



ANSI Response to Request for Information

Re: Federal Agencies' Participation in Standards and Conformity Assessment Activities

One of the great strengths of the U.S. approach to standards and conformance is the “public-private partnership” – a term that stakeholders in government and industry use to describe the long-standing, effective, and cooperative working relationship between the public and private sectors. An understanding of the particular strengths of this partnership is key to increased and improved participation by federal agencies in the standardization system, and to driving the continued success of that system. Especially in times of increased global competition and economic stress, we are all in this together – in the search for innovative and consensus-based approaches to solving complex problems, and in offering global leadership for the development and implementation of standardization solutions.

By way of introduction, the American National Standards Institute (ANSI) would like to articulate three main points that underscore the rest of this input.

- The public-private partnership in the United States is strong because it is a true partnership. Neither government nor industry claims or exerts overall authority over the other, and by working together in respectful cooperation, we are able to most effectively respond to the strategic needs of the nation. This dynamic makes our standardization system unique in the world.
- Leadership of initiatives can come from both parties – the public-private partnership is a two-way street. Depending on the need, it may make sense for the private sector to take the lead in developing a standards-based solution. In other instances, the government may step up to lead a critical initiative through to completion.
- ANSI's unique role within this partnership is as a neutral forum – acting as the convener of diverse parties and sectors in a problem-solving approach that is focused on results.

ANSI is a private, not-for-profit membership organization that was founded in 1918 by five organizations and three government agencies because these groups saw the need for an impartial national body to coordinate the development of voluntary standards. Over the years, the ANSI Federation has worked to build an effective partnership in the standards area between the government and the private sector. The importance of that collaborative effort has been recognized many times since, and was most recently ratified in the December 2000 [Memorandum of Understanding](#) (MOU) between ANSI and the National Institute of Standards and Technology (NIST), describing a partnership designed to “enhance and strengthen the national voluntary consensus standards system of the United States and to support continued U.S. competitiveness, economic growth, health, safety and protection of the environment.” Today, the ANSI Federation includes 837 public- and private-sector members – including approximately 225 standards developing organizations (SDOs) – and ANSI continues to partner with the U.S. government in establishing national standards policy.

ANSI is pleased to provide these comments in response to the Request for Information published in the *Federal Register* on December 8, 2010 (Docket No. 0909100442-0563-02). In particular, ANSI provides input in the following general areas: (1) how the U.S. standards system works today; (2) ways in which government engagement and ANSI engagement in standards activities can be improved; (3) effective coordination of cross-stakeholder standards activities; and (4) intellectual property considerations relating to the standards setting process.

1. How the U.S. Standards System Works Today

The U.S. national standardization system is a profoundly democratic process that thrives on the active participation and engagement of all affected stakeholders. Currently, the U.S. has the most robust standards system in the world and holds a competitive advantage precisely because of the democratic nature of our standardization system.

This standardization system and its consensus-based, public-private partnership are reflected in the *National Technology Transfer and Advancement Act of 1995* ([NTTAA](#)), Public Law 104-113. This law directs all federal government agencies to use for regulatory, procurement, and other agency activities, wherever feasible, standards and conformity assessment solutions developed or adopted by voluntary consensus standards bodies in lieu of developing government-unique standards or regulations. The NTTAA also encourages government agencies to participate in standards development processes, where such involvement is in keeping with an agency's mission and budget priorities.

The NTTAA remains the cornerstone for promoting the use of voluntary consensus standards and conformance in both regulation and procurement at the federal level. The Office of Management and Budget (OMB), through its [OMB Circular A-119](#), establishes government policy on the use of voluntary consensus standards including recommendations on how and to what extent federal agencies must support voluntary consensus standards activities. In doing so, the OMB Circular confirms that close interaction and cooperation between the public and private sectors is critical to developing and using standards that serve national needs and support innovation and competitiveness.

ANSI systematically brings all interested parties into the process of standards development. ANSI-accredited SDOs create standards that meet current needs and are usable across sectors. It is critical to the continued success of our democratic standardization system that the U.S. government continues to promote the system and participate actively to identify and support the technical work that it perceives to be in the national interest.

