Comments of ASTM International

FR Doc. 2010-30864

Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for National Science and Technology Council Subcommittee on Standardization

February 28, 2011

Introduction

On behalf of ASTM International, we would like to take this opportunity to provide comments on the effectiveness of Federal agency participation in standardization in select technology sectors as requested via FR Doc. 2010-30864.

Public/Private Collaboration in ASTM International

U.S. domiciled standards development organizations (SDOs) - such as ASTM International - help to drive innovation and advance our nation's competitiveness through the development of voluntary consensus standards used in research and development, commercialization, product testing, and quality systems. ASTM International finds that current policies for the development and use of private sector technical standards continue to be extremely effective benefiting the Federal government and the regulated community alike. Such polices include reliance on the Office of Management and Budget (OMB) Circular A-119 (which implements Section 12(d) of P.L. 104-113, the National Technology Transfer and Advancement Act of 1995) to utilize voluntary consensus standards for regulatory purposes; and the U.S. government's commitment to base technical regulations on international standards that meet World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement principles. The government's commitment to these policies have led to an increased use of voluntary standards in the U.S. and elsewhere, and have made government regulation and procurement more efficient and globally relevant.

Existing U.S. standards policies affirm and ensure that the nation has a decentralized system of standardization driven by the diverse and evolving needs of stakeholders from every sector of the economy. As the largest and most prolific SDO domiciled in the U.S., ASTM International is a leading venue for technical experts, consumer advocates and regulators alike to engage directly under an open, transparent and balanced process in the development of voluntary consensus standards that can be utilized to meet regulatory objectives, promote safety and the environment, or to improve the overall quality of life. Over 1,300 individuals from U.S. Federal agencies are actively engaged in 90 percent of our standards writing technical committees. While nearly every Federal agency participates, the agencies with the most representation in our standardization work include the Department of Defense (305 ASTM members), the Department of Commerce (198 ASTM members), the department of Health and Human Services (133 ASTM members) and the Environmental Protection Agency (112 ASTM members).

One way to quantify the success of such policies and engagement is the extent to which voluntary consensus standards are accepted and utilized by U.S. agencies to meet regulatory and procurement needs. According to the NIST Standards Incorporated by Reference Database, 2,215 standards from ASTM International have been incorporated by reference in the U.S. Code of Federal Regulations. NIST also reports that as many as an additional 500 ASTM standards are relied upon in the Federal acquisition process. While case examples from companies and trade associations have demonstrated that there are numerous benefits to the private sector of this Public/Private collaboration resulting in the government's reliance on voluntary consensus standards[1], the government also benefits from the reduced costs of standards development and the ability to purchase a wider variety of commercially available goods and services.[2]

Recommendations

Recognizing that the Subcommittee on Standards is specifically interested in recommendations to improve and enhance Federal agency engagement in standards development for technologies that are complex, multi-disciplinary, involving multiple government agencies, and that address specific national priorities, we offer the following recommendations to ensure that our nation's vital Public/Private collaboration in standards development is positioned to respond to new challenges and opportunities created by advanced technologies of tomorrow:

1. **Enhanced and more robust public/private collaboration and "upstream" government engagement in standards development is critical to meet emerging regulatory needs and policy challenges of the future**.

Virtually all governmental agencies depend on voluntary consensus standards to fulfill their import 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, engagement is most effective when invested at the front-end of standards development activities by providing critical technical information and strategic input - such as a projection or estimation of regulatory needs – to ensure that the voluntary consensus standards development process is in-sync and well positioned to meet emerging regulatory or policy needs. Some agencies do a very good job of providing strategic input and engagement, but it varies agency-by-agency (and even within different sub-units of agencies). Overall, both the quality and volume of government engagement in activities of SDOs needs to be enhanced.

