U.S.-domiciled developers of international standards such as ASTM International often enjoy strong working relationships with U.S. government agencies. Representatives of these agencies both participate in technical committees and collaborate with SDOs to meet the needs of their stakeholders.

Working together, U.S.-domiciled standards developers and the federal government can move to enhance their already strong relationship in ways that will benefit industry, national competitiveness and global trade. This article provides seven policy-related recommendations to promote public-private collaboration in standards development.
Current federal policies for the development and use of voluntary consensus standards are extremely effective, benefiting the federal government and the regulated community alike. Such policies include reliance on the Office of Management and Budget’s Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, to utilize voluntary consensus standards for regulatory purposes, and the U.S. government’s commitment to base technical regulations on international standards that meet the principles of the World Trade Organization Technical Barriers to Trade Agreement.¹

The government’s commitment to such policies as these have led to an increased use of voluntary standards in the United States and elsewhere, and have made government regulation and procurement more efficient and globally relevant. Existing U.S. standards policies ensure that the nation has a successful, decentralized system of standardization driven by the diverse and evolving needs of stakeholders from every sector of the economy.

Today’s operational environment, however, requires federal agency engagement in standards development for technologies that are complex and multidisciplinary, and which address specific national priorities. In this context, ASTM International offers the following recommendations to ensure that our nation’s vital public–private collaboration in standards development is positioned to respond to the new challenges and opportunities created by advanced technologies that cut across multiple industries and disciplines.
1. A more robust public–private collaboration and upstream government engagement in standards development is critical to meet the emerging regulatory needs and policy challenges of the future.

Virtually all government agencies depend on voluntary consensus standards to fulfill their important mission and to meet the demands of their stakeholders. Therefore, it is vital to the competitiveness of U.S. industry and the safety of the public that federal agencies engage in standards development activities and fully implement OMB A-119.

While government engagement is necessary at all points in the development process, it is most effective when invested at the front end of standards development activities. Government involvement at the technical committee level provides critical technical information and strategic input — such as the projection of regulatory needs — and ensures that the standards development process is ready for and positioned to meet emerging regulatory or policy needs. Some agencies provide ample strategic input and engagement, but this involvement varies across agencies (and even within different subunits of agencies). Overall, both the quality and volume of government engagement in the activities of standards development organizations needs to be enhanced.

As a model of upstream regulatory engagement in standards development to address emerging technologies or new hazards in the marketplace, consider the approach of the U.S. Consumer Product Safety Commission. When CPSC staff members identify the need for a voluntary standard that will advance the objective of protecting the public from the threat of injury or death due to an unsafe consumer product, they submit a recommendation to an SDO based on consumer product incident data and analysis of that data.

Typically — and as is the case with ASTM International — the SDO organizes a task group to perform a technical assessment and prepares a draft standard (or revision to an existing standard) for review and comment. Once the voluntary standard or revision is approved, it usually becomes the recognized norm for that industry group and product type.

A specific example of this process lies in recent revisions to ASTM F963, Consumer Safety Specification for Toy Safety. When CPSC recognized a pattern of incidents involving children swallowing small magnets found in toys, they engaged ASTM International and sought a revision to the standard to address the newly identified hazard. Armed with the CPSC incident data and their expert analysis, an ASTM task group of stakeholders (toy manufacturers, retailers, consumer advocates, test laboratories, emergency room physicians, CPSC staff, etc.) diligently worked together to develop the new safety requirements. The revision of ASTM F963 containing the initial provisions to...
address magnets was approved March 15, 2007, nine months following the initial establishment of the task group in June 2006. Nine months of development time, given the complexity of the task in a full consensus environment, is a success and is directly attributable to the strategic engagement of CPSC and the dynamic and robust response from the experts on the ASTM task group.

