Federal Engagement in Standards Activities to Address National Priorities

Background and Proposed Policy Recommendations

Subcommittee on Standards
National Science and Technology Council

October 2011
Dear Colleagues:

I am pleased to share with you the report *Federal Engagement in Standards Activities to Address National Priorities*. This report provides an overview of the current legal and policy frameworks for government engagement in private-sector standardization and conformity-assessment activities; describes how the government engages in those activities; summarizes stakeholder observations in response to a request for information about government engagement in standardization; and outlines policy recommendations to supplement existing guidance to agencies.

Standardization and conformity-assessment challenges facing the government and private-sector in emerging technology areas—such as smart grid, health information technology, and other areas where interoperability is key to broad deployment of advanced technology solutions—point to the need to review the effectiveness of Federal government engagement in standardization and/or conformity-assessment activities. In December 2010, the National Institute of Standards and Technology, on behalf of the Subcommittee on Standards (SoS) of the National Science and Technology Council, invited the public to provide perspectives on the effectiveness of Federal agencies’ participation in the development and implementation of standards and conformity-assessment activities, and related programs in select technology areas. This information was to assist the SoS develop case studies that Federal agencies can consider in their future engagement in standards development and conformity assessment, particularly for multi-disciplinary technologies or technologies involving engagement by multiple Federal agencies. Through this study, SoS confirmed the need for supplementary guidance to agencies in instances where the Federal government chooses to take a leadership or coordinating role in standardization and/or conformity-assessment activities to ensure a rapid and coherent response to a national priority, as defined in statute or Administration policy, and to ensure efficient and effective investment of public resources.

As noted in the President’s *Strategy for American Innovation* “…the true choice in innovation policy is not starkly between government management and no government involvement, but rather choosing the right role for government in supporting private sector innovation.” This notion applies to standardization and conformity-assessment activities which are, after all, tools of innovation. This report provides context for future discussions within government and between the government and the private-sector regarding government engagement in standardization and conformity-assessment activities in support of national priorities.

Sincerely,

[Signature]

John P. Holdren
Assistant to the President for Science and Technology
Director, Office of Science and Technology Policy
Introduction

This report provides a high-level overview of the current legal and policy framework for government engagement in private-sector standards activities and describes how the government engages in these activities. It summarizes stakeholder observations in response to the December 2010 Request For Information (RFI) issued by the National Institute of Standards and Technology on behalf of the Subcommittee on Standards of the National Science and Technology Council about government engagement in standardization generally and in specific technology areas. Finally, the report outlines policy recommendations for consideration as a component of proposed supplementary guidance to agencies engaging in private-sector standards activities to address national priorities specified by Congressional mandate or Administration policy.

Background

Standards can play an important role in enabling technological innovation by defining and establishing common foundations upon which product differentiation, innovative technology development and other value-added services may be developed. Standards are also essential for enabling seamless interoperability between and across products and systems. In the United States private-sector-led standards development that is informed by market needs has played a foundational role in facilitating competition, innovation and global trade.

The introduction to the third edition of the U.S. Standards Strategy, released by the American National Standards Institute (ANSI), outlines key aspects of the standards environment to be considered by both the government and private sector in developing a strategic approach to standardization. In particular, the Strategy recognizes that,

“At home,

- Investment by public and private sectors in the development of global standards is directly related to the health of the economy.
- Economic downturns produce reductions in the resources available for global standards development.
- Users of standards are increasingly aware of their importance and are demanding a U.S. system that can produce and deliver standards with maximum efficiency and minimum cost, eliminate duplication, and optimize the benefits of a decentralized system.
- Government agencies at the Federal, state, and local levels are willing to invest in voluntary consensus standards that have been developed in accordance with globally accepted principles.
- The national interest in some emerging areas of standardization such as homeland security, smart grid, healthcare, energy efficiency, nanotechnology, and cybersecurity, demands a new level of coordination and effort, and will require the development of new ways for the public and private sectors, as well

---

as large numbers of standards development organizations and consortia, to work together in order to preserve national competitiveness.