[1] See: http://www.standardsboostbusiness.org/government.aspx

[2] Twelfth Annual Report on Federal Agency Use of Voluntary Consensus Standards and Conformity Assessment publish by NIST and available at: https://standards.gov/NTTAA/resources/nttaa_ar_2008.pdf

As a model of "upstream" regulatory engagement in voluntary standards development to address emerging technologies or new hazards in the marketplace, consider the approach of the Consumer Product Safety Commission (CPSC). The CPSC 2011-2016 Strategic Plan details its strategic approach towards engaging in voluntary standards development activities. 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[3]. 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 existing standard) for review and comment. During this comment period, the CPSC staff provides expert advice, technical assistance, and clarifying analyses. After evaluating and incorporating technical comments on the proposal, the task group works with the standards writing committee to achieve approval of the final voluntary standard or revision to existing standard (the CPSC does not hold an official vote per agency policy but provides non voting member commentary that is given full consideration). Once the voluntary standard or revision is approved, it usually becomes the recognized norm for that industry group and product type.

As an example of a regulatory agency's successful upstream engagement in voluntary standards development, consider the ASTM F963 Consumer Safety Specification for Toy Safety which establishes safety requirements for toys. ASTM F963 - due to its comprehensive nature and the dynamics of an evolving industry - is under constant evaluation to address changing needs from both a product and emerging hazard standpoint. When CPSC recognized a pattern of incidents involving children swallowing small magnets that were built into toys, or that were part of a building play set with small parts intended for older children, they engaged ASTM 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 labs, 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 NIST. As importantly, government technical experts from the National Institute for Occupational Safety and Health (NIOSH) and the CPSC help to guide and shape standards development activities of a new subcommittee (ASTM E56.06 on Nano-Enabled Consumer Products) tasked to develop scientifically credible standards for the identification, evaluation and assessment of engineered nanomaterials in consumer

[3] Consumer Product Safety Commission 2011-2016 Strategic Plan

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 Federal and state agencies have an interest in the environmental, health and safety aspects of nanotechnology and ASTM International allows them to be directly positioned in the process to provide input and shape the development of related ASTM standards. In an ideal scenario, these government technical experts would capitalize on this opportunity to engage their peers from industry and academia upstream through contributing a projection of regulatory needs and through investing their data, analysis and technical expertise in a manner similar to the approach of CPSC as outlined above in the toy safety example.

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

Many of today's most complex legislative and regulatory policy initiatives require the deployment of new technologies which are, in part, linked to the development and application of standards. Government policies – whether in the U.S. or elsewhere – that limit government engagement to specific standards organizations, or that create preferences for standards from specific standards development organizations, threatens innovation and undermines 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 standards needs of every industry or cross cutting regulatory challenge.

Fortunately, Federal agencies in the U.S. have the flexibility to choose from a broad portfolio of standards to best meet their specific needs and objectives. As an example, the Department of Health and Human Services (HHS) has referenced a standard specification from ASTM International, as well as standards from other organizations, in the July 2010 Final Rule implementing Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology. The ASTM E2369 Standard Specification for the Continuity of Care Record (CCR) is an XML-based standard developed to enhance patient safety and reduce medical errors and costs through the efficient and interoperable exchange of health information. Under the HHS Final Rule, the ASTM standard is one of multiple tools that health care providers, institutions, and patients can choose from in order to advance the broader policy objective of HHS "to help move Americans into a 21st century health care 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 regional or international harmonization of technical regulations.

3. Foreign technical regulations can act as a barrier to global regulatory convergence for emerging technologies.

The U.S. government is a signatory to the WTO TBT Agreement and is pledged to use international standards as the basis for technical regulations whenever possible, with a view towards eliminating the use of standards as barriers to trade. Our standards system is rooted in the principles of consensus, openness and assistance to others. Unfortunately, the standards policies of other countries and regions are more restrictive and often result in U.S. companies (including SMEs) 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 ISO and IEC where countries are represented by a single "national body" organization.