Looking forward at an advanced technology that cuts across numerous scientific disciplines and multiple government agencies, consider nanotechnology. ASTM Committee E56 on Nanotechnology is chaired by a government scientist from the National Institute of Standards and Technology. Government technical experts from the National Institute for Occupational Safety and Health and CPSC are helping to guide and shape the standards development activities of a new subcommittee, E56.06 on Nano-Enabled Consumer Products. E56.06 is tasked with developing scientifically credible standards for the identification, evaluation and assessment of engineered nanomaterials in consumer products, including standards for determining the presence of engineered nanomaterials in consumer products and understanding the potential for exposure from the use of these consumer products.

Numerous other federal and state agencies have an interest in the environmental, health and safety aspects of nanotechnology, and ASTM International enables the agencies to be directly positioned in the process to provide input into and shape the development of related ASTM standards. In an ideal scenario, such government technical experts would capitalize on this opportunity to engage their peers from industry and academia earlier in the process by contributing a projection of regulatory needs and by investing their data, analysis and technical expertise in a manner similar to the CPSC involvement in the ASTM toy safety standard example outlined above.

2. The ability to choose from a broad portfolio of relevant standards better equips industry and government to deploy technologies associated with national policy priorities.

Many of today’s most complex legislative and regulatory policy initiatives require the deployment of new technologies that are, in part, linked to the development and application of standards. Government policies — whether in the United States or elsewhere — that limit government engagement to specific standards organizations or which create preferences for standards from specific standards development organizations, threaten innovation and undermine the effectiveness of legislative or regulatory initiatives. In today’s complicated business environments, industries and regulators need standards from multiple sources because no single standards developer is able to satisfy the diverse standards needs of every industry or cross-cutting regulatory challenge.

Fortunately, federal agencies in the United States have the flexibility to choose from a broad portfolio of standards to best meet their specific needs and objectives. As an example, the U.S. Department of Health and Human Services has referenced a standard specification from ASTM International, as well as standards from other organizations, in the July 2010 final rule on health information technology. ASTM standard E2369, Specification for Continuity of Care Record (CCR), is an XML-based standard developed to enhance patient safety and reduce medical errors and costs through addressing the efficient and interoperable exchange of health information.

Under the HHS final rule, the ASTM International standard is one of multiple tools that healthcare providers, institutions and patients can choose from that will advance the broader policy objective of HHS to “help move Americans into a 21st century healthcare system, where patients and doctors take control of their health information.”

The flexibility to choose standards based on important considerations such as technical quality, market relevance and global coherence often results in the utilization of standards that best match the emerging regulatory need. It is a model regulatory policy for other nations and should be promoted as the U.S. government pursues the regional or international harmonization of technical regulations.
3. The U.S. government should continue to seek full implementation of the WTO TBT Agreement.

The U.S. government is a signatory to the WTO TBT Agreement, which requires that international standards bodies adhere to principles such as consensus, openness and assistance to developing economies; the United States is pledged to use international standards as the basis for technical regulations whenever possible, with a view toward eliminating the use of standards as barriers to trade. The U.S. standards system adheres rigorously to the WTO TBT principles.

Unfortunately, the standards policies of other countries and regions are often more restrictive and often result in U.S. companies (including small and medium enterprises) having to comply with unfamiliar technical standards that were developed with limited U.S. input. In some instances, foreign governments dictate that international standards can only emanate from organizations such as the International Organization for Standardization (ISO) and the International Electrotechnical Commission, wherein countries are represented by a single “national body.”

The flexibility of the U.S. standards process empowers the federal government and private sector to participate in international standards activities in a variety of ways: through organizations such as ISO and IEC; through treaty organizations where governments are members; through consortia, whose membership is typically technology-based; and through professional and technical organizations and U.S.- domiciled SDOs whose membership is on an individual or organizational basis. Our national standards process offers enormous benefits to businesses, consumers and society, facilitating innovation and strengthening economic competitiveness. But this process is not well understood by many outside the United States.

Accordingly, the U.S. government should collaborate with other U.S. stakeholders to do more to help global stakeholders understand the benefits of the approach embodied in the U.S. standards system. Additionally, to advance the diverse international standards objectives and interests of U.S. stakeholders, the U.S. government should continue to seek full implementation of the WTO TBT Agreement and annexes as well as decisions taken in the WTO TBT Committee.

To that end, the U.S. government should continue to foster and support the unique character and strengths of the public-private partnership in standards development as it pursues trade and other international agreements, regulatory harmonization, and legislative and regulatory approaches. In summary, U.S. companies of all sizes should invest their technical resources in the development of standards that match their interest and business objectives. When barriers to the acceptance of such standards impair companies’ ability to utilize them, it is these companies who are most affected by the need for additional product testing or even the need for product redesign to achieve market access.

ASTM International encourages the U.S. government to engage their European Commission counterparts and to recommend that the commission: 1) incorporate the international standards principles outlined in the decision of the WTO TBT Committee into its legal framework; and 2) in the context of Europe’s “New Approach” to technical harmonization and standardization, extend the presumption of conformity to any standard that fulfills the essential requirements of a directive and which is developed in accordance with these standards development principles. Implementing this internationally agreed-upon approach would have far-reaching and significant effects, including increases in harmony, efficiency, choice, flexibility and much-needed relief from expensive, duplicative procedures for companies that trade internationally. The ability to utilize a broader array of international standards would particularly benefit advanced technologies via lower costs and reduced development time.
4. Rather than using federal funds to develop and deploy standards, redirect funding to ensure strategic government engagement in the standards development process.

Today, NIST reports that there are references to over 9,000 standards incorporated in the Code of Federal Regulations. Most of these standards were developed by SDOs without direct funding from the government. ASTM International does not receive any direct federal funding for the development of ASTM standards. In our experience, stakeholders from public and private sectors collaborate most effectively in standards development when they are united in a purpose and committed to address a demonstrated market or regulatory need.

As an example, consider the ASTM standard E1527, Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process. In this case, the regulator (the U.S. Environmental Protection Agency) and the regulated community (bank and insurance companies that make commercial loans, purchasers, consultants who produce environmental assessment reports and environmental lawyers) recognized that there was a need to better define good commercial and customary practice for conducting an environmental site assessment of a parcel of commercial real estate with respect to the range of contaminants within the scope of the Comprehensive Environmental Response, Compensation and Liability Act. Under the ASTM process, these parties collaborated to develop E1527 to satisfy legal requirements for how to conduct “all appropriate inquiries” consistent with the act.

Developed with no direct federal funding, this standard today serves as a fundamental component of the EPA All Appropriate Inquiries law and has made a prodigious contribution to the commercial real estate marketplace in the United States. Because it was developed by a consensus process that is in accordance with WTO TBT principles and is globally recognized for its technical excellence and relevance, real estate markets in Korea, Japan and Taiwan also currently rely on E1527.

5. Federal agencies seeking to advance the development and deployment of standards for specific advanced technologies should consider the model of issuing requests for proposals to allow SDOs to compete.

In recent years, agencies such as NIST and the U.S. Federal Aviation Administration have issued requests for proposals seeking non-governmental standards development organization partners in developing specific suites of standards of strategic importance for regulatory or market needs. Applicant SDOs were assessed based on established selection criteria, and a selection was made under a merit-based competitive process.

For example, following a NIST workshop of stakeholders from the 3D imaging systems sector held in 2006, ASTM International was selected under a competitive process as the standards venue of choice to work in partnership with NIST and the emerging 3D imaging industry. Selection factors included ASTM International’s consensus process and standards development infrastructure.

Since its inception, ASTM Committee E57 on 3D Imaging has worked with NIST (the committee is chaired by a NIST expert) to develop voluntary consensus standards and test methods for the performance and use of 3D imaging systems of importance to a wide variety of industries, including construction, mapping, manufacturing, mining and forensics. ASTM standards and test methods have been published that advance market acceptance and consumer confidence in 3D imaging technology through the improved evaluation and performance of commercial products such as laser scanners, optical scanners, range cameras and 3D flash laser radars. Ongoing Committee E57 standards activities are unlocking the possibilities for innovative new commercial uses of this advanced technology.
6. Stronger global enforcement of intellectual property rights is needed to combat piracy and ensure the continued vibrancy of standards development in the future.

When a federal agency has a demonstrated need for access to intellectual property contained in ASTM International standards, ASTM works with the agency to meet reasonable needs. For instance, ASTM often provides read-only access to certain copyrighted materials for review and comment, offer inexpensive license agreements for certain constituencies or provide fixed-rate access through a federal agency for certain numbers of their constituents.

In countries where copyright laws are respected, ASTM International standards are largely protected from illegal reproduction. The WTO Trade-Related Aspects of Intellectual Property Rights Agreement and the intellectual property provisions of free trade agreements prevent copyright abuses. But in countries where pirated goods are traded freely, agreements and laws have little effect and the piracy of ASTM International property is a serious issue.

To combat the misuse of the intellectual property of U.S.-based SDOs, the U.S. government should continue to seek greater global awareness and enforcement of protections for standards and related technical information.

7. The federal government and private sector need to do more to promote coherence in standards development, both domestically and in international venues.

In today’s domestic marketplace, there are over 200 organizations that are accredited by the American National Standards Institute to develop standards. While diversity and freedom of choice are important aspects of our national system, it is possible for the proliferation of accredited standards developers to reach a threshold of diminishing return. The criteria and requirements for ANSI accreditation should be closely examined to avoid the unnecessary confusion in the marketplace that results from multiple standards from multiple organizations addressing the same technical issue.

It is interesting to note that the standards from five U.S.-domiciled SDOs account for 41 percent of all the standards incorporated by reference in the Code of Federal Regulations as compiled by NIST. This suggests that certain standards organizations have a demonstrated track record of successfully working to meet the needs of the federal government. While there may be many players in the U.S. standards arena, a handful of organizations have stood the test of time and are well positioned to meet the emerging standardization needs of the future.

An important WTO TBT principle addresses coherence as follows: “In order to avoid the development of conflicting international standards, it is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential.”

Over the years, ASTM International has experienced the duplication of
its standards development activities in other venues. ASTM International encourages its technical committees and the industries they represent to carefully and strategically develop a standards strategy that meets their needs: minimize the duplication of international standards, utilize the standards that exist, normatively reference existing standards instead of duplicating them, harmonize if possible and necessary, respect the intellectual property of developers and allocate resources to support the standardization strategy.

As a model for joint standards development work, ASTM International has pointed to the successful precedent of promoting coherence in standards development as demonstrated in the collaboration between ASTM and ISO to develop a global portfolio of standards in the area of radiation processing dosimetry standards. During a five-year period between 1999 and 2004, ISO and ASTM International conducted and successfully ran a pilot project, “Radiation Processing Dosimetry Standards,” in which 25 published ASTM dosimetry standards were transformed into ISO/ASTM standards. Detailed procedures were developed whereby the ISO/ASTM standards were periodically reviewed and maintained by ASTM International with unrestricted participation and input from ISO. The process called for the revised standards to be balloted independently by ISO and by ASTM International using their normal ballot procedures. These procedures were implemented in 2001, and all of the standards have now proceeded through the full maintenance cycle.

Opportunities to forge collaborations in the global standards development community are rare, and ASTM International stands ready to work with others to avoid duplication of effort and deliver societal benefits that improve the lives of people worldwide.

REFERENCES
1. The WTO/TBT principles are 1) openness, 2) transparency, 3) impartiality and consensus, 4) relevance and effectiveness, 5) coherence and 6) the development dimension.

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