- The U.S. government has enhanced its efforts to coordinate agency standards activities and engagement and continues to recognize the integrity of the existing U.S. standards process both through active participation in standards development and as user of the standards for regulation and procurement.”

Recent public-private-sector efforts to engage participants from multiple disciplines that traditionally have not worked together to develop standards (e.g., health information technology (IT), smart grid, and other areas where a national priority has been identified) point to the need to provide both private- and public-sector participants greater clarity early in the process about the nature and purpose of Federal government engagement.

**Current Legal and Policy Framework**

Federal government agencies engage in standardization in a wide range of mission-specific roles, including contributing to the development of standards in the private sector; advocating for U.S. interests in the development and use of standards (e.g., ensuring that standards are not used as technical barriers to trade by trading partners); using standards for procurement, regulatory or policy actions; and addressing competition-related aspects of standards-setting activities.

A series of statutes, regulations, and administrative orders comprise the legal framework that defines the Federal government’s use of standards, and its participation in the development of standards. Unlike a number of other countries, the United States does not have an overarching “standardization law” that provides the basis for standards and standardization-related activities.

Statutes and administrative requirements that contain provisions addressing standards development, use, and related government engagement include:

- National Technology Transfer and Advancement Act of 1995
- Trade Agreements Act of 1979 (as amended)

In addition, the following statutes provide more detailed mandates for Federal agencies’ responsibilities with regard to the use of specific standards and associated standards development initiatives:

- Standards Development Organization Advancement Act of 2004
- National Cooperative Research and Production Act of 1993
- Telecommunications Act of 1996
Health Insurance Portability and Accountability Act of 1995 and the Health Information Technology for Economic and Clinical Health Act of 1996
Energy Independence and Security Act of 2007 (EISA)
Federal Information Systems Management Act of 2002

National Technology Transfer and Advancement Act of 1995
The National Technology Transfer and Advancement Act (P.L. 104-113 or NTTAA) directs Federal agencies to use technical standards “that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments,” except where inconsistent with applicable law or impractical. The National Institute of Standards and Technology (NIST) is charged with coordinating Federal agency implementation of standards and conformity-assessment-related NTTAA provisions.

OMB Circular A-119
The policies outlined in the Office of Management and Budget Circular A-119 on Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity-Assessment Activities apply to all executive branch departments and agencies, and to independent regulatory agencies. The Circular was last revised in 1998, in part to provide guidance on how agencies could meet the intent and implement the standards and conformity-assessment-related provisions of the NTTAA. It 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 to agencies on participation in the development of voluntary consensus standards, and articulates policies relating to the use of standards by Federal agencies.

Trade Agreements Act of 1979 (as amended)
The Trade Agreements Act of 1979 (as amended) prohibits U.S. agencies from engaging in standards-related activities that create unnecessary obstacles to trade, and gives the U.S. Trade Representative (USTR) the responsibility to coordinate the consideration of international trade policy issues resulting from standards and related measures, such as conformity-assessment procedures.

How the Government Engages
Government engagement in the U.S. standards system varies widely depending upon individual agencies’ missions and functions. Roles include those of user, person setting specifications, participant, facilitator, advocate, technical advisor/leader, convener and source of funding. Agencies at every level of government use standards to support regulation, procurement and policy activities, as well as incorporate standards into voluntary programs. Government agencies also use standards extensively to provide citizen services, enable connectivity of commercial information technology systems to government systems, and support disbursements of grants, loans, and other similar financial tools and incentives.

2 [http://standards.gov/standards_gov/nttaa.cfm](http://standards.gov/standards_gov/nttaa.cfm)
In instances where the government acts as a standards user, government agencies and their staff often participate in the development of standards to ensure that specific standards meet their legislative and mission requirements. In FY 2010, Federal agencies reported that 2,837 employees participated in 531 private-sector standards development organizations in roles including standards development, management of standards activities, workshops, seminars, etc. It is important to note that this number does not capture the very large number of state and local government officials from the approximately 3000 counties and other local jurisdictions in the United States who participate in the development of model codes (primarily for building construction and related activities), which are widely adopted as local building construction codes, or other standards activities.

Competition agencies, primarily the U.S. Department of Justice and the Federal Trade Commission, have an interest in ensuring that private-sector standards setting organizations and associated standards development activities are not used in ways that harm competition, or violate antitrust, intellectual property and/or consumer protection laws. In these instances, the Federal government’s interest goes beyond specific technologies to private-sector competitive behavior.

Government Use of Conformity-Assessment Systems

Federal conformity-assessment activities are a means of providing confidence that the products and services regulated or purchased by Federal agencies, or that are the subject of Federal assistance programs, have the required characteristics and/or perform in a specified manner. The NTTAA directs NIST to coordinate Federal, state, and local government standards and conformity-assessment activities with those of the private sector, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity-assessment requirements and measures. Numerous Federal agencies are engaged in conformity-assessment activities. In addition, as part of its role mandated by the NTTAA, many Federal programs utilize NIST support to help design and implement appropriate and effective conformity-assessment programs.

Responses to the Request for Information

Respondents to the December 2010 Request for Information (RFI), issued on behalf of the National Science and Technology Council’s Subcommittee on Standards (NSTC SoS) to seek broad input about the effectiveness of Federal agencies’ participation in private sector led standardization activities conveyed a wide range of views. Responses indicated that Federal agency participation in standardization activities can

---

3 14th Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment, June 2011, currently in the clearance process
5 http://standards.gov/standards_gov/mastercomments030711.cfm
have one of two effects: (a) agency involvement can contribute positively to standardization activities, resulting in an overall improvement in product reliability and cost containment or, (b) agency involvement can limit or hinder the advancement of technology, resulting in mandates that detract from research and development efforts in response to market-driven forces. Most respondents noted that U.S. government contributions and participation could be improved to maximize benefits and minimize obstacles.

There was agreement among respondents that the U.S. government should continue to play the role of participant in private sector standards setting processes. Many commended the U.S. government’s support of open, consensus-based, transparent standards processes. There was also general agreement that the effectiveness of government participation depends on the level and consistency of involvement and commitment of resources, both staff and budgetary, to the process. Lack of coordination among agencies, where more than one agency has an interest in a standards activity, was cited by many respondents as having a negative impact on government effectiveness. Specifically, respondents noted that where agency objectives are seen as overlapping or unclear, agencies may be providing redundant support or even competing with one another for work in different standards portfolios.

Many comments emphasized the existence of strong public-private relationships and the willingness of industry to provide subject matter experts to participate in standards activities identified as important to government regulatory, procurement or policy needs, where relevant. These factors have fostered a public-private partnership that allows industry to participate in the implementation of regulatory and procurement policy in a way that is, in most cases, efficient and cost effective. Most respondents supported a strong partnership whereby the government participates in standards development as one of many stakeholders, rather than in a lead role. Suggestions for enhancement of the public-private partnership included: (a) better communication – both between the public and private sectors and within the government; (b) more clearly identified end goals for government engagement in a particular standards activity; (c) enhanced and robust collaboration and engagement; and (d) better framing of the technical and policy issues.

Several questions specific to intellectual property rights (IPR) in standards were included in the RFI. A number of respondents noted that there is no one ideal, one-size-fits-all IPR policy and that standards organizations7 are in the best position to establish effective policies for addressing IPR issues related to the standards they develop. The respondents specifically recommended that IPR policies of standards organizations need to take into account the interests of both IPR holders and those seeking to use or implement the IP included in the standard or standards. Also, standards organization IP

---

7 A standards organization is defined as a private sector association, organization or technical society that develops, establishes or coordinates standards, specifications, handbooks or related documents. The term is inclusive of both formal consensus standards developers as well as consortia and for a. (OMB Circular A-119, Section 3)
policies should be easily accessible and the rules governing the disclosure and licensing of IPR should be clear and unambiguous.

**Government Leadership in Select Technology Areas**

In a limited number of specific cases, such as cybersecurity, health IT, smart grid and public safety communications, the Federal government has taken on a leadership role in private sector standards development. Detailed review of the government’s participation in these technology areas leads to some preliminary observations about the necessary preconditions to support success when the government takes on a leadership or coordination role in standards development. These observations are based on input from the December 2010 RFI and interviews with agency staff engaged in these areas.

For example, in the case of smart grid, EISA establishes clear roles for NIST, the Federal Energy Regulatory Commission (FERC) and the Department of Energy (DOE), and cites NIST-identified standards both as those that FERC may consider for adoption and as a criterion in evaluating DOE investment grant applications. Simultaneously, industry-wide recognition and support of the need for a strong Federal role in coordinating standards for the smart grid\(^8\) has made possible the rapid pace of work and the delivery of meaningful early results. The open and transparent process used to gather input for framework, identification of standards needs, and coordination in standards development has enabled broad buy-in and support for this work.

Similarly in the case of electronic health records interoperability, the Office of the National Coordinator for Health Information Technology (ONC) used the Standards and Interoperability (S&I) framework to provide a strong federal role in coordinating standards and providing an innovative platform to accelerate standards development and adoption to support meaningful use. The S&I framework uses an open, community driven, and transparent process to rapidly prototype and pilot HIT standards, and provide the HIT Standards Committee (HITSC) with additional real-world information regarding HIT standards. For example, in less than twelve months, the Direct Project community was able to pilot multiple approaches for secure point-to-point messaging, reach consensus across the healthcare industry on a single standardized approach, and successfully demonstrate using this approach for a real information exchange\(^9\). This approach has been replicated in the S&I Framework to reach consensus on other HIT standards to support meaningful use and health information exchange\(^10\). The Direct

---

\(^8\) [http://standards.gov/standards_gov/sos_rfi_docs/73_AT&T.pdf](http://standards.gov/standards_gov/sos_rfi_docs/73_AT&T.pdf)  

\(^9\) [http://directproject.org](http://directproject.org): The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the Internet.

Project was launched by ONC to bring together several companies and organizations in the health information technology community to contribute to the development of standards.

Thus a policy framework and/or standardization mandate outlined in legislation and/or via Administration directives needs to be combined with visible high level government support for the specific projects undertaken, with a clear rationale for why expedited standards development efforts are necessary. Where the Federal government itself is a major user or customer, as in electronic health records or information system security, specific government needs should be clearly articulated within the standards process. Coordination among interested and affected government agencies is also important. Various coordination modes have been used in the past, including National Science and Technology Council committees or subcommittees, interagency working groups, task forces, and/or fast-track action committees. Standards setting activities are also more likely to be successful if a robust, open process, in which private and public sector stakeholders are invited to provide input, is established at the outset. In assuming a leadership or coordination role, the Federal government should clearly articulate its needs, expectations and the mechanisms by which it intends to engage with the stakeholders. The Federal government should also clearly explain how leadership will transition to the private-sector when appropriate, or will be terminated upon reaching certain well-defined objectives. Such policies can help establish a robust foundation for standards efforts that may take place over long periods of time and thus require sustained private-sector stakeholder participation, and ultimately private sector leadership.

Early development of a framework that identifies standards gaps and priority areas that need to be addressed and identification, where relevant, of a dedicated Federal effort to address those priorities is important. Well-articulated frameworks help assure the private sector that its role in developing the needed standards is well understood and valued by the government.

Conformity assessment requirements and implementation should be addressed as an integral component of these frameworks. Conformity assessment mechanisms provide confidence that products and systems meet the standards in question, and ensure interoperability. Conformity assessment that leverages existing private-sector programs can help lower the cost of implementation, and also provide added impetus for innovation and competitiveness.

When participating in standards development efforts, particularly in a leadership or coordination role, the Federal government should proactively promote industry-led efforts and widely accepted standards and practices. Close collaboration with stakeholders can help address the challenges associated with the need to accelerate standards development to keep pace with rapid technological advances. A designated Federal lead official who serves as the go-to person for the standards effort can help bring clarity in communication about leadership and decision-making responsibilities.
This also provides both the government and the private-sector participants a point person to approach and hold responsible for progress.

Following the initiation of these efforts, continuing support of senior leadership can be instrumental in sustaining a rapid pace of activities. Continuous, sustained and systematic public outreach and engagement should be a critical element of a Federal government leadership role.

**Policy Recommendations**

1. Recognize that in most government-private-sector standards engagements, the primary role of the government will continue to be that of active contributor to the private-sector-led process.

Most standards that are developed and used in the U.S. market are created with little or no government involvement. The U.S. government has long recognized that the private-sector, driven by innovators and market need, is ordinarily in the best position to drive standardization in a technology area. In most instances when government engages in the private-sector-led standards process, the preferred government role is as an active contributor. There are limited circumstances, however, where the Federal government engages in a leadership or coordinating role in private sector standardization activities to address national priorities established in statute or Administration policy. Recent examples include multidisciplinary technology areas such as smart grid and health IT. In the case of smart grid, government leadership brought together stakeholders from the various domains constituting the smart grid in a short time frame. Ordinarily, it might have taken much longer for these different stakeholders to coalesce in a single forum to rapidly identify critical gaps and needs limiting the development and adoption of an interoperable smart grid.

2. Identify the context(s) where Federal government leadership/coordination may be appropriate.

In specific cases, Congressional mandates have directed a Federal agency (or agencies) to lead standards development efforts to address a specific legislative priority. The Federal government may also determine that, based on public and/or executive branch input, there is a need to ensure that relevant standards are available on a timely basis to support a rapid, coherent response to a national priority identified in Administration policy. Government leadership may be necessary to assure that key public policy goals are met in a timely manner.

In this context, it should be noted that the American National Standards Institute (ANSI), a private sector, not for profit federation, has a long history of convening cross-sector standards panels and coordination initiatives that address key national priorities, including homeland security, nanotechnology, biofuels, nuclear energy, chemical regulations, healthcare information technology, electric vehicles, and identity-theft protection and identity management. The mission of each of these activities has been to bring all relevant stakeholders together swiftly to identify, coordinate, and harmonize the
voluntary consensus standards that are critical to supporting each area. Many of these activities were initially formed at the request of a government agency or agencies, and all have robust participation from both public- and private-sector experts.

Federal government engagement in a leadership or coordination role in private-sector standardization should be considered carefully. Such engagement should be undertaken pursuant to existing legal and policy obligations, and be open, transparent and provide for broad participation.

3. Outline objectives for government engagement in standardization activities to support national priorities.

As the Federal government considers more active engagement in a standardization process, irrespective of the level of Federal government engagement, such engagement should be guided by the following fundamental objectives:

a) Ensuring timely availability of effective standards and efficient conformity assessment schemes critical to addressing national priorities established in statute or Administration policy.

b) Achieving cost-efficient, timely, and effective solutions to regulatory, procurement, and policy objectives.

c) Promoting standards and standardization systems that enable innovation and foster competition.

d) Enhancing U.S. competitiveness while ensuring national treatment.\textsuperscript{11}

e) Facilitating international trade and avoiding the creation of unnecessary obstacles to trade.

In order to realize these objectives, the Federal government should partner with the private sector to address common standards needs. In this context, the government must strategically and judiciously exercise its various roles in the standardization system – user, person setting specifications, participant, facilitator, advocate, technical advisor/leader, convener and source of funding. There should also be an active effort to promote information sharing and coordination across Federal agencies. The Federal government should detour from its typical modes of engagement in standards development with the private sector and take on a leadership or coordination role only when it is essential to do so to assure that key public policy goals are met in a timely and effective manner.

4. Effective coordination and participation by agencies.

Significant public and societal benefits can accrue from government support in the development of consensus standards and their subsequent use by the government. For example, staff at the Consumer Product Safety Commission worked with ASTM

\textsuperscript{11} National treatment is the principle of giving others the same treatment as one’s own nationals. (http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm)
International and the baby walker industry to develop a standard to reduce the number of injuries from the use of baby walkers. 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. The standard, which included performance requirements to address stair falls, was published in 1997, and by 2005 the estimated number of baby walker injuries treated in hospital emergency rooms had dropped dramatically to 2,600 – a 90% reduction.

The entire standardization lifecycle – development, implementation, assessment and implementation of conformance requirements, and review – should be considered in developing and implementing government-led standards efforts. Agency leaders should ensure effective intra- and inter-agency coordination of engagement in standards development activities, prioritizing needs, and establishing clear timelines. When an agency (or agencies) commits to a cooperative standards development effort with industry, that commitment should be clearly articulated and maintained to the extent possible. Agencies should use existing processes and, where necessary, establish new processes for effective and open communication with the private sector with the aim of understanding their interests and ensuring that private sector concerns are given objective consideration. To the extent practical, agencies should continue to provide technical and policy expertise, and where appropriate, leadership efforts in mission critical standards setting activities. Agencies should periodically review their standards activities to identify gaps in representation for mission-critical areas as part of their long-range planning and establish policies that value and reward participation in standardization activities.

5. Clarify agency responsibilities with respect to the full range of standards setting alternatives.

Agencies should continue to look to private-sector standards development processes to meet their needs, as directed in law and policy. Preference should be given to processes, whether formal consensus processes or other, that are well coordinated, are internationally accepted, and deliver the most generally favorable technical and economic outcomes, such as improved interoperability, product differentiation, and others. The current diversity of standards organizations affords a range of opportunities for identifying appropriate venues for successful standards development, taking into account the scope and recent track record of candidate standards organizations in a particular area of standards development. In national priority areas, coordination among standards organizations may be necessary in specific instances to promote interoperability, maximize the utility of standards projects, extend the field of application for existing protocols, and promote efficient use of resources.

Agencies should take into account the impact of their standards choices on innovation and the global competitiveness of U.S. enterprises, including the impact of intellectual property incorporated in standards, and should explicitly include consideration of conformance assessment approaches that enable the least burdensome compliance with
standards specified by agencies. Often such approaches can be built using elements from international systems that have significant private sector endorsement and minimize duplicative testing, rather than creating government unique conformity assessment schemes that are often expensive to develop and maintain and are not recognized beyond national boundaries.

6. Lay out key principles underpinning voluntary standardization processes.

A limited set of foundational attributes of standardization activities are called out in OMB Circular A-119, focusing on voluntary, consensus standards activities. It is important to recognize as well the contributions of standardization activities that take place outside of the formal voluntary, consensus process, particularly in emerging technology areas. The following additional attributes should also be considered, to maximize the impact of those activities on enabling innovation and fostering competition, while also assuring fulfillment of agency regulatory, procurement, and policy missions:

- **Transparency**: essential information regarding standardization activities is accessible to all interested parties.
- **Open Participation**: all interested or affected parties have an opportunity to participate in the development of a standard, with no undue financial barriers to participation.
- **Flexibility**: different product and services sectors rely on different methodologies for standards development that meets their needs.
- **Effectiveness and Relevance**: standards are developed in response to regulatory, procurement and policy needs, and take account of market needs and practices as well as scientific and technological developments.
- **Coherence**: the process avoids overlapping and conflicting standards.
- **International Acceptance**: as product and service solutions cross borders, the public and private sectors are best served by standards that are international in scope and applicability.
- **Net Benefit**: standards used to meet regulatory and procurement needs should maximize net benefits of the use of such standards.

In addition, agencies should give consideration to the following attributes of standards organization processes:

- **Access and Availability**: the text of standards and associated documents should be available to all interested parties on a reasonable basis, which may include monetary compensation where appropriate.
- **Clear Intellectual Property Rights (IPR) Policies**: standards organization IPR policies should take into account the interests of both IPR holders and those seeking to use or implement the IP included in the standard or standards. These policies should be easily accessible and the rules governing the disclosure and licensing of IPR should be clear and unambiguous.
- **Timeliness**: standards should be available in a timely manner.