2. ANSI's Views on How to Strengthen Public/Private Partnership to Improve the U.S. Standardization System

Working together, the public and private sectors can develop viable and effective solutions to address current and emerging issues. This section describes ways that the government and the private sector can open lines of communication, improve coordination, and strengthen the public-private partnership.

A. What the Government Can Do

i. Notify the Standards Community at Early Phase of Regulatory Process

Government officials at the highest level must understand the power of standards and the importance of bringing standards developers together when technical solutions are needed to solve problems that are in the national interest. SDOs with relevant expertise should be brought into the fold at the beginning of the process to ensure that the best possible solutions to emerging national issues are identified. This is particularly important as standardization solutions become more embedded in large public policy initiatives such as smart grid, cybersecurity, and global supply chain issues. At the earliest practicable moment in the development of a public policy initiative, and in the most transparent manner possible, potential private-sector participants should be identified and notified. Given ANSI's role as the national coordinating body for standards development activities, ANSI is uniquely suited to assist in

establishing an “early warning system” for upcoming regulations that would ensure the prompt identification, notification, and assembly of all interested stakeholders and assure that the government’s needs are reflected in the standards that underpin new regulations.

ii. Improve Interagency Coordination

The coordination of federal agencies’ standards development activities is managed through the Interagency Committee on Standards Policy (ICSP). The ICSP seeks to promote effective and consistent standards policies and foster cooperation between government, industry, and other private organizations involved in standards activities. The Committee reports to the Secretary of the Department of Commerce (DOC) through the Under Secretary of Commerce for Standards and Technology. As per Section 15 of the OMB Circular, the ICSP membership consists of one principal representative from each Federal Executive Agency. The representative is an official at the Senior Executive Service or higher level appointed to serve as the Agency Standards Executive with certain defined responsibilities.

It has been observed that the federal agencies may not always provide sufficient support to the Standards Executives and that some Executives may lack the authority within their respective agencies to fulfill their coordinating role. ANSI believes, therefore, that the participants in the ICSP themselves should be given expanded and enhanced responsibilities. This would enable them to develop and articulate a single unified point of view that their agency can support to better and more strategically address future standards issues as part of their interagency function.

A reinvigoration and enhancement of the role of the Standards Executive would enable each agency to better identify future standards issues, develop a unified position within that agency, and provide strategic direction to other agencies as part of the larger federal agency infrastructure. In this regard, support for the work of the ICSP and the individual Standards Executive from the senior management of each agency is critical.

ANSI also believes that the ICSP should continue to: facilitate federal agency participation, coordination, and communication on standards issues; foster a single unified position on federal standards policy wherever possible or practicable (recognizing each agency’s right to determine its own views); and ensure that the most senior federal-agency policy officials, including the Standards Executives, actively support the work of the Committee. A stronger, more effective ICSP would best serve U.S. interests in a manner that fosters competition, innovation, and growth.

ANSI welcomes the opportunity to engage regularly with the ICSP and serve as a link to the private sector, especially in those areas where collaboration and discussion across industry sectors is meaningful. ANSI also recognizes that many of its members have direct relationships with federal government agencies, and such relationships should continue going forward.

iii. Improve Process of Updating Standards Incorporated in Regulation

The U.S. standards system is by nature dynamic and responsive. Standards are updated on a constant basis as revisions are created and/or identified that improve the qualities of the standard or better meet the needs of the marketplace. However, federal agencies that reference such standards in rules and regulations may not be able, for procedural or other reasons, to make timely updates to rules that accommodate changes in the referenced standards. This may even be the case when the agency’s own analysis supports the use of the updated standard for the purpose of the rule. In other cases, regulated industries, especially small and medium-sized enterprises (SMEs), prefer the older methods because they are unable to update their own equipment to meet the newer standard. Currently there does not seem to be enough flexibility to enable agencies to meet the regulatory needs and make use of

updated standards without imposing an extraordinary burden on the agency. At times this situation can create difficulties where an agency continues to reference a particular standard that has been superseded. Such a situation may create confusion and frustration for manufacturers and purchasers. This may also impede an agency's ability to enforce its health and safety mandates and ensure that only the safest and most-improved products are available (i.e., those that reflect the most recent revision of a standard).