The flexibility of our national standards process empowers the U.S. government and private sector to participate in international standards activities in a variety of ways: through organizations such as ISO and IEC where the United States is represented by a single "national body" organization; 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[4]. 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 foreign stakeholders understand the benefits of the approach embodied in the U.S. Standards System. 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 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 their ability to utilize them, it is these companies who are most affected through the need for additional product testing or possibly the need for product redesign to achieve the desired market access.

While there is currently no legal mechanism that exists in the European regulatory infrastructure to allow standards from U.S. domiciled organizations to achieve the same acceptability as European standards, U.S government agencies often utilize European standards for government purposes. Consider the 2010 example of the U.S Department

[4] United States Standards Strategy, 3rd Edition, available at: http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/NSSC/USSS_Third_edition/USSS%202010-sm.pdf

of Homeland Security's adoption of the final standards for the Voluntary Private Sector Preparedness Accreditation and Certification Program (PS-Prep). To help implement a key program recommended by the 9/11 Commission intended to improve private sector preparedness for disasters and emergencies, the PS-Prep partnership between DHS and the private sector enables private entities to receive emergency preparedness certification from a DHS accreditation system created in coordination with the private sector. The three voluntary consensus standards adopted by DHS in the PS-Prep Program were developed by the National Fire Protection Association, the British Standards Institution (BSI), and ASIS International, and were published in a Federal Register notice on June 15, 2010[5]. The BSI is the National Standards Body of the United Kingdom.

ASTM International encourages the U.S. government to engage their European Commission counterparts and recommend that they incorporate the international standards principles outlined in the Decision of the WTO TBT Committee [6] into its legal framework and, 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 is developed in accordance with these 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. Fast moving areas involving advanced technologies stand to benefit the most from the ability to utilize a broader array of international standards through lower costs and time spent in developing standards.

4. The U.S. standards landscape has evolved with the pace of technology and the evolving needs of society.

In today's competitive environment, SDOs have to be dynamic and strive to meet the needs of their members. In some cases, standards developers collaborate with other organizations to jointly address a need and avoid unnecessary duplication of effort and resources. And they have invested in advanced tools to enhance collaboration and further speed the development of standards. As we face demands for standards to address complex multidisciplinary technologies, standards developers are committed to accelerating the development of standards through the utilization of electronic tools and on-line collaboration. The dynamic of speed is also of the essence when it comes to a need for a revision or introduction of standards to address emerging hazards or consumer safety issues.

Our ever-evolving use of technology empowers ASTM International to introduce new high-quality, relevant standards into the marketplace as quickly as possible. We have streamlined the average time to develop new standards to 14-17 months and the average time for revisions to 6-8 months. For the past 10 to 15 years, ASTM has committed significant resources and financial investment to the creation of a "Digital Path" that

[5] See http://www.fema.gov/privatesector/preparedness/adoption_standards.shtm
[6] See the USTR TBT Agreement web page for a review of the Agreement, Decisions and Annexes at: http://www.ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade

provides an integrated electronic process from the inception of an idea for a new standard or revision to an existing standard through to its approval, publication and delivery. For example, virtual meetings, which combine teleconferencing with Internet document viewing and editing, have been a valuable tool in engaging additional experts and accelerating the development process. Other resources such as electronic balloting with accompanying project management functionalities, the electronic distribution of meeting minutes, website tools for committee members and online collaboration areas for task group work add efficiencies to the process and further facilitate timely response to industry needs. Through this deployment of technology, ASTM is able to quickly respond to developments in fast-moving sectors and is well placed to deliver cutting edge standards in a timely manner. While speed is important, our steadfast commitment to the principles of quality, transparency and consensus amongst all interested parties is never compromised in our standards development process.

As an example of collaboration among standards developers, code bodies, and related scientific and technical societies working with a common purpose to meet an emerging area of commercial and regulatory need, consider the example of the International Green Construction Code (IGCC). In 2009-2010, ASTM International joined the International Code Council; the American Institute of Architects (AIA); the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE); the U.S. Green Building Council (USGBC); and the Illuminating Engineering Society (IES) in a collaborative effort to launch an initiative aimed at developing a model code focused on new and existing commercial buildings addressing green building design and performance. By committing to a common purpose and goal, the green buildings-related standards and technical resources of U.S. industry are being more efficiently utilized and unnecessary duplication of effort is being avoided. This collaborative and private sector lead effort is helping the U.S. commercial building industry to meet their 2030 Carbon Neutrality Goal.

5. Federal funding is not a significant success factor in the development and deployment of standards (but strategic government engagement is).

Today, NIST reports there are references to 9,211 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 currently 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 E1527 Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process. Recognizing 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 Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the regulator - the EPA - and the regulated

community - bank and insurance companies that make commercial loans, purchasers, consultants who produce environmental assessment reports, and environmental lawyers – collaborated under the ASTM consensus-based standards development process to develop a practice to satisfy legal requirements for how to conduct "all appropriate inquiries" consistent with the Act. Developed with no direct Federal funding, ASTM E1527 today serves as a fundamental component of EPA All Appropriate Inquiries law and has made a prodigious contribution to the commercial real estate market place in the U.S. And 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, the ASTM standard is currently being relied upon in the real estate markets of Korean, Japan and Taiwan.

6. **Federal agencies seeking to advance the development and deployment of standards for specific advanced technologies should consider the model of issuing requests for proposals or public tenders.**

In recent years agencies such as NIST and the Federal Aviation Administration (FAA) issued tenders as "requests for proposals" seeking non-governmental standards development organizations to apply to partner with the agency in the development of a specific suite 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 proven consensus process and state-of-the-art standards development infrastructure. Since its inception, ASTM International 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 improved evaluation and performance of commercial products such as laser scanners, optical scanners, range cameras, and 3D flash laser radars (LADARs). The ongoing ASTM standards activities are unlocking the possibilities for innovative new commercial uses of this advanced technology.

In summary, this competitive model of selecting SDOs has worked well for Federal agencies and their stakeholders and the Subcommittee on Standards should consider this mechanism to address emerging technology standardization needs the cut across many Federal agencies.

7. **The value and significance of standards is often underappreciated or underestimated by policymakers and corporate decision-makers, but**

standards have a demonstrated impact on business productivity and profitability.

The U.S. has strong community of standards developers, encompassing thousands of volunteers from industry and all stakeholder communities. Private sector funding and resources drives our system of standards development. Considering the scope and breadth of all of the organizations involved in standards development, the impact of standards development is practically incalculable. If our national system was to change models to employ a top-down approach where the Federal government drives and funds standardization activities, our 114 years of experience suggests that the Federal government would be hard-pressed to play this type of role while maintaining the same level of volunteer commitment in the process and technical excellence in the resulting standards. This spirit of volunteerism inherent in the U.S. Standards System is both unique and envied around the globe.

One of the core tenants of our U.S. Standards System that is not well understood by non-participants is the decentralized nature of the participation and membership in SDOs. In the case of ASTM International, we rely on a network of 33,000 individual members to drive our standardization activities to reflect their needs. These participants engage and vote in our process as individuals. ASTM International acts as platform or service provider, but does not seek to influence or drive the process.

Contrary to the perception that standards development is dominated by the interests of large businesses and corporations, the reality is that 51 percent of the ASTM International membership comes from companies or organizations that have 250 employees or less. At a time when policymakers in Europe are examining ways to boost the engagement of small and medium sized enterprises (SMEs) in standards development activities, individuals from SMEs are well represented in the important work of ASTM International. SMEs play a critical role in today's global economic infrastructure and their voice and technical expertise is crucial as ASTM International works to meet the standards related demands and expectations of our stakeholders.

U.S. policymakers and corporate decision makers often fail to realize that U.S. domiciled SDