

NISTIR 7413

Tenth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment

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Summary Report on Federal Agency Use of Private Sector Standards and Conformity Assessment Activities for FY 2006

1.0 – Executive Summary

The U.S. Department of Commerce presents this summary report for the Office of Management and Budget (OMB) in compliance with OMB Circular A-119 and Public Law 104-113, the National Technology Transfer and Advancement Act (NTTAA). As required by Section 9 of the Circular, this report, prepared by the National Institute of Standards and Technology (NIST), describes activities related to the use of voluntary consensus standards (VCSs) by 27 federal agencies during fiscal year (FY) 2006.

Federal agencies have made tremendous progress in increasing their reliance on voluntary consensus standards in regulation and procurement. NIST, through its Standards Incorporated by Reference database, independently tracks government uses of private-sector standards in regulation and procurement. As of the date of this report, NIST has identified more than 20,000 citations of standards incorporated by reference in procurement and regulatory documents. This online interactive database illustrates the existing broad use of voluntary standards throughout the U.S. Government.

For FY 2006, federal agencies reported 591 *new uses* of VCSs. About 22 percent or 132 of these were substitutions for government-unique standards. Federal agencies promulgated only five new government-unique standards in lieu of VCSs during FY 2006, bringing the total number of government-unique standards used in lieu of VCSs reported since 1997 to 73. The continued adoption of significant numbers of VCSs and the low rate of adoption of new government-unique standards in lieu of VCSs illustrates the success that the NTTAA has had in encouraging agencies to first look to voluntary consensus standards to meet their needs rather than to develop government-unique standards.

Agencies reported 4,075 personnel participating in a total of 413 standards-developing organizations. The number of agency staff reported to be participating in standards activities is at an all time high, exceeding the previous high, in 2005, by 121. A number of agencies appear to be doing a more thorough job in tracking and reporting staff involvement, although there may be opportunities for additional improvement in this area. Continuous agency support is essential because these representatives work to ensure that voluntary standards adequately meet the needs of federal agencies by communicating these needs directly to standards development committees, thereby fulfilling the intent of the NTTAA.

Reports for FY 2006 show that agencies and affected stakeholders continue to realize benefits from federal participation in the development and adoption of VCSs to support agency missions. These adoptions result in cost savings to agencies, businesses, and ultimately the taxpayer through increased transactional efficiencies, reduced administrative burdens, reduced injuries and deaths, and lower costs of products and services.

During FY 2006 numerous agencies reported measurable benefits. These include over \$1.5 million in annual savings and 25,000 pages of regulations avoided by the Coast Guard through adoption of private-sector standards; reductions in over 13 million pounds of hazardous materials, 3 million pounds of non-hazardous materials, and 600,000 megawatts of energy over a five-year period reported by the Environmental Protection Agency through the consensus development of the *Electronic Products Environmental Assessment Tool*; a 90 percent reduction in baby walker injuries reported by the Consumer Product Safety Commission as a result of the widespread use of a private-sector standard specifying stair-fall requirements for baby walkers; and savings of hundreds of thousands of dollars in the inspection and testing of fire protection systems since the 1990s when the Department of Energy adopted private-sector standards addressing this area. These examples illustrate the various ways in which the adoption and use of voluntary consensus standards benefit the United States.

2.0 – Overview and Scope

In close consultation with OMB, NIST formulates this report based on inputs submitted to NIST by federal agencies in fulfillment of the requirements of OMB Circular A-119 and the reporting requirements of Section 12 of the NTTAA. It describes federal agency activities related to the use of private-sector standards in regulation, procurement and conformity assessment during FY 2006. A list of reporting agencies may be found in Appendix A.

3.0 – Federal Agency Use of Standards

The OMB Circular requires that federal agencies use¹ voluntary consensus standards in lieu of government-unique standards in their regulatory and procurement activities. However, a federal agency is given the discretion to decide whether to use existing voluntary consensus standards if the agency determines that use of such standards would either be inconsistent with applicable laws or otherwise impractical.² The Circular also directs agencies to establish a process for a continuing review of their use of standards for purposes of updating such use, including substitution of private-sector standards for government-unique standards wherever possible.

¹ According to Section 6 of the OMB Circular, “Use” means the incorporation of a standard in whole, in part, or by reference for procurement purposes, and the inclusion of a standard in whole, in part, or by reference in regulation(s).

² “Impractical” includes circumstances in which such use would fail to serve the agency’s program needs; would be infeasible; would be inadequate, ineffectual, inefficient, or inconsistent with agency mission; or would impose more burdens, or would be less useful, than the use of another standard.

3.1 – Government-Unique Standards Used in Lieu of Voluntary Consensus Standards

The OMB Circular requires that agencies report their use of standards on either a “categorical” or a “transactional” basis. Those agencies that report on a “categorical” basis are not required to list each instance that a government-unique standard is used in lieu of a private-sector standard in procurement actions. Such agencies are required to have a system in place to ensure that government-unique standards are developed only when suitable private-sector standards are not available for use. At present, only the Department of Defense (DoD) and the National Aeronautics and Space Administration (NASA) consistently report on a “categorical” basis. Additionally, in those cases when government-unique standards are required because private-sector standards do not exist, use of the government-unique standard is not subject to reporting.

Table 3.1 illustrates the cumulative use of government-unique standards (that is, the total number used, by agency and the U.S. Government as a whole, by year) in lieu of private-sector standards since FY 1997, as well as the number of government-unique standards introduced and discontinued in each fiscal year. During FY 2006, federal agencies incorporated five new government-unique standards.^{3,4} The Department of the Labor (DOL), the Access Board (ACCESS), and the General Services Administration (GSA) each reported one and the Department of Health and Human Services (HHS) reported two new government-unique standards.

Agency ⁵	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
USDA									1	1
HHS		3	3	3	3	3	3	3	2	4
HUD				2	2	2	2	2	2	2
DOL					1	2	4	5	5	6
DOT	1	2	2	2	2	3	3	3	3	3
EPA		3	28	29	40	45	50	50	50	50
GSA				3	2	2	3	2	2	3
NARA				1	1	1	1	1	1	1
CPSC				1	1	1	2	2	2	2
GPO				4	4	4	4	4	0	0
ACCESS										1
New Uses		4	4	25	12	12	7	9	1	5
Discontinued					1			2	4	0
Total In Use		4	8	33	45	56	63	72	71	73

³ The Department of the Interior reported four new geographic standards that were developed by the interagency Federal Geographic Data Committee (FGDC); however, these standards are not ‘in lieu of’ existing voluntary standards and therefore are not included in this report. According to OMB Circular A-16, FGDC activities are restricted to “areas of special data standardization not covered by other voluntary standards consensus bodies as defined by OMB Circular A-119.”

⁴ The Government Printing Office reported one new government-unique standard which was not ‘in lieu of’ an existing voluntary standard; therefore it also was not included in this report.

⁵ See Appendix A for list of agency acronyms.

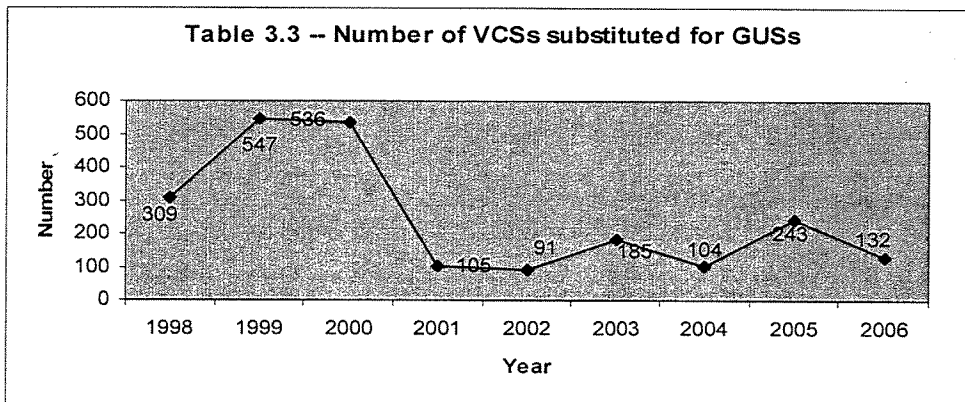
Listed in Appendix C are the government-unique standards promulgated by agencies in 2006 along with the justifications for not using the specified relevant voluntary consensus standard. For a complete listing of the government-unique standards used in lieu of voluntary consensus standards and the justifications from FY 1997 through FY 2006 see NIST's Standards website <<http://standards.gov>>.

3.2 – New Uses of Voluntary Consensus Standards (VCSs) By Federal Agencies

For FY 2006, federal agencies reported the adoption of 591 new Voluntary Consensus Standards. This represents about 9 percent of the estimated total number of VCSs in use by the Federal Government. The Federal Communications Commission, Department of Defense and the National Aeronautics and Space Administration account for about 63 percent of the reported new uses.

3.3 – Current Agency Reporting on Voluntary Consensus Standards Substituted for Government-Unique Standards

Federal agencies also report annually on the number of voluntary consensus standards they have substituted for government-unique standards during the year. Table 3.3 illustrates the substitutions for each year since FY 1997. In FY 2006, federal agencies substituted 132 voluntary consensus standards for government-unique standards.⁶ After an intense initial effort to substitute many standards, there has been an average of 143 substitutions per year since 2001, fluctuating from 50 to 100 around this mean.



⁶ Government-unique standards being substituted include the universe of GUSs, i.e. those in use prior to the implementation of NTTAA reporting, those that were not 'in lieu of VCSs', and those which were in lieu of VCSs. NIST began collecting data during reporting for FY 1998. Since 1998, there have been 2,402 reported substitutions of VCSs for GUSs across agencies. While we do not know the entire universe of GUSs, we know from published sources that DoD (the largest user of GUSs) still uses over 20,000 GUSs counting military, federal and NATO specifications and as of FY 2006 is using more than 9,200 private-sector standards. 7,400 private-sector standards were adopted by DoD before 1997. Of 9,646 standards incorporated by reference in the Code of Federal Regulations, 1409 - or 15 percent - are GUSs.

4.0 – Federal Participation in Private Sector Standards Activities

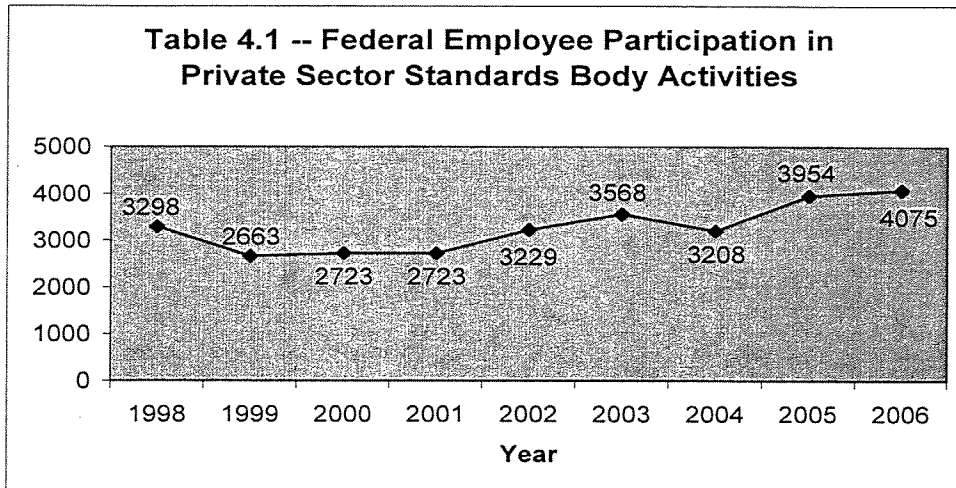
OMB Circular A-119 states that federal agencies “must consult with voluntary consensus standards bodies, both domestic and international, and must participate with such bodies in the development of voluntary consensus standards when consultation and participation is in the public interest and is compatible with their missions, authorities, priorities, and budget resources.” The Circular goes on to declare that “agency support provided to a voluntary consensus standards activity must be limited to that which clearly furthers agency and departmental missions, authorities, priorities, and is consistent with budget resources.”

4.1 – Participation Data for FY 2006

In FY 2006, agencies reported participation in 413 private sector standards bodies, compared to 409 in FY 2005. The list of organizations includes American National Standards Institute (ANSI)-accredited voluntary consensus standards developers, other (non-ANSI accredited) standards developers, industry and trade associations, international organizations, and consortia.

Federal agencies are also required by OMB to report the number of federal employees who participate in private sector standards bodies. This includes not only those who serve on technical standards development committees, subcommittees, or workgroups, but also those who participate in management activities, annual meetings, or seminars. In FY 2006, agencies reported that 4,075 employees participated in private-sector standards body activities. This was an increase of 121 reported participants over the previous year. Table 4.1 illustrates total federal employee participation in private sector standards body activities since FY 1997. Data detailing FY 2006 participation for each agency is provided in Appendix B. It should be noted that several agencies reported large increases or decreases in participation. While these agencies appear to be doing a more thorough job in correctly tracking and reporting staff involvement, there may be opportunities for continued improvement. For example, the establishment of Department-level standards councils involving all agencies within each Department could serve to better manage intra-departmental standards efforts and also further the goals of the NTTAA

A complete listing of the standards developing organizations in which federal agencies participated can be viewed in the extended appendices to this report located at <<http://standards.gov>>.



5.0 – Federal Agency Conformity Assessment Activities

The NTTAA requires NIST to coordinate federal, state, and local standards activities and conformity assessment activities with private sector standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. Federal conformity assessment activities are a means of providing assurance that the products and services regulated or procured by federal agencies have the required characteristics and/or perform in a specified manner. Agency conformity assessment procedures may include sampling and testing, inspection, accreditation, certification; licensing; product listing; the submission to an agency of manufacturing, operational, and related data for review; manufacturer self-declaration of conformity to agency requirements; mandatory labeling and advertising requirements; establishment of national requirements, which are adopted/enforced at state and local government levels; issuance of regulatory guidelines; pre-marketing approval requirements; post-marketing monitoring requirements; and the conduct of environmental impact assessments.

The full report of FY 2006 agency conformity assessment activities may be found in the *Addendum to the Tenth Annual Report on Federal Use of Voluntary Consensus Standards and Conformity Assessment* <<http://standards.gov/NTTAA>>.

6.0 – Evaluation of the Effectiveness of OMB Circular A-119

During FY 2006, the majority of reporting agencies either had no comment on the effectiveness of OMB Circular A-119 or indicated that they found the Circular effective in helping them manage their standards development programs. However, some agencies did provide substantive comments concerning the Circular and these are summarized below.⁷

⁷ It is within OMB's purview to consider and respond to these comments, as appropriate.

- Department of Defense recommended that agencies report only on standards activities that are directly related to implementing the national priorities of each particular agency as reflected in the President's annual budget. DoD also suggested that instead of relying on numerical data, the standards report should be more of a narrative summary of standards activities, which would “provide Congress a clearer indication of the importance of standards and standardization to the workings of the U.S. government.”
- Department of Health and Human Services and DoD questioned the accuracy of the data collected (as required by the Circular) due to issues of interpretation or the lack of data availability.
- Department of Homeland Security proposed that the Circular encourage government-wide use of risk-based methodologies in standards development and assessments. This approach has resulted in substantial costs savings for the Coast Guard.
- Environmental Protection Agency suggested that it would be helpful if the Circular emphasized participation in standards development and their use by regulatory agencies outside of the regulatory activity of the agency.
- Department of the Interior requested additional guidance on cooperative activities for agencies to engage in, in order to aid agency involvement in the development and adoption of consensus standards.

The full text of agency comments may be found in the *Addendum to the Tenth Annual Report on Federal Use of Voluntary Consensus Standards and Conformity Assessment* located at <<http://standards.gov/NTTAA>>.

7.0 – The Interagency Committee on Standards Policy (ICSP)

During FY 2006, 58 individuals served on the ICSP including agency Standards Executives, their alternates, NIST support staff, and representation from OMB and the Executive Office of the President. The ICSP met three times in FY 2006, including one joint meeting with the American National Standards Institute’s Government Member Forum. Information concerning the ICSP including membership, charter and meeting minutes may be found at the following link:
<<http://standards.gov/icsp/query/index.cfm>>.

8.0 – Success Stories: Examples from Federal Agencies

Leveraging the private sector standards development process for government purposes has led to significant resource savings for agencies and stakeholders throughout the Federal Government. Several examples of successes from fiscal year 2006 are:

- Consumer Product Safety Commission (CPSC)

Baby walkers are one example of the importance of voluntary standards in the achievement of CPSC’s mission. Baby walkers used to account for more injuries

than any other type of nursery product. In 1992, an estimated 25,700 children younger than 15 months of age were treated in U.S. hospital emergency rooms for baby walker injuries, most related to falls down stairs. CPSC staff worked with ASTM International and the baby walker industry and a new ASTM International safety standard was published in 1997. This standard includes performance requirements to address stair falls. Manufacturers have complied with this standard by using “gripping strips” under the walker base to stop the walker at the edge of a step. By 2005, the estimated number of baby walker injuries treated in hospital emergency rooms had dropped dramatically from 25,700 to 2,600 - a 90 percent reduction. Moreover, a recent CPSC staff effectiveness study published in the *Journal of Safety Research* concluded that the stair-fall requirements of the voluntary standard reduced the baby walker injury rate by over 60 percent.

- U.S. Coast Guard (USCG)

The U.S. Coast Guard is part of the Department of Homeland Security and is committed to developing and adopting nationally and internationally recognized standards as a means to improve maritime safety and marine environmental protection, and to promote an internationally competitive U.S. maritime industry. Today the Coast Guard supports at least 30 non-government organizations and actively participates on over 100 standards committees. Becoming an integral part in this process has enabled the USCG to avoid drafting unnecessarily detailed regulations and in some cases avoiding regulation completely. This has helped the Coast Guard evolve from a regulatory process that reacts to disaster to a more orderly process that recognizes technical innovation and progressive ideas aimed at preventing disaster. To date, the USCG has adopted over 450 industry standards, saving over 25,000 pages of federal regulations and the associated regulation maintenance, while specifying standards already familiar to the industry regulated. It is estimated that USCG’s participation on standards committees saves over \$1.5 million annually and increases the effectiveness of its inspection and technical force 100 times.

- Environmental Protection Agency (EPA)

EPA was actively involved in the development of the *Electronic Products Environmental Assessment Tool* (EPEAT), a tool that helps purchasers select and buy greener computers, laptops, and monitors. The criteria were developed with input from over 100 stakeholders and finalized through the consensus process run by IEEE (a U.S.-based standards development organization) into the IEEE 1680 *American National Standard for the Environmental Assessment of Personal Computer Products*. EPA projects that over the next five years, purchases of EPEAT rated products will result in reductions of more than 13 million pounds of hazardous materials, 3 million pounds of non-hazardous materials, and 600,000 megawatts of energy.

- Department of Energy (DOE)

The Department of Energy has historically used voluntary consensus standards promulgated by the National Fire Protection Association (NFPA) in the development and implementation of fire safety and emergency response programs at its sites. DOE and its predecessor agencies⁸ have done so for a number of reasons. NFPA is universally recognized for the diverse expertise of the members of its technical committees. (DOE and its contractor employees are widely represented within these committees.) The scope of fire safety issues with the Department is vast. Attempting to address these issues solely with internal directives would be cost prohibitive. NFPA codes and standards, through the “Equivalency” principle, allows for the flexible and cost-effective implementation of requirements. Since the 1990s DOE has saved literally hundreds of thousands of dollars in the inspection and testing of fire protection systems through the adaptation of this principle, as delineated in NFPA Standard 25, *Inspection, Testing and Maintenance of Water-Based Fire Protection Systems*, and NFPA Standard 72, *The National Fire Alarm Code*.

Additional agency success stories may be found in the responses to Question 1 in the *Addendum to the Tenth Annual Report on Federal Use of Voluntary Consensus Standards and Conformity Assessment* located at: <<http://standards.gov/NTTAA>>.

9.0 – Challenges and Opportunities

As of FY 2006, ten years since the start of the NTTAA reporting requirement, federal agencies indicate that there are 73 government-unique standards being used in lieu of voluntary consensus standards. This number has remained relatively constant over the past several years. The fact that such a small number of government-unique standards are being referenced by federal agencies indicates a real and growing reliance on voluntary consensus standards. The Act has successfully encouraged agencies to look first to voluntary consensus standards to meet their needs rather than to develop government-unique standards.

NIST continues to assist federal agencies and their stakeholders involved in standards management. NIST hosts the internet portal <<http://standards.gov>>, providing a one-stop e-government location for information related to the use of voluntary consensus standards. The website offers background, materials, useful links, and search tools for locating information about the use of standards in government including a searchable database, “Standards Incorporated by Reference” <<http://standards.gov/sibr/query/index.cfm>>. The web site also serves as a forum for providing ongoing, practical guidance, tools, and information needed by agencies to successfully implement the NTTAA as well as a means to electronically report standards activities required by the NTTAA and OMB Circular.

⁸ Atomic Energy Commission and Energy Research and Development Administration.

Building on the success of the NTTAA in reducing reliance on government-unique standards along with the trend towards e-government, NIST is working with agencies to shift to the next phase of reporting, with the goal of providing more timely and accurate information to the standards community while refining the information to better reflect the intent of the NTTAA and direction from OMB. In addition, NIST is working with agency standards executives and OMB to integrate standards participation and use more directly into the missions, decision making processes, and strategic goals of the federal agencies.

Future reports will focus on enhancing “information dissemination” and will leverage information technology resources in order to provide data in a format that is more usable, up-to-date, and accessible to the public and the larger standards community.

Therefore, beginning next year, in addition to preparing and transmitting the annual report to OMB, NIST will expand the resources available at standards.gov to facilitate federal agency participation in the development and use of private sector standards. NIST will also work with agencies as they establish websites that reflect required NTTAA and OMB Circular A-119 data and up-to-date information on agency standards activities. Each agency will identify a single point of contact for standards-related information.

The annual report fulfills the reporting requirements of both the NTTAA and OMB Circular. Expanded use of standards.gov and agency websites will consolidate information gathering and support efficient communication between agencies and stakeholders.

Appendix A -- FY 2006 List of Federal Agencies That Report

<u>Agency</u>	<u>Acronym</u>
Department of Agriculture	USDA
Department of Commerce	DOC
Department of Defense	DoD
Department of Energy	DOE
Department of Education	ED
Department of Health and Human Services	HHS
Department of Homeland Security	DHS
Department of Housing and Urban Development	HUD
Department of the Interior	DOI
Department of Justice	DOJ
Department of Labor	DOL
Department of State	DOS
Department of Transportation	DOT
Department of the Treasury	TRES
Department of Veterans Affairs	VA
Environmental Protection Agency	EPA
Agency for International Development	USAID
General Services Administration	GSA
National Archives and Records Administration	NARA
National Aeronautics and Space Administration	NASA
National Science Foundation	NSF
Consumer Product Safety Commission	CPSC
Federal Communications Commission	FCC
Federal Trade Commission	FTC
Nuclear Regulatory Commission	NRC
Government Printing Office	GPO
Access Board	ACCESS

Appendix B -- FY 2006 Federal Agency Information on Participation/Adoption of Voluntary Standards Activities Required by OMB Circular A-119

Agency	Government-unique standards used in lieu of voluntary consensus standards	Voluntary consensus standards substituted for government-unique standards	Voluntary consensus standards used this year ⁹	Employee participation in voluntary consensus standards bodies	Change from previous year	Voluntary consensus standards bodies with agency participation	Change from previous year
USDA	1	2	41	72	20	38	21
DOC	0	0	0	403	-39	83	-15
DoD	*	126	121	1106	0	112	-6
DOE	0	0	44	820	59	74	4
ED	0	0	0	4	0	5	0
HHS	4	1	20	763	169	131	17
DHS	0	0	9	35	-125	51	1
HUD	2	0	0	3	0	5	1
DOI	0	2	0	114	40	33	7
DOJ	0	0	0	1	0	0	0
DOL	6	0	0	50	-2	16	0
DOS	0	0	0	8	0	1	0
DOT	3	0	12	206	-3	48	1
TRES	0	0	1	3	3	1	1
VA	0	0	0	4	0	20	0
EPA	50	0	38	44	-8	25	-1
USAID	0	0	0	0	0	0	0
GSA	3	0	48	23	1	24	-1
NARA	1	0	0	16	0	11	1
NASA	*	1	94	147	-25	34	3
NSF	0	0	0	4	-1	3	-1
CPSC	2	0	0	24	-4	12	4
FCC	0	0	156	33	-3	14	14
FTC	0	0	0	0	0	0	0
NRC	0	0	0	187	34	16	1
GPO	0	0	0	0	0	0	0
ACCESS	1	0	7	5	5	6	6
Totals	73	132	591	4075	121	**	**

⁹ Figures reported include only new uses of VCSs for FY 2006 *vice* total uses reported in prior years.

* Agencies reporting on a categorical basis per OMB Circular A-119, Section 12.

** Totals not provided. Totals would result in multiple counting due to participation in standards bodies by two or more federal agencies.

Appendix C -- FY 2006 Government-Unique Standards used in lieu of Voluntary Consensus Standards

1	Agency:	Access Board
	Government-Unique Standard:	36 CFR Part 1194 Electronic and Information Technology Accessibility Standards (December, 2000) [Incorporated: 2006]
	Voluntary Standard:	ANSI/IEEE Standard for Hearing Aid Compatibility with Wireless Devices
	Rationale:	A provision in the Section 508 Standards requires that interference to hearing technologies be reduced to the lowest possible level that allows a user of hearing technologies to utilize a telecommunications product. Individuals who are hard of hearing use hearing aids and other assistive listening devices, but they cannot be used if products introduce noise into the listening aids because of electromagnetic interference. The ANSI/IEEE Standard for Hearing Aid Compatibility with Wireless Devices was not completed in time for reference by the agency in its final rule published in FY 2000. However, the agency will consider using the Standard in FY 2007. In the meantime, because the requirement in the agency rule is a performance standard, the agency considers compliance with the VCS to meet the agency Standard.
2	Agency:	Department of Labor (DOL)
	Government-Unique Standard:	29 CFR 1926.1002 Roll-Over Protective Structures [Incorporated: 2006]
	Voluntary Standard:	SAE J1194-1999
	Rationale:	Many consensus standards were relied upon for various provisions in the final rule. The primary VCS that applies directly to ROPS is SAE J1194-1999, which incorporates by reference several other VCSs. If SAE J1194-1999 was adopted into the OSHA provisions, the regulated community would have to consult not only the primary VCS but all of the VCSs that are incorporated into it as well. OSHA believes it is less burdensome for the regulated community to use one OSHA standard rather than require the purchase and use of several VCSs.
3	Agency:	General Services Administration (GSA)
	Government-Unique Standard:	FF-L-2937 [Incorporated: 2006]
	Voluntary Standard:	UL 768

	Rationale:	Federal Specification FF-L-2937 – Combination lock, mechanical used in lieu of UL 768 Combination Locks. The lock covered by the GUS is used for the protection of classified information and weapons. The UL specification did not meet identified government needs for dialing tolerance and bolt end pressure.
4	Agency:	Department of Health and Human Services (HHS)
	Government-Unique Standard:	FDA Dosage Form and Route of Administration [Incorporated: 2006]
	Voluntary Standard:	HL7 Dosage Form and Route of Administration
	Rationale:	FDA uses some government-unique standards such as 'dosage form' and 'route of administration' in lieu of voluntary consensus standards. FDA had considered using HL7's 'dosage form' and 'route of administration' voluntary standards, but rejected such voluntary standards for several reasons, including (1) pre-coordination of disparate terms, (2) cumbersome and untimely terminology maintenance, and (3) inadequate terminology coding and versioning. The government-unique standards (developed by FDA and jointly maintained by FDA and NCI) for 'dosage form' and 'route of administration' adequately address all of these HL7 'deficiencies'. These particular government-unique standards were chosen as a CHI standard and mandated throughout the Federal Government, which is yet another compelling reason why FDA chose to continue to use them.
5	Agency:	Department of Health and Human Services (HHS)
	Government-Unique Standard:	Government eligibility inquiry and response standards [Incorporated: 2006]
	Voluntary Standard:	X12 270/271 standards
	Rationale:	Pending completion of a system to support real-time use of the X12 270/271, CMS has permitted providers and our contractors to continue to use government eligibility inquiry and response standards. Use of these GUSs is not in lieu of, but in addition to the X12 270/271 standards to avoid industry disruption prior to full transition to use of the HIPAA X12 270/271 standards with Medicare via the Internet and an Intranet.