study Groups and Working Parties that actually write the standards. Within that process, a great deal of interaction takes place with other international SDOs, such as the International Organization for Standardization. In addition to accrediting and supporting delegations to the ITU, the Department's International Organization Affairs Bureau accredits and funds participation by relevant specialized agencies (Departments of Agriculture, Commerce, and Transportation, and NIST) and private sector groups in the deliberations of the Economic Commission for Europe (ECE) Working Party on Standardization, especially where they have a direct bearing on U.S. commercial interests. While the standards developed in the ECE are not officially adopted for use in the United States they serve as guides for adjusting product design and are widely taken into account in manufacturing plans.

DEPARTMENT OF TRANSPORTATION (DOT)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

146

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

211

3. Number of Voluntary Consensus Standards Used in FY 2000:

153

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

11

| <u>Voluntary Standard</u> | <u>Government Standard</u> |
|---------------------------|----------------------------------|
| NFPA 59A Provisions | 65 FR 10950 March 1, 2000 |
| NFPA 59A Provisions | 65 FR 10950 March 1, 2000 |
| NFPA 59A Provisions | 65 FR 10950 March 1, 2000 |
| NFPA 59A Provisions | 65 FR 10950 March 1, 2000 |
| NFPA 59A Provisions | 65 FR 10950 March 1, 2000 |
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| NFPA 59A Provisions | 65 FR 10950 March 1, 2000 |
| NFPA 59A Provisions | 65 FR 10950 March 1, 2000 |
| NFPA 59A Provisions | (11 DOT-unique standards in all) |

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

The general consensus is 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 recommendations to change OMB Circular A-119 at this time.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

N/A

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

None.

DEPARTMENT OF THE TREASURY (TREASURY)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

6

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

10

3. Number of Voluntary Consensus Standards Used in FY 2000:

8

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

2

| <u>Voluntary Standard</u> | <u>Government Standard</u> |
|--|---------------------------------------|
| Common Criteria V2.1/ISO 15408:1999 | Military Standard 5200.28/Orange Book |

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

2

| <u>Government Standard</u> | <u>Voluntary Standard</u> | <u>Explanation</u> |
|---|---------------------------|--------------------|
| Customs and Trade Automated Interface Requirements (CATAIR) | | |

CATAIR is used by the Customs brokerage industry. The maintenance of the government-unique standards within Customs applications, the CATAIR and CAMIR formats, are at the request of the participating industry groups that use those standards.

Customs Automated
Manifest Interface
Requirements (CAMIR)

CAMIR is used by some parties in the transportation sector. The maintenance government-unique standards within Customs applications, the CATAIR and CAMIR formats, are at the request of the participating industry groups that use those standards.

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

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

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

The standards the Department has adopted will involve conformity assessment activities, which include internal audit and eventual certification in conformance with acceptable practices.

8. Provide Any Examples or Case Studies of Standards Successes:

Between 1998 and 2000, the U.S. Customs, Office of Information Technology, Program Office, used these government-unique standards: Year 2000 Computing Crises, An Assessment Guide (GAO/AIMD-10.1.14); Year 2000 Computing Crisis, A Testing Guide (GAO/AIMD-10.1.21); and Year 2000 Computing Crisis, Business Continuity and Contingency Planning (GAO/AIMD-10.1.19). After a series of reviews, GAO issued the following report: Year 2000 Computing Crisis, Has Established Effective Year 2000 Program Controls (GAO/AIMD-99-37), and testified before Congress on February 24, 1999, stating: Year 2000 Computing Crisis, Customs is Effectively Managing its Year 2000 Program (GAO/T-AIMD-99-85) and again on June 29, 1999: Year 2000 Computing Crisis, Customs Is Making Good Progress (GAO/T AIMD-99-225).

9. Comments:

None.

DEPARTMENT OF VETERANS AFFAIRS (VA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:
26
2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:
12
3. Number of Voluntary Consensus Standards Used in FY 2000:
0
4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:
0
5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:
0
6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

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

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:
The VA does not engage in conformity assessment activities. VA strives to use industry-based standards and commercial off-the-shelf products.
8. Provide Any Examples or Case Studies of Standards Successes:
N/A
9. Comments:
Federal regulations prescribe standards that must be used (e.g., Environmental Protection Agency laboratory standards and Occupational Safety and Health Administration monitoring/sampling 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 a 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 B:

Other Agency and Commission Reports

AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

0

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

0

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

USAID has no suggestions for changing Circular A-119.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

USAID participates in the Contractor Performance System established by the National Institutes of 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.

8. Provide Any Examples or Case Studies of Standards Successes:

Nothing to report.

9. Comments:

None.

CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

8

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

28

3. Number of Voluntary Consensus Standards Used in FY 2000:

1

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

1

| <u>Government Standard</u> | <u>Voluntary Standard</u> | <u>Explanation</u> |
|-------------------------------------|---------------------------|--|
| CPSC CFR Parts 1213, 1500, and 1513 | 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. |

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

During FY 2000, 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.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

N/A

8. Provide Any Examples or Case Studies of Standards Successes:

The CPSC staff provided technical support to the development of over 20 new, revised, or reaffirmed voluntary safety standards that were completed in FY 2000.

9. Comments:

The 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 October 1989.

Since the principles set forth in the Revised OMB Circular A-119 were published, the Commission has consistently supported them. The CPSC Voluntary Standards Coordinator, who also serves as CPSC's Standards Executive for the purpose of implementing the Revised OMB Circular A-119, provides general oversight for staff involvement in existing standards projects. The Voluntary Standards Coordinator establishes agency views on standards issues and decisions through Commission response to staff briefing packages and recommendations. These views are reflected in the Commission's Operating Plan and Budget. Coordinating participation within the Commission and with others in voluntary standards activities is a responsibility of the Voluntary Standards Coordinator. Likewise, the Voluntary Standards Coordinator is responsible for meeting reporting requirements applicable to voluntary standards involvement of Commission staff.

The Commission had 28 employees directly participating in 64 voluntary standards development projects during FY 2000. Since October 1, 1999, the Commission incorporated, by reference, portions of one voluntary standard in CPSC regulations. During FY 2000, the Commission's efforts to enhance voluntary standards development was complemented by the overall Federal policy set forth in the Circular. CPSC involvement in voluntary standards activities was consistent with Revised OMB Circular A-119. There are no recommendations for changes in the Circular at this time.