Often an agency must follow a laborious rule-making process to recognize a revision of an accepted standard. ANSI recommends an alternative approach, namely, the adoption of a rule of construction that would give an agency 90 days after the promulgation of a revision of a referenced standard to update the Code of Federal Regulations (CFR). If the agency does not do so within the 90-day period, it will be presumed that the revision of the standard would be accepted as the new standard. An agency could create a due diligence requirement that such a revision has to be noticed in the *Federal Register* for 30, 60, or 90 days. If no significant opposition has been heard, the revision becomes the new standard. A number of agencies have successfully used this approach.

iv. Boost U.S. Competitiveness in the Global Marketplace

The development and application of standards, technical regulations, and conformity assessment (e.g., testing, inspection, certification, etc.) has a significant impact on global trade. When developed and applied in an effective manner, standards and conformance open global markets for U.S. products and services. However, intentional or unintentional misapplication of standards and conformance can create trade barriers for U.S. exporters.

The U.S. government should continue its efforts to aggressively address individual trade barriers as they arise in international markets – both through advocacy and enforcement. These efforts not only help the companies affected by specific barriers, but also send a message about the importance of fair and open trade and the U.S. commitment to ensuring that our trading partners fully implement any relevant trade agreements. To advance the diverse interests of U.S. stakeholders, the U.S. government should continue to seek full implementation of the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement and annexes, as well as decisions taken by the WTO TBT Committee. Committing even more government resources to such activities can only be beneficial.

v. Improve Educational Outreach

Increased educational programs sponsored by the federal government are a vital informational tool that would help ensure greater participation in standards efforts, both national and international. ANSI believes that the government should significantly enhance standards education programs that address the needs of specific groups within the United States. These programs must reflect the multidisciplinary environment in which standards development takes place and must address national and international standards development procedures; the relationship between private- and public-sector standards; the environment, health, safety, sustainability, international trade, public policy, competition, legal issues, economic benefits, and strategic considerations; and how to balance the interests of stakeholders. Similarly, the government should encourage universities and colleges within the United States to create standardization education programs in fields of study such as engineering, science, technology, government and public policy, business, economics, and law. As just one example, this could be accomplished by encouraging accrediting bodies such as the Accreditation Board for Engineering and Technology (ABET) to strengthen their requirements for the inclusion of engineering standards in the classroom.

ANSI also recommends that the government increase its support for programs that educate policy makers in key international markets about the *U.S. Administrative Procedures Act (APA)*¹, the U.S. standardization system, and the process by which American National Standards (ANS) are developed. One example of such a program is the Vietnam Standards Training Program (VSTP), sponsored by the U.S. Trade and Development Agency (USTDA) following Vietnam's accession to the WTO. This program educated Vietnamese officials on these U.S. policies, resulting in the adoption of similar approaches in Vietnam and long-term improvement for U.S. access to the Vietnamese market. Similar programs would be highly beneficial in other emerging economies, including Brazil and the Middle East.

vi. Greater Participation and Support by Government in Standards Process

The NTTAA is clear on the need for government agencies to rely on private-sector standards wherever possible. Agencies with an interest in standards – whether from a regulatory or procurement perspective – should actively participate in domestic and international standards development.

More government agencies should be encouraged to join ANSI and its member organizations, participate in the ANSI Government Member Forum, and seek office on the Institute's Board of Directors. They should also give greater support to U.S.-domiciled SDOs and Technical Advisory Groups (TAGs) to the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) by encouraging qualified government technical personnel to participate in SDO and TAG work whenever possible as a matter of policy. By becoming more involved and doing so in a more coordinated fashion, the government can alert the impacted communities when a cross-sector, standards-based solution is needed, and SDOs in turn can alert the government when key standards are being developed or revised.