For further information, please contact CPSC's Standards Executive:

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Voluntary Standards and International
Activities Coordinator
U.S. Consumer Product Safety Commission
Room 600C
Washington, D.C. 20207
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ENVIRONMENTAL PROTECTION AGENCY (EPA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

15

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

23

3. Number of Voluntary Consensus Standards Used in FY 2000:

229

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

2

| <u>Government Standard</u> | <u>Voluntary Standard</u> | <u>Explanation</u> |
|----------------------------|---------------------------|---|
| 40 CFR 89 & 92 | ISO 8178 | 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. |
| 40 CFR 90 | ISO 8178 | |

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

a. EPA finds the Circular to be generally effective. However, as the last comment in section 9 of this report shows, the Agency believes that the Office of Management and Budget (OMB) should consider a revision of required elements to more accurately fit the manner in which at least this regulatory agency uses voluntary standards. As discussed in our comment, counting the "use" of standards is not always a meaningful representation of how the Law and Circular are actually being implemented.

For example, in the regulatory process it is more meaningful to look at the relationship between regulatory actions involving technical standards and the reference of voluntary standards. In other words, counting standards outside the context of specific regulatory decisions is misleading at best and inaccurate at worst.

EPA would welcome the opportunity to work with OMB and the National Institute of Standards and Technology (NIST) to devise a method of reporting that could be more helpful both to the internal management of standards use and participation in their development, and also to the evaluation of Agency standards-related needs by standards organizations.

- b. EPA would welcome clarification on the issue of whether or not Departments and Agencies may use appropriated funds for membership in voluntary standards bodies. While it is implied, particularly in section 7, it may be helpful to provide specific language in future revisions.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

National Environmental Laboratory Accreditation Council.

8. Provide Any Examples or Case Studies of Standards Successes:

EPA Supports Use of Voluntary Consensus Standards by State Agencies to Address Leaking Underground Storage Tanks (LUST)

Results of a nationwide study show that the American Society for Testing and Materials (ASTM) guidelines for risk-based corrective action have helped State environmental agencies manage environmental cleanups resulting from LUST sites more effectively through faster case-processing rates, reduced costs, and more effective targeting of resources toward higher-risk sites.

Since the law regulating LUST sites is implemented at the State level rather than the Federal level, EPA's Office of Underground Storage Tanks, within the Office of Solid Waste and Emergency Response, funded this study and distributed the results to State environmental agencies and EPA Regional Offices with a memo noting the extent to which the standards were consistent with EPA's goals and guidance. Thus, this is a good example of how EPA uses voluntary consensus standards to influence positive results to difficult problems in a disjointed regulatory framework.

EPA Helps Construct Green Building Standard Queries

EPA's Environmentally Preferable Purchasing (EPP) Program has been working to engage nongovernmental standards developing organizations in developing environmental standards for use in Federal procurement. In a major step forward for EPP in buildings, ASTM's Buildings Performance Committee passed a standardized questionnaire on the environmental performance of building materials this past October.

The standard questionnaire, officially titled "Standard Practice for Data Collection for Sustainability of Building Products," will be accessible through the ASTM Web site (www.astm.org) in spring 2001. The questionnaire provides 31 questions that are applicable to all building products. In the future, the committee plans to ballot revisions to the standard, adding questions that are specific to certain types of products, such as structural steel, wood products, and different types of floor coverings. The intended audience for the standard includes building industry professionals -- planners, developers, architects, engineers, contractors, and others -- who possess a broad, general understanding of sustainability issues relative to the performance of buildings, but who would benefit from additional data to inform their product choices. For more on the EPP program see:
<http://www.epa.gov/opptintr/epp>.

Performance Track

The Agency's flagship environmental performance partnership program, the National Environmental Performance Track, is based upon a voluntary consensus standard -- the International Organization for Standardization (ISO) 14001 environmental management system (EMS) standard. As part of its initial tier, the program requires that participating facilities have an operational EMS similar to, or based upon ISO 14001, with elements that: (a) demonstrate environmental achievements, (b) commit to continuous improvement of environmental performance, (c) demonstrate public outreach, (d) report on the facility's EMS and performance commitments, and (e) have a record of sustained compliance and a commitment to continuous compliance. With such EMS features and by meeting additional requirements of the program, facilities are eligible for Agency recognition and certain administrative incentives. Details on the program can be obtained at
<http://www.epa.gov/performancetrack>.

EPA/Chemical Emergency Preparedness and Prevention Office's Activities on the National Fire Protection Association (NFPA) Technical Committee on Liquefied Petroleum Gas (NFPA-58)

In the final Risk Management Program (RMP) rule (40 CFR Part 68), EPA required hazardous chemical facilities to implement an accident prevention program. Among the original universe of regulated sources were thousands of fuel facilities, mostly LP-Gas (propane) distributors and large users. However, at the urging of the propane industry, in mid-1999 Congress enacted P.L. 106-40, the Chemical Safety Information, Site Security, and Fuels Regulatory Relief Act (CSISSFRRRA). CSISSFRRRA amended the Clean Air Act to, among other things, prohibit EPA from regulating flammable substances under the EPA RMP when used as fuel or when sold as fuel at a retail facility. This exempted most propane facilities from RMP coverage. However, in CSISSFRRRA, Congress encouraged EPA to work with voluntary standards organizations to incorporate accident prevention measures in voluntary codes, and specifically called for changes to NFPA-58 (the Liquefied Petroleum Gas Code) to incorporate certain provisions of the RMP rule.

This was important, because NFPA-58 is almost unique among voluntary standards, in that it serves as the basis for State propane regulations in all 50 States. So, by changing NFPA-58 to incorporate additional accident prevention measures, such measures will likely eventually become State law.

To initiate these code changes, EPA applied for membership on the LP-Gas Technical Committee, and NFPA granted that membership request. In June 1999, EPA submitted several proposals to modify NFPA-58 to incorporate additional accident prevention measures into the code. These proposals were vetted through the deliberative committee process over the course of the last 1½ years, and barring any last-minute action to reverse the proposed changes at the final code-adoption meeting on November 15, they will be incorporated into the next edition of NFPA-58, to be published in early 2001.

This is an example of EPA working with a voluntary standards organization to accomplish its public health and safety mission without using Federal regulations.

Standards, Trade, and Environment

EPA, like many agencies, is also active in the interagency trade policy development process with international trade agreements that govern the use of standards in regulations by agencies. Specifically, EPA participates in the development of U.S. positions in negotiations in review of the Technical Barriers to Trade (TBT) Agreement and in formulation of a potential TBT or chapter on standards-related measures in the Free Trade Area of the Americas (FTAA). The FTAA, in particular, represents a key opportunity as many stakeholders believe it retains important clarifications on the relationship of regulation, standards, and trade disciplines made in the North American Free Trade Agreement (NAFTA) and not necessarily explicit in the TBT. Similar to some of the NAFTA text, the recently signed U.S. Free Trade Area with the Kingdom of Jordan highlights the right of countries to establish their own levels of protection for health, safety, and the environment.

International Work

In addition, EPA serves an important role in encouraging the use of international voluntary consensus standards in key organizations with which it works, including the Organization for Economic Cooperation and Development, United Nations Environmental Program, and United Nations Council for Trade and Development. This encouragement is not only important to achieving environmental goals, but means that U.S. business and industry stakeholders have a vested interest in, and opportunity to participate in, the international standards that reflect harmonization among governments as well as industry users.

Organization for Economic Cooperation and Development (OECD)

Although OECD is not, strictly speaking, a standards developing body under the definition of the Office of Management and Budget (OMB) Circular A-119, it has a Test Guidelines

Program (TGP) that develops consensus documents to which the United States, as a member of OECD, subscribes. The Agency believes participation in the development of the Test Guidelines (TGs) to be consistent with the intent of the Circular.

The OECD is a formal intergovernmental organization that currently consists of 29 member countries with advanced market economies producing and using over 75 percent of the world's chemicals. The OECD's TGP was established in 1981 with publication of 51 consensus TGs for the conduct of a variety of test methods to assess the characteristics of chemicals (e.g., solubility in water, toxicity to rodents, to fish, etc.). The purpose of the OECD's TGs is to help minimize nontariff trade barriers between member countries, avoid the duplication of testing, and minimize the use of animals in testing. There are currently 95 OECD TGs.

The U.S. National Coordinator has a contact list of about 60 groups, organizations, and/or individuals with expertise who have indicated an interest in providing expert comments on some or all of the OECD TGs distributed to the United States. This list includes distributions to expert contacts at several Federal and State agencies, industry associations, chemical industry and testing laboratories, and a variety of expert contacts at nongovernmental organizations such as academic institutions.

As a member of OECD, the United States comments on TGs when they are developed. The TGs are consensus documents and are likely to be among the most widely used in the industrialized world for testing chemicals.

9. Comments:

This report and comments are submitted on behalf of EPA by Dr. Mary C. McKiel, EPA Standards Executive.

EPA appreciates the Federal database format created by NIST to facilitate individual agency/department annual reporting under the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119. EPA information contained in Section 9 of the NIST database is intended to accompany the required reporting elements in order to provide a complete Agency report. The open format of Section 9, in combination with the more standardized elements, enables OMB, Congress, and any reader to get a comprehensive view of the Agency's standards-related activities. In particular, this section allows each Agency the option to highlight achievements and activities in accordance with the priorities, mission, and goals of the individual Agency.

HIGHLIGHTS

- a. EPA's commitment to the letter and spirit of the NTTAA is evident in regulatory, contracting, and voluntary activities throughout the Agency. EPA promulgated 600 final, proposed, and other rules. In the 585 final rule makings, EPA used voluntary consensus standards in 453 of them, or 77 percent. That is a 42-percent increase from 1999. The success of EPA's implementation is largely due to the efforts of the Agency's Standards

Program and the Office of General Counsel working cooperatively with the EPA regulatory Policy Steering Committee, the rule writers, and standards coordinators throughout the Agency.

- b. A total of 122 contracts, including 6 ADP/IT, 37 construction, and 79 lab contracts included voluntary standards.
- c. The Agency refined its ability to track use of voluntary consensus standards in complex rulemakings, many of which reference use of voluntary standards from previous rule makings. The ability to sort a given year's references as "newly used" versus "previously used" in the same regulation means the Agency can provide a more accurate and informative report.

Based on an inquiry from OMB, EPA undertook further analysis of the number of voluntary consensus standards rejected in lieu of government-unique standards shown in our FY 1999 EPA Report on the Implementation of the NTTAA and OMB Circular A-119. The analysis supplements the 1999 Report and provides additional clarification to OMB, specifically identifying the voluntary consensus standards that EPA deemed impractical for regulatory purposes and providing an explanation for each impracticability determination. We also explained the discrepancy between the initial report and the results of this analysis and have confidence that the numbers resulting from the analysis are accurate.

The Agency believes that the preparation of this information, and the insights we learned in the process about the application of the OMB Circular to EPA regulatory activities, will benefit the Interagency Committee on Standards Policy, and in particular, those members of the Regulatory Agencies Working Group.

An important highlight of the analysis is that the number of EPA decisions made regarding use of government-unique standards in lieu of existing voluntary consensus standards does not necessarily equal the number of standards involved. EPA's 1998 annual submission, based on review of preamble language to NTTAA-related rulemakings, reports the instances where we rejected a voluntary standard, but these cases did not involve multiple uses of the same standard. The 1999 report involved more than three times the number of rulemaking actions, many of which involved multiple standards decisions. Preamble information for final rules provided all the information to the public and the standards bodies, but there was no way to track considerations of the same standard, for the same use, in multiple rules. As the following shows, EPA has now identified the sources of "counting" discrepancy, determined the exact number of decisions and standards that amend our initial report, and taken necessary steps to ensure accuracy in subsequent annual reports.

In order to respond to OMB's request to review our FY 1999 report on voluntary consensus standards that the Agency found impractical in rulemaking, EPA rule writers retrieved the

documented information from their files and performed additional analysis in partnership with the Office of General Counsel and the EPA Standards Executive. In doing so, the Agency identified the following two major factors:

- a. First, EPA found that the Agency had occasionally reported “rejected as impractical” some voluntary consensus standards that, upon more thorough examination, were not applicable to the rule in question even though they were flagged on a database search. However, these “rejections” were cited in preambles and, therefore, counted in the annual report. EPA has taken steps to ensure that our rule writers have more accurate guidance in the identification of applicable voluntary consensus standards that are covered by the NTTAA and OMB Circular.
- b. Second, EPA found several cases where the same standard was found to be impractical for a number of different rules. In reporting on the number of voluntary consensus standards rejected in lieu of government-unique standards, however, the Agency counted each decision separately without recognizing that the same standard was involved multiple times. In the final analysis, we found 83 instances involving 18 standards where the voluntary consensus standards were genuinely impractical for use in lieu of government-unique standards.

The Agency has since provided additional guidance that expands and improves the NTTAA sections in the preamble of our rules. EPA believes this will clarify our reporting of identified standards that are impractical for use in Agency rules as well as improve the transparency of our impracticability determinations.

As noted in a June 14 letter to OMB, the possible use of voluntary consensus standards and thereby the reported number of standards used or rejected, is partially a function of the number and nature of rules promulgated each year as published in our regulatory agenda. The number of standards used or rejected in a single rule also varies as individual rulemakings may consider “0,” “1,” or multiple voluntary consensus standards. Consequently, it is difficult to construct meaningful trends from year-to-year or rule-to-rule without assessing or considering more contextual information.

The search for, and use of, standards are now part of EPA rule writers regular and best practices. EPA typically requests information concerning voluntary consensus standards in proposed rulemakings and engages in its own proactive searches for applicable voluntary consensus standards. In preambles to final rulemakings, EPA explains its decisions with respect to identified and applicable voluntary consensus standards that it found impractical for use in lieu of government-unique standards. EPA also publishes its responses to comments on any voluntary consensus standards-related determinations in final rulemakings.

EPA gave OMB a matrix that highlights the multiplicity factor identified above. Although voluntary consensus standards were found to be impractical in 83 cases for 10 rules, only 18 different standards were involved. A majority of the 10 rules that found voluntary

consensus standards to be impractical, sought to measure and regulate the same pollutants from different sources. Thus, the same voluntary consensus standards were considered and determined to be impractical several times over.

EPA also explained the impracticability determination for each voluntary consensus standard in EPA's 10 FY 1999 final rules. Over and above NTTAA reporting requirements, the Agency also analyzed voluntary consensus standards that were under development at the time of the rulemaking, noting that such voluntary consensus standards may be appropriate for future use. In many cases, EPA noted instances where no corresponding voluntary consensus standards were found to substitute for existing government-unique methods. Furthermore, some new rules and amended rules make use of existing government-unique methods when relevant and applicable voluntary consensus standards are not found. When the Agency finds that its use of a voluntary consensus standard may be impractical, EPA rarely expends public resources to develop a new government-unique method; instead, EPA relies on existing, previously developed methods. Voluntary standards organizations and their members have found this kind of information from EPA to be useful in planning their own work.

In summary, EPA's response for FY 1999, regarding the requirement of the Circular to report on our Agency's decisions to use government standards in lieu of existing voluntary consensus standards, was corrected from "91" to "83." The correct number of standards rejected is 18. EPA believes that both elements of information are needed in order to assess the Agency's implementation of the Law and Circular.

FEDERAL COMMUNICATIONS COMMISSION (FCC)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

1

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

5

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

The policies of 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.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

None.

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

This Web-based procedure for reporting works well.

FEDERAL EMERGENCY MANAGEMENT ASSOCIATION (FEMA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

4

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

7

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

N/A

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

FEMA does not have any recommendations as to the effectiveness of Circular A-119.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

Does not apply.

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

As described above, FEMA is one of the first Federal agencies to recognize the value of voluntary consensus organizations, and within the building science community, has been successfully working with these organizations since the early 1980s. By using these organizations for almost 20 years, FEMA has been able to get design and construction provisions that reduce the threat from natural hazards into the hands of the public in an effective and timely manner without the undue burden of additional Federal regulations.

FEDERAL TRADE COMMISSION (FTC)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

0

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

0

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

See response to question 9.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

See response to question 9.

8. Provide Any Examples or Case Studies of Standards Successes:

See response to question 9.

9. Comments:

FTC is an independent agency of the U.S. 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, nor does it adopt standards promulgated by private voluntary consensus standards organizations, participate in developing private voluntary standards, or engage in other standards activities pertinent to OMB Circular A-119.

GENERAL SERVICES ADMINISTRATION (GSA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

81

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

47

3. Number of Voluntary Consensus Standards Used in FY 2000:

10

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

10

| <u>Voluntary Standard</u> | <u>Government Standard</u> |
|---------------------------|----------------------------|
| ANSI Z87.1 | A-A-1994 |
| ASME B107.11 | A-A-2330 |
| ASTM D6123 | A-A-113 & A-A-883 |
| ASTM D98 | A-A-169 |
| ASTM D632 | A-A-1545 |
| GPA 2140 | A-A-2897 |
| NFPA 1964 | A-A-2279, 2280, & 2281 |
| SAE AMS-C-22542 | MIL-C-22542 |
| UL 32 | A-A-1674 |
| UL 924 | A-A-2085 |

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

4

| <u>Government Standard</u> | <u>Voluntary Standard</u> | <u>Explanation</u> |
|----------------------------|---------------------------|-------------------------|
| AA-V-2737 | UL 608 | See Section 9, Comments |
| KKK-A-1822D | ASTM F2020-00 | See Section 9, Comments |
| AA-D-600B | UL 608 | See Section 9, Comments |
| FF-L-2740 | UL 768 | See Section 9, Comments |

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

We have no comments or recommendations for change concerning OMB Circular A-119.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

GSA has been very active in the National Aerospace and Defense Contractors Accreditation Program. This involved identifying and verifying appropriate standards for critical aerospace sealants. We have conducted over 60 audits as a member of this group, in addition to providing and developing direction and guidelines. This partnership has eliminated the need for government testing of these sealants, while at the same time ensuring consistent product quality and faster delivery of these limited shelf-life products. The government-industry partnership currently has over 1,000 accredited suppliers, and the Air Force and GSA save over \$300,000 per year on sealant testing.

8. Provide Any Examples or Case Studies of Standards Successes:

None.

9. Comments:

GSA continues to expand its emphasis on the procurement of commercial off-the-shelf products and services.

Since 1994, GSA has replaced 93 government standards with voluntary standards and adopted an additional 86 voluntary standards.

Acronyms:

ANSI - American National Standards Institute
ASME - American Society of Mechanical Engineers
ASTM - American Society for Testing and Materials
GPA - Gas Processors Association
NFPA - National Fire Protection Association
SAE - SAE International
UL - Underwriters Laboratories

The following government-unique standards are being used in lieu of existing voluntary standards:

AA-D-600B, Door, Vault, Security, and AA-V-2737, Modular Vault Systems, in lieu of UL 608.

FF-L-2740, Locks, Combination, in lieu of UL 768.

These government specifications cover products used for the protection of national security information. The standards were developed after government review and testing determined that the commercial standards did not provide the required level of protection, or those commercial products that did provide the level of protection significantly exceeded the price of products meeting the government standards.

KKK-A-1822D, Ambulance, Emergency Medical Care Surface Vehicle, in lieu of ASTM F2020-00.

This Federal specification is referenced in an existing contract. The ASTM standard is currently being reviewed for possible use in future contracts.

GOVERNMENT PRINTING OFFICE (GPO)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

3

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

2

3. Number of Voluntary Consensus Standards Used in FY 2000:

108

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

4

| <u>Government Standard</u> | <u>Voluntary Standard</u> | <u>Explanation</u> |
|----------------------------|--|--|
| FED-STD 209 | ISO 14644-1 & ISO 14644-2 | Second ISO standard not issued until end of FY 2000. |
| MIL-STD 105 | ANSI/ASQC Z1.4 | Cited in small number of contracts due to editing errors. These are being corrected. |
| MIL-STD 1189 | ANSI/AIM X5-2 & ANSI X3.182 | Cited in small number of contracts due to editing errors. These are being corrected. |
| MIL-STD 498 | IEEE/EIA 12207.0, IEEE/EIA 12207.1, & IEEE/EIA 12207.2 | Cited in small number of contracts due to editing errors. These are being corrected. |

6. 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.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

N/A

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

The number reported for No. 3 comprises standards mentioned explicitly in a contract or incorporated by reference to GPO Contract Terms documents.

INTERNATIONAL TRADE COMMISSION (ITC)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

1

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

1

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

Circular A-119 does not have a significant impact on our operations and we have no basis for an evaluation.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

We are nominal members of the National Institute of Standards and Technology standards group, but do not participate in a substantial way. We collect data for trade investigations using whatever standards that prevail in whatever industry we are studying.

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

None.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

38

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

156

3. Number of Voluntary Consensus Standards Used in FY 2000:

860

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

N/A

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

Office of Management and Budget Circular A-119 continues to provide stimulus for NASA's effort to improve its technical standards management system, enhance the use of voluntary consensus standards products, and challenge the need for NASA-unique technical standards requirements. However, there is a need to clarify the term "use" of standards and its interpretation for "categorical" reporting. Using the same basis as for "transactional" reporting could place an unreasonable burden on "procurement" (versus regulatory) agencies such as NASA.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

As an acquisition-oriented agency, conformity assessment is a major element of our policies and procedures to ensure the safety and mission success of NASA programs. NASA has a long-standing practice of working with other government agencies and the public sector to integrate best practices into our activities. NASA continues to work with the Department of Defense (DOD) and the aerospace industry to adopt and define consistent quality practices.

NASA also cooperates with DOD in the implementation of their Single Process Initiative that is used to identify and apply common standards and criteria at facilities that produce equipment for many end users within both DOD and NASA. The reduction of multiple

quality requirements to a single set of quality requirements applicable to all programs eliminates the need for contractors to maintain duplicate or overlapping quality systems and permits more uniform conformity decision process.

NASA routinely utilizes other Government agencies to assist us 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 are ongoing relationships that utilize the expertise and infrastructure that are resident within these agencies and allow NASA to limit our unique conformity assessment activities. The management and monitoring processes established for these CAS activities provide a mechanism to continually exchange ideas and best practices related to conformity assessment. Additionally, in the past year NASA undertook a major step to include commercial entities as a significant element of our conformity assessment activities with the award of a comprehensive Agency-wide Supplier Assurance Contract (SAC). Complementing the award of the SAC, NASA conformity assessment policy, as contained within NASA Procedures and Guidelines 8735.2, was also updated this year to reflect use of contractors as an element of the potential sources of conformity assessment sources.

NASA extensively utilizes the DoD specification and standards system operated by the Defense Supply Center Columbus (DSCC) for ensuring compliance of its suppliers across the agency. DSCC performs audits, monitors, and assesses documentation and performance conformance to specifications and standards used to procure most of the electronic parts used for NASA spaceflight systems. NASA cooperates with the various arms of DoD to develop and maintain these joint-use specifications and standards.

NASA has initiated a cooperative effort that includes representation from the Navy and Air Force to coordinate auditing and surveillance activities for electronic parts when such audits cannot be performed by DSCC or by DSCC alone. The objective of this initiative is to share conformance information and activities amongst the participants to avoid duplication of effort and to limit the number of audit teams encountered by suppliers.

8. Provide Any Examples or Case Studies of Standards Successes:

The NASA Technical Standards Program has initiated three new activities that will enhance its use and support of voluntary consensus standards. The agency-wide Full-Text Technical Standards System will provide full-text on-line documents for NASA use for adopted and other nongovernment standards products. For those standards products not available electronically, a hard copy will be made available. The Standards Update Notification (Alert) System will provide users with notices of updates to standards products that they have identified for use on their programs. The Lessons Learned/Best Practices/Application Notes system will provide links to internal recommendations for use of individual standards products. These Lessons Learned, Best Practices, or Application Notes will be of great benefit in adopting voluntary consensus standards to NASA use. The results of “pilot”

actions on these three systems to date have been outstanding in terms of user interests and value to their activities on NASA Programs and Projects. This "case study" will be expanded to agency-wide involvement in FY 2001.

In collaboration with DOD, NASA prepared a paper entitled "Participation By Federal Agencies In Voluntary Consensus Standards Bodies." The paper was published by the Standards Engineering Society in their Journal and by the American Society for Testing and Materials (ASTM) in their ASTM Standardization News. It focuses on Federal employee participation responsibilities and encourages participation on standards developing organization (SDO) committees.

Use of the NASA Technical Standards System, and access to voluntary consensus standards, has grown significantly due to the availability of standards products online and supporting information programs. Brochures have been distributed within the Agency as well as at conferences and professional meetings. The Program has taken advantage of any Center's training opportunities to include short training courses on standards policy and the availability of voluntary consensus standards through the Program. We fully expect these awareness activities to increase the use of voluntary consensus standards to meet standards information needs, as well as eventually increasing participation on SDO committees.

9. Comments:

None.

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION (NARA)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

5

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

9

3. Number of Voluntary Consensus Standards Used in FY 2000:

25

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

2

| <u>Voluntary Standard</u> | <u>Government Standard</u> |
|---------------------------|----------------------------|
| NFPA 231C | MIL-M-17194C |
| NFPA 231 | AS-S-271 or AA-S-1047 |

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

1

| <u>Government Standard</u> | <u>Voluntary Standard</u> | <u>Explanation</u> |
|----------------------------|--------------------------------------|---|
| NARA data standards. | MARC, EAD, APPM, ISAD(G), ISAAR(CPF) | These voluntary standards did not meet the precise needs of the agency. |

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

NARA employees involved in standards-setting activities are cognizant of the importance of using technical voluntary consensus standards. Where possible, we have incorporated, by reference in our regulations, voluntary standards rather than government-unique standards. This has been especially important in our revised records storage standards regulation since private companies now have to comply with these standards if they plan to house Federal Government records in their facilities.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

NARA has worked with the Department of Defense (DoD), Joint Interoperability Test Command (JITC), to evaluate DoD 5015.2-STD: Design Criteria for Records Management Application Software. NARA endorsed this standard as “one acceptable means of automating records management.” NARA has also certified JITC's software certification testing process, such that software certified by the JITC testing process could be recognized for use by civilian Federal agencies as one acceptable means of automating records management functions. While we recognize that this is a government-unique standard, there are no voluntary consensus standards that address this issue.

NARA's records center facility standards (36 CFR Part 1228) became final in January 2000. As a requirement of this regulation, NARA reviews leased facilities (or facilities being considered for lease) for conformance with our standards.

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

While resource constraints limit the number of NARA staff involved in standards-setting activities, NARA will continue to actively participate in the setting of national and international standards that affect the mission of NARA.

NATIONAL SCIENCE FOUNDATION (NSF)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:

3

2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:

3

3. Number of Voluntary Consensus Standards Used in FY 2000:

0

4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:

0

5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:

0

6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

A-119 allows effective agency participation in standards activities. No changes are recommended.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

N/A

8. Provide Any Examples or Case Studies of Standards Successes:

N/A

9. Comments:

None.

NUCLEAR REGULATORY COMMISSION (NRC)

1. Number of Voluntary Consensus Standards Bodies in Which There is Agency Participation:
18
2. Number of Agency Employees Participating in Voluntary Consensus Standards Activities:
141
3. Number of Voluntary Consensus Standards Used in FY 2000:
36
4. Number of Voluntary Consensus Standards Substituted for Government-Unique Standards:
0
5. Number of Government-Unique Standards Used in Lieu of Voluntary Standards:
0
6. Provide an Evaluation of the Effectiveness of Circular A-119 Policy and Recommendations for Any Changes:

The policy guidelines provided in Office of Management and Budget (OMB) Circular A-119, for participating in voluntary consensus standards bodies and using voluntary consensus standards, are generally consistent with longstanding NRC practices. The staff believes that these guidelines provide appropriate direction and encouragement for Federal agencies to develop internal agency-wide guidelines to implement Public Law (P.L.) 104-113 and OMB Circular A-119. These guidelines also provide sufficient and reasonable flexibility for each agency to make an independent case-by-case determination as to the usability of a particular standard within that agency's scope and responsibility.

7. Provide the Conformity Assessment Activities in Which the Agency has been Involved:

No report for conformity assessment activities in FY 2000.

8. Provide Any Examples or Case Studies of Standards Successes:

In FY 2000, NRC took several actions to increase the effectiveness and efficiency of our process for implementing P.L. 104-113 and OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. NRC Management Directive 6.5, NRC Participation in the Development and Use

of Consensus Standards, was issued on November 2, 1999. The Directive provides: (a) direction for implementing P.L. 104-113 and OMB Circular A-119 and (b) organizational responsibilities and guidance for NRC staff participating in the development of consensus standards and for NRC use of consensus standards. The NRC staff met with representatives from the standards developing organizations who provide codes and standards for the nuclear industry twice during this reporting period (December 8, 1999, and July 27, 2000). The NRC has been hosting these meetings on a semiannual basis. The purpose of these meetings is to foster better communication and discuss standards under development, current needs, and priorities. These exchanges have proved to be very beneficial; the last meeting was held in January 2001.

9. Comments:

None.

Appendix C:

Charter of the
Interagency Committee
on
Standards Policy

DEPARTMENT OF COMMERCE

CHARTER
OF THE
INTERAGENCY COMMITTEE ON STANDARDS POLICY

Establishment

1. The Interagency Committee on Standards Policy (herein after referred to as the Committee) is established to advise the Secretary of Commerce and the heads of other Federal agencies in matters relating to standards policy.
2. The Committee fulfills the mandates set out in paragraph 13.b of the Office of Management and Budget (OMB) Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," in its revision of February 19, 1998.
3. The Committee reports to the Secretary of Commerce through the Director of the National Institute of Standards and Technology.

Purpose

The purpose of the Committee is to ensure effective participation by the Federal Government in domestic and international standards and conformity assessment activities and to promote the adherence to uniform policies by Federal agencies in the development and use of standards and in conformity assessment activities. Well-considered Federal policies reflecting the public interest can expedite the development and adoption of standards that stimulate competition, promote innovation, and protect the public safety and welfare. The establishment and application of appropriate standards for the characteristics or performance of goods, processes, and services can contribute significantly to national and international prosperity, economic growth, and public health and safety. The establishment of such standards can also further national goals for environmentally sound and energy efficient materials, products, systems, services, or practices. Heightened national and international awareness of the importance of standards activities, as reflected by enactment of the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113, signed into law March 7, 1996), and recommendations presented in the National Research Council's report "Standards, Conformity Assessment, and Trade into the 21st Century" (National Academy Press, 1995) call for the Committee to intensify its efforts to identify the broad roles and appropriate interactions of agencies in exercising the Government's authority.

Objective

The objective of the Committee shall be to promote effective and consistent standards and conformity assessment policies in furtherance of U.S. domestic and foreign goals and, to this

end, to foster cooperative participation by the Federal Government and U.S. industry and other private organizations in standards activities, including the related activities of product testing, management system registration, certification, and accreditation programs.

Functions

1. As appropriate, the Committee shall gather, analyze, and maintain current information about standards; product testing; management system registration; accreditation and certification; and related regulations, rules, policies, and activities:
 - (a) conducted within or established by Federal agencies;
 - (b) conducted by private domestic and foreign national standards bodies and by regional and international private and intergovernmental organizations engaged in such programs; and
 - (c) pertaining to the relationships among agencies of the Federal Government with industry and the various national, regional, and international organizations engaged in such programs.
2. On the basis of such information and when appropriate with respect to the activities named in paragraph one above, the Committee shall make recommendations to the Secretary of Commerce to:
 - (a) strengthen coordination of standards-related and conformity assessment-related policies and activities among the Federal agencies;
 - (b) improve the efficiency within the Federal Government of standardization efforts with the U.S. private sector, as well as with regional and international organizations, both private and governmental;
 - (c) promote standards-related policies, including directories of personnel participating in standards activities, within the Federal Government consistent with statutory obligations in regard to interactions with non-Federal Government organizations;
 - (d) ensure effective representation of the Federal Government at significant regional and international standards-related meetings and conferences;
 - (e) promote the use of internationally acceptable standards and related activities with a view to increasing trade and economic integration and development;
 - (f) monitor U.S. technical obligations as a signatory to the World Trade Organization, the U.S.-Canada Free Trade Agreement, the North American Free Trade Agreement, and other treaties encompassing standards-related trade issues;
 - (g) encourage the development of agency strategic plans for managing and monitoring use of voluntary standards and participation in standards-related activities;
 - (h) promote the use of standards that serve national goals related to increased use of the metric system of measurement and environmentally sound and energy efficient materials, products, systems, services, and practices; and
 - (i) assess and improve the adequacy of such agency plans and activities.

Membership

1. Together with the Department of Commerce the following agencies constitute the membership of the Committee:

Department of Agriculture
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of the Interior
Department of Justice
Department of Labor
Department of State
Department of Transportation
Department of the Treasury
Department of Veterans Affairs
Consumer Product Safety Commission
Environmental Protection Agency
Federal Communications Commission
Federal Emergency Management Agency
Federal Trade Commission
General Services Administration
International Trade Commission
Office of Management and Budget
National Aeronautics and Space Administration
National Archives and Records Administration
National Communications Systems (Dept. of Defense) (non-voting member)
National Science Foundation
Nuclear Regulatory Commission
U.S. Agency for International Development
U.S. Government Printing Office (legislative liaison - non-voting member)
U.S. Postal Service
Office of the U.S. Trade Representative

The head of each member agency shall ensure representation by a responsible high level policy official (Senior Executive Service or higher) who serves as the agency representative on the Committee. Such agency representative shall also serve as the "Standards Executive" as defined in section 15 of OMB Circular No. A-119. Appointments to the Committee shall be for an indefinite term.

2. Agency representatives may designate alternates of equivalent senior status to serve in their absence.

3. Experts from organizations within the member agency may be designated by agency representatives to serve on task groups established by the Committee.
4. Other Federal agencies may become members of the Committee upon application to or invitation by the Secretary of Commerce.

Administrative Provisions

1. The Director of the National Institute of Standards and Technology (NIST) or the Director's designee shall chair the Committee.
2. NIST shall provide administrative arrangements for the Committee including secretarial services, calling of meetings, arranging for a meeting place, and preparation of an agenda, discussion material, and reports.
3. The Committee shall meet at least three times each year. Other meetings may be called at the discretion of the Chair or at the written request of five (5) members of the Committee.
4. The Committee may establish task groups as appropriate.
5. Attendance at Committee meetings by at least one half of the designated members of the Committee shall constitute a quorum. Decisions internal to the Committee's operations, such as formation of a task group, shall be made by a majority of those present and voting. Voting on Committee business and proposals shall be limited to designated agency members. Decisions concerning Committee recommendations to the Secretary of Commerce on governmental policy or other matters set out in paragraph two of the section entitled "Functions" shall require ratification by two-thirds of the members present and voting. Dissenting positions of the decision may be made a matter of record. The Chair shall not vote except in the case of a tie vote.
6. The annual cost of operating the Committee is estimated at \$25,000 (with overhead) which includes 0.10 staff year for staff support.
7. The Committee shall submit an annual report to the Secretary of Commerce so that the Secretary may satisfy the reporting requirements set forth in OMB Circular No. A-119, as applicable to the Secretary, and in P.L. 104-113, as applicable to the head of each agency. Each such report shall also summarize the Committee's activity during the period covered and shall include a listing of all recommendations formulated by the Committee during that period.

Duration

The need and mission of the Committee shall be reexamined three years after the date of this Charter to determine the need for the Committee's continuation.

/signed/
Secretary of Commerce

Dated: October 26, 2000

Appendix D:

Membership of the Interagency Committee on Standards Policy

Fiscal Year 2000

AGENCY MEMBER**Agency for International Development, U.S. (USAID)****REPRESENTATIVE**

Ms. Kathleen O'Hara
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Agriculture, Department of (USDA)

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Commerce, Department of (DOC)

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Consumer Product Safety Commission (CPSC)

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Defense, Department of (DoD)

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Appendix E:

List of National Institute of Standards and Technology Publications Related to Public Law 104-113

STANDARDS AND CONFORMITY ASSESSMENT RELATED PUBLICATIONS

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NTTAA PUBLICATIONS:

The National Technology Transfer and Advancement Act - Plan for Implementation (NISTIR 5967)

Toward a National Standards Strategy - Conference Report (NISTIR 6290)

Toward A National Standards Strategy: Conference Summary Report (NISTIR 6259) by
Walter G. Leight and Krista J. Johnsen Leuteritz, published September 23, 1998

Towards Strategic Management of Standards Activities at NIST (NISTIR 6292)

Conference on Using Voluntary Standards in the Federal Government - September 8, 1997

Using Voluntary Standards in the Federal Government (NISTIR 6086)

1998 Federal Standards Workshop: Standards Management - A World of Change and
Opportunities – Conference Handbook -- A joint DOE, NIST, EPA, NASA, Partnership in
RMS, FDA publication

1998 Federal Technical Standards Workshop Proceedings (CONF-980822) – A joint DOE,
NIST, EPA, NASA, Partnership in RMS, FDA publication

1998 Annual Report on the Implementation of Office of Management and Budget (OMB)
Circular A-119 and P.L. 104-113, March 16, 2000 (NISTIR 6493)

1997 Annual Report on the Implementation of Office of Management and Budget (OMB)
Circular A-119 and P.L. 104-113, October, 1999 (NISTIR 6412)

INTRODUCTORY PUBLICATIONS ON STANDARDS AND CONFORMITY ASSESSMENT ACTIVITIES:

The ABC's of Standards-Related Activities in the United States (NBSIR 87-3576)

The ABC's of Certification Activities in the United States (NBSIR 88-3821)

The ABC's of the U.S. Conformity Assessment System (NISTIR 6014)

Laboratory Accreditation Activities in the United States (NISTIR 4576)

Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues (NISTIR 4721)

More Questions and Answers on the ISO 9000 Standard Series and Related Issues (NISTIR 5122)

The U.S. Certification System from a Governmental Perspective (NISTIR 6077)

ISO Environmental Management Standardization Efforts (NISTIR 5638-1)

NACLA PUBLICATIONS:

Report on NIST-NACLA MOU Workshop, July 6, 2000 (NISTIR 6540)

Report on the Open Forum on Establishment of the National Council for Laboratory Accreditation (NACLA) at the National Institute of Standards and Technology, January 7, 1997 (NISTIR 6008)

Examination of Laboratory Accreditation Programs in the United States and the Potential Role for a National Laboratory Accreditation System (NIST GCR 97-714)

Proceedings of the Open Forum on Laboratory Accreditation at the National Institute of Standards and Technology, October 13, 1995 (NIST SP 902)

DIRECTORIES:

Directory of International and Regional Organizations Conducting Standards-Related Activities (NIST SP 767)

Directory of European Regional Standards-Related Organizations (NIST SP 795)

Standards Activities of Organizations in the United States (NIST SP 806, 1996 Edition)

Directory of Federal Government Certification and Related Programs (NIST SP 739, 1999 Edition)

Directory of U.S. Private Sector Product Certification Programs (NIST SP 903)

Directory of Federal Government Laboratory Accreditation/Designation Programs (NIST SP 808)

Directory of State and Local Government Laboratory Accreditation/Designation Programs
(NIST SP 815)

Directory of Professional/Trade Organization Laboratory Accreditation/Designation Programs
(NIST SP 831)

Standards Setting in the European Union - Standards Organizations and Officials in EU
Standards Activities (NIST SP 891, 1997 Edition)

Profiles of National Standards-Related Activities (NIST SP 912)

An Overview of the Development of Technical Infrastructure in the Asia-Pacific Region: The
Work of the Asia-Pacific Economic Cooperation (APEC) Sub-committee on Standards and
Conformance (SCSC) and the Specialist Regional Bodies (SRBs) (NISTIR 6325)

Free Trade Area of the Americas (FTAA) Conformity Assessment Infrastructure (NIST SP 941)

Semi-Annual Listing of North American Quality System Registration Organizations (NAQSRO)

Annual Directory of DOC Memberships on Outside Standards Committees

NVLAP PUBLICATIONS:

NIST Handbook 150: NVLAP Procedures and General Requirements

Directory of Accredited Laboratories

NVLAP Program-Specific Handbooks

NVLAP Policy Guides:

PG-1-1998: NVLAP Traceability Policy (March 1998)

PG-2-1998: Accreditation Documents for Laboratories Whose Accreditation Has Been
Suspended, Revoked, or Otherwise Terminated (May 1998)

PG-3-1999: Delegation of Authority from the Director of NIST to the Chief of NVLAP
(November 1999)

MISCELLANEOUS PUBLICATIONS:

TBT Agreement Activities of the National Institute of Standards and Technology

Environmental Management Systems Voluntary Project Evaluation Guidance (NISTIR 6120)

A Selective Review of Testing Laboratory Accreditation Movements in the United States
(NIST GCR 98-740)

Survey on the Implementation of ISO/IEC Guide 25 by National Laboratory Accreditation Programs (NISTIR 5473)

Government's Role in Standards-Related Activities: Analysis of Comments (NISTIR 4367)

MAGAZINE ARTICLES:

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Leight, W.G., Preserving the Miracle. Partnership in RMS Standards: A Newsletter for Professionals, January 2000, pp. 1-6.

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Breitenberg, M., Conformity Assessment: An Important Policy Issue. ASTM Standardization News, November 1997, pp. 20-23.

Johnsen Leuteritz, K., Toward Strategic Management of Standards Activities at NIST. ASTM Standardization News, December 1999, cover article. Reprinted in DOE's "The Standards Forum," March 2000.

Johnsen Leuteritz, K., The New MOU. ASTM Standardization News,

Johnsen Leuteritz, K., The Church of Accreditation. American Society for Quality, February 1999.

Overman, J., NIST and Strategic Standardization. ANSI Reporter, September 2000.

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Johnsen Leuteritz, K., Standards Summit: A First Step Toward a National Strategy. Energy and Environment Update, American Society for Quality, October 1998.

Johnsen Leuteritz, K., Why the Work of the Multi-State Working Group Matters to Federal Agencies. Energy and Environment Update, American Society for Quality, May 1998.