B. What ANSI Can Do

i. Encourage Private Sector to Better Understand and Respond to Government Needs

Our national standardization system reflects a strong history of partnership between the public and private sectors. This system has worked well – arguably better than any other global system of standardization – and has positioned the United States in a strong, competitive role in the global marketplace.

Whenever past attempts have been made to re-examine or alter the balance of the system, the end result has always been recognition that the collaborative public-private partnership is the most constructive and effective approach. The strength of this partnership is reflected in the relationship between ANSI, its members, and NIST, and is well expressed in this RFI.

While partnerships are about collaboration, they also involve trust and open information sharing. At times – especially when government stakeholders appear to be considering ways to change the standardization dynamic – the private sector can seem slow or reluctant to act. In this respect, ANSI, and in certain cases its members, can play a leadership role in catalyzing the private sector to work through the public-private partnership approach and put their best-faith efforts into understanding and responding to the underlying policy needs that are articulated by the government.

¹ United States Code, Title 5, Chapter 5 (1946) <http://www.archives.gov/federal-register/laws/administrative-procedure/>

ii. Work to Minimize Unnecessary Duplication

Coordination of standards development in the U.S. benefits the public, government, and industry. Within this context, a key tool that is missing at this time is a robust, publicly available, easily accessible, and current database of standards development projects across sectors. ANSI, with NIST's support, has undertaken a project to address this need.

ANSI will host a workshop in May 2011 to identify current issues related to standards coordination, including conflict and duplication among various sectors, and to identify how efforts including an improved NSSN² database could facilitate coordination and awareness of existing and proposed projects – not only within the ANS process but also among all interested standards developing organizations and consortia. Work to enhance the database will take place during the next two years. ANSI is also actively reviewing its ANS procedures to determine whether changes to address similar issues would result in improved transparency, efficiency and coordination.

iii. Improve Educational Outreach

The *United States Standards Strategy* articulates the importance of educating the next generation of standardizers through training, outreach, and awareness initiatives. Education programs covering the development and implementation of standards need to become a high priority within the United States. These programs must focus on the needs of leaders and top executives, those who participate in the development of standards, university and college students, and other interested parties.

Specifically, ANSI – independently and with its Federation of members – will work to develop new or significantly enhance existing standards education programs that address the significance and value of standards to the well-being of the United States and to global economies. Through its Committee on Education, the Institute will also develop a robust communications network for standardization education programs among all interested parties in the private, public, and academic sectors. Finally, ANSI will continue to administer and coordinate the [Standards Boost Business](#) initiative, which aims to educate executive leaders about how standards help companies to reduce costs, increase efficiencies, facilitate market access, and gain more competitive advantage.

iv. Boost U.S. Competitiveness in Global Marketplace and Continue Strong U.S. Participation in International Standardization

The expansion of global trade is increasingly important to the growth of our domestic economy, to productivity and innovation, and to the continued revitalization of the American workforce. But without perspective on the international standardization landscape, our nation's products, services, and personnel cannot hope to be competitive in the global marketplace.

This is especially true in emerging technology areas, such as nanotechnology, smart grid, information and communication technologies (ICT), cybersecurity, and electric vehicles. Developing and developed economies alike are playing an increasingly significant role in standardization activities. It is vital for the U.S. to maintain its key role in developing globally relevant, responsive standards – we simply cannot afford not to be at the table where international standards are being set.

The U.S. standards system acknowledges that there are multiple paths to global relevance. Whether we are talking about work done through ISO and IEC technical committees, or the many SDOs and consortia that operate on the international stage, what matters is that the standards were

² NSSN: Search Engine for Standards (www.nssn.org)

developed according to the principles of the WTO TBT Agreement, which are also consistent with ANSI's [*Essential Requirements*](#) for standards development. The process must be consensus-based, open, with balanced participation – and include all other elements that are the hallmarks of our standards system in this country.

As the sole U.S. representative to ISO, and, via the U.S. National Committee (USNC), the IEC, ANSI enables U.S.-based technologies and experts to have a prominent role in those standards organizations. With the support and backing of U.S. trade associations, SDOs, industry, and government agencies, our experts play leadership roles on nearly all ISO and IEC technical and policy committees to advance U.S. interests and minimize unnecessarily duplicative standards activities.

As U.S. representative to ISO and IEC, ANSI is also uniquely able to monitor the activities and priorities of our competitors and trade partners. From proposed new areas of technical activity to policy decisions at the highest level of ISO and IEC, the responsibility to coordinate and disseminate this important strategic information rests with ANSI through close coordination with the SDOs, government, consumers, and industry that constitute its membership.

The key to the nation's continued success on the global stage is to make sure that all U.S. stakeholder needs are taken into account, that we approach ISO and IEC with a clear and strong national position, and that we effectively leverage relationships with our partners internationally to gain support for these positions. To that end, ANSI will work with U.S. TAG Administrators to attract greater and more diverse government and industry participation in ISO and IEC activities. Doing so will assure that the broad spectrum of views from the public and private sectors are taken into account as U.S. positions are formed. To facilitate this greater level of engagement, ANSI will work to improve access to publicly available information on TAG activities, and will coordinate efforts with federal agencies to ensure that all interested government stakeholders are aware of opportunities for participation.

To facilitate stronger support for U.S. positions from our international partners, ANSI will increase its leadership and engagement in regional bodies such as the Pacific Area Standards Congress (PASC) and the Pan American Standards Commission (COPANT). ANSI will also increase training and capacity building projects that advance U.S. perspectives while building stronger relationships and goodwill with strategic partners such as China, India, Vietnam, and Korea. Selected examples of such projects are outlined below:

- *Standards Portal (www.standardsportal.org)*
In an effort to continue to share market access information concerning key U.S. trading partners, ANSI developed the StandardsPortal, an online resource that provides information on standards and conformance requirements and systems in the U.S., China, India, and Korea, with other key markets to be added in the future. Developed in partnership with NIST and USTDA, this successful program has increased transparency for U.S. exporters, and helps to promote U.S. best practices internationally.
- *India Standards and Conformance Cooperation Program (SCCP)*
Supported by a grant from USTDA and in cooperation with the Indian government and industry, the SCCP aims to increase U.S.–Indo cooperation on standards and conformance with the aim of preventing trade barriers before they arise, and strengthening the U.S. voice in India as this emerging market develops its standards and conformance systems. In addition to expanding the StandardsPortal to India, this program supported several industry sector–specific workshops and the development of a directory of market requirements that will be used to advocate for the adoption of U.S. approaches in India.

- *ANSI Manufacturer Member Roundtable in China*
The ANSI Manufacturer Member Roundtable in China provides a forum for U.S. manufacturing companies to discuss challenges and strategies, exchange information across industry sectors, and provide perspectives on issues that affect their ability to do business in China. Monthly meetings of the Roundtable also facilitate the opportunity for U.S. company representatives to exchange views on key issues with Chinese policy makers in a relaxed, open, and constructive format. This increases the frequency and overall impact of the U.S. voice in China.

These programs would not be possible without strong government support, including guidance, participation, and funding. We hope that support for such programs will increase in the future with the aim of strengthening U.S. competitiveness in the global marketplace.

v. Convene Regular Information-Sharing Events for Public and Private Stakeholders

In an effort to provide a regular venue for information sharing and communication, ANSI could host an annual or semi-annual “check-in” event for government and industry stakeholders. Having the opportunity to address issues and challenges – and to acknowledge successes in a public forum – would help to boost the cooperative spirit that fuels our public-private partnership. Such a meeting would be open to any and all interested U.S. stakeholders, and would provide an excellent venue for robust discussion and dialogue.

As an example of this type of coordination and information sharing, in April 2010 ANSI hosted an open meeting with the standardization community and leaders of the then newly formed NSTC Subcommittee on Standards. This event offered a unique opportunity for open dialogue and discussion between the public and private sectors on the nature of the Subcommittee and its specific strategy and goals. At the request of Subcommittee leaders for more information on effective interaction with the private sector, ANSI then convened a meeting and webinar in May 2010 to capture the thoughts of more than 115 representatives from the standardization community. The resulting input document, [“Forging an Even Stronger Public-Private Partnership,”](#) was transmitted to the Subcommittee leadership in October 2010.

3. ANSI’s View on Coordinating Cross-Stakeholder Standards Activities

According to the RFI, the NSTC Subcommittee on Standards wishes to hear lessons learned regarding standards development in areas that are multidisciplinary, exhibit system-type characteristics, involve multiple government agencies, and address specific national priorities.

Starting in the 1990s with the Information Infrastructure Standards Panel, ANSI 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, and identity theft protection and identity management. The mission of each of these activities has been to bring all relevant stakeholders together 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 behest of government agencies, and all have robust participation from both public- and private-sector experts.

In the Institute’s experience, a good cross-collaborative standardization model provides the process and framework for public- and private-sector stakeholders to work together to address an identified national priority and to do so with a sense of urgency. Such a model affords a unique opportunity to bring together the intellectual assets of all those who have a stake in the specific area to be

addressed. By participating in a collaborative standardization effort, each individual organization, company, or agency is strengthened by its demonstrated willingness to join forces with other organizations representing the domains and disciplines that are critical to the scope of work.

Specific characteristics of such an effective, cross-collaborative standardization model include:

A. Early development of by-laws and/or charter and other associated documentation

In order for this cross-collaborative model to be successful, it must have a well- documented governance structure that is fair, open, and balanced, and designed to provide reach across the entire spectrum of stakeholders, including SDOs and consortia, industry, government, academia, and other materially affected parties. A policy for the protection of Intellectual Property Rights (IPR) should also be developed (please see section 4 of this response).

B. Development of a policy assuring openness, transparency, impartiality, effectiveness, relevance, consensus, coherence, and due process

In order to be most effective, any cross-stakeholder standardization collaborative should operate under the following principles:

- Openness – participation is open to all affected interests
- Transparency – essential information regarding the activities of the collaborative is accessible to all interested parties
- Impartiality – no one interest dominates the process or is favored over another
- Effectiveness and relevance – the output of the collaborative is relevant and effectively responds to market and regulatory needs as well as scientific and technological developments
- Consensus – decisions are reached through consensus among those affected
- Coherence – the collaborative process encourages coherence to avoid unnecessary overlap and duplication³
- Due process – all views are considered and a dispute resolution process exists

³ With regard to the information and communications technology sector, INCITS and ISO/IEC JTC 1 endorsed Resolution 49 in ISO/IEC JTC 1 N9417 (2008-11-18), which states in part:

Further, consistent with ISO's and IEC's "one standard" principle (for example TMB's policy and principle statement on Global Relevance), there are times when one standard is all that is required to meet the needs of the marketplace, especially in a particular application area, and there are other instances where multiple standards make the most sense to respond to market requirements and to the needs of our society. In reducing the number of alternatives to a reasonable minimum, JTC 1 and other SDOs have demonstrated that it is not necessary and may not be desirable to choose only one alternative or option for standardization.

Further, JTC 1 notes that the cycle of innovation in the ICT sector has resulted in the continuous introduction of new technologies that improve upon existing standards. Any attempt to choose only one standard would ignore and threaten to inhibit the cycle of innovation that continues to fuel this industry.

Therefore, JTC 1 recognizes its commitment to ISO's and IEC's "one standard" principle; however, it recognizes that neither it nor its SCs are in a position to mandate either the creation or the use of a single standard, and that there are times when multiple standards make the most sense in order to respond to the needs of the marketplace and of society at large. It is not practical to define, a priori, criteria for making these decisions. Therefore each standard must be judged by the National Bodies, based on their markets, on its own merits.

C. Early development of a road map to guide the work efforts

It is very important that all stakeholders have a good understanding of what needs to be done to accomplish the task and what constitutes success. Therefore, the early development of a standardization road map should be undertaken to identify the functional and interoperability requirements necessary to support the effort and to determine where standards exist to support these requirements, where there are gaps, and where new or revised standards may be needed.

D. Early development of a process to identify standards that meet requirements, identify gaps, and minimize duplication

An environmental scan should be conducted to determine whether or not any national, international, or other broadly accepted standards exist to support the identified requirements. A consolidated baseline inventory of the relevant standards should be developed that includes information about the technical characteristics of the standards as well as their level of maturity. The function of the collaborative itself should not be to act as a standards development organization. Rather, where there are gaps between existing standards or where no applicable standards exist, an outreach effort should be undertaken to communicate with the relevant standards development bodies in order to obtain their agreement either to fill the gaps or to undertake new standards initiatives to satisfy the needs. The process should also provide for a periodic review of the need for the continued existence of the collaborative.

E. Establishment of a framework for conformity assessment

A conformity assessment – or compliance – framework is critical to ensuring the success of any standardization effort. This framework must rely upon a solid understanding of the fundamental internationally standardized principles and terminology surrounding conformance activities. These include first-, second-, and third-party conformity assessment and their components and schemes, such as: accreditation, testing, inspection, verification, calibration, certification, peer review, and mutual acceptance schemes.

An analysis should be undertaken of the particular conformity assessment models, programs, and approaches used for the products, systems, and services that are critical to the initiative. The analysis should include measures such as effectiveness, cost and benefits, and gaps and deficiencies.

F. Development of a sustainable business model

An initial business plan should be developed with the expectation that a sustainable business model will be in place within a specified timeframe.

4. ANSI's Views on Issues Relating to the Inclusion of Proprietary Intellectual Property (IP) in Standards

ANSI believes that an acceptable patent policy is one that is created with the objective of finding a balance among the multiple rights of interested parties, including: patent holders, competing manufacturers seeking to implement the standard, technical experts from different stakeholder groups, SDOs, and consumers. ANSI's Patent Policy is included as part of the ANSI's [Essential Requirements](#) for the 224 ANSI-accredited SDOs seeking approval for specific standards as ANS.⁴ It effectively allows for

⁴ In addition to its Patent Policy, ANSI also publishes "[Guidance on Software in Standards](#)," "[Current Attempts to Change Established Definition of 'Open' Standards](#)," and "[Guidance on Embedded Trademark](#)"

efficient standards development while avoiding unnecessary strictures that would discourage participation in the standards development process. In ANSI's view, there is no one-size-fits-all solution to this issue.

The ANSI Patent Policy is very similar to the common patent policy of ISO, IEC, and the International Telecommunication Union (ITU). These policies all recognize that it is permissible to develop standards that mandate the use of patented items if there are sufficient technical justifications. One recognized result of standards setting pursuant to internationally recognized and accepted patent policies is the opportunity to have the "best" technical solution – which may belong exclusively to a patent holder – incorporated into a standard and made available to all relevant manufacturers to exploit in competing commercial products.

The ANSI Patent Policy covers the policies with which an ANSI-accredited standards developer (ASD) must comply in addressing essential patent claims that are included in American National Standards. Under the Policy, when the ASD receives notice that a proposed ANS or an approved ANS may require the use of an essential patent claim, the ASD shall receive an assurance from the patent holder. That assurance must be a written or electronic statement indicating that the patent holder will offer to provide licenses either on (a) reasonable and non-discriminatory (RAND) terms and conditions or (b) a compensation-free basis (that may include other RAND terms and conditions), or whether the patent holder does not hold and does not currently intend holding any essential patent claims. If the patent holder submits a patent statement to the effect of either (a) or (b) above, then this creates a commitment by the patent holder to offer such licenses. Implementers and users may assert third-party beneficiary rights in the standard in accordance with applicable law.

Actual license agreements generally are negotiated bilaterally in a commercial context outside of the standards-setting environment. The SDO usually does not have the capability and necessary resources to adjudicate what are primarily commercial and legal issues. The SDO's major responsibility is to ensure that the due process-based procedures for developing consensus on the standard are properly followed. Subject matter experts that develop standards within SDOs are technical experts that do not have legal or business responsibilities with regard to licensing issues.

Nothing in the ANSI policy prohibits a patent holder from voluntarily disclosing its proposed licensing terms and conditions. Discussion or negotiation of specific license terms, however, should take place outside of the standards-setting venue to permit the most efficient development of standards, in part because the expertise of those in attendance usually is technical in nature as distinct from commercial or legal.

The consideration of specific license terms and potential costs of standardization, which may involve the costs of patented technology included in a standard, has been recognized, including by the U.S. Department of Justice Antitrust Division, as having potential pro-competitive effects. Such considerations, however, if they were to occur in a standards-setting venue, will still be subject to antitrust review and could be challenged as anti-competitive. The Department of Justice Antitrust Division and the Federal Trade Commission have explained in their 2007 Joint Report⁵ that any such challenges will be examined under a "rule of reason" analysis:

"The Agencies take no position as to whether [standards setting organizations] SSOs should engage in joint *ex ante* discussion of licensing terms but recognize that joint *ex ante* activity to establish licensing terms as part of the standard-setting process will not warrant *per se* condemnation."

⁵ See the Joint Report entitled "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition" which can be located at <http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf>.

The ANSI Patent Policy continues to evolve and is regularly updated to address issues and concerns as seen in the global standards community. SDOs (including ASDs) also continue to evolve their own IPR policies which can go into considerable additional detail depending on their environment and the market they serve. A major strength of the ANSI approach is that it provides the flexibility to permit SDOs to develop their own innovative approaches to handling IPR issues that are unique to that SDO.

The ANSI Patent Policy has proven over time to be a flexible and effective means of addressing the incorporation of patented technology into standards. Indeed, out of the approximately 10,000 current ANS, for only a relatively small number have questions ever been formally raised regarding the ANSI Patent Policy, including issues relating to improper “hold up.” ANSI generally seeks to address broader patent-related issues vis-à-vis its Patent Policy and Guidelines, while recognizing that bilateral disputes are often best resolved through legal proceedings as opposed to wholesale changes to the ANSI Policy.

Conclusion

Standards and conformity assessment activities are inextricably linked to all facets of our national economy and are vital to the continued global competitiveness of U.S. industry. By identifying and collaborating with the right private-sector partners on standardization initiatives – and, as necessary, working alongside ANSI in its neutral coordination role – it is clear that government agencies can work faster to meet and exceed their directives and mandates.

Our nation’s public-private partnership has worked well for more than 100 years, but improvements to the ways that government and industry communicate and share information would be helpful as we work together to respond to national priorities.

By articulating their needs firsthand, government agencies can help the standards community to be a more effective and proactive partner. And if the private sector does a better job of sharing information about standards development activities already underway – both here in the United States and internationally – then agencies will better understand the current landscape. A successful public-private partnership will yield faster, technically viable, and more economically feasible standards that are more likely to be embraced and rapidly implemented than those standards that are developed under different means.

Throughout this response ANSI has addressed its role as neutral forum, convener of cross-stakeholder standardization activities, and coordinator of our national standardization system. But equally important – especially through the lens of President Obama’s goals for increasing U.S. exports and competitiveness in the global marketplace – is ANSI’s role as U.S. member of the two non-treaty international standardization bodies: ISO and IEC. In this capacity, ANSI not only secures a seat at the table for our U.S. experts, but also is in the unique position to provide information and intelligence about what our competitors and trade partners around the world are doing. In addition, ANSI can provide a strategic link to those U.S.-domiciled SDOs developing international standards that support global competitiveness. Decisions made about our national standardization system and our priorities for action reach far beyond our borders, especially when it comes to the continued success of our products, services, and workforce on the global stage.

As one of the biggest users of standards, the U.S. government’s participation in standards development activities is of the utmost importance. The standardization community highly values the expert input that government employees provide and the reliance that agencies demonstrate by adopting and relying on voluntary consensus standards and compliance programs. Through greater focus, input, and interagency coordination, the NSTC Subcommittee on Standards can build upon the success of the NTTAA, especially in areas of strategic national importance where technology and policy intersect. ANSI and its Federation of members look forward to a close relationship and robust dialogue between members of the Subcommittee and the private-sector stakeholders from the standardization community. We thank you for this opportunity to provide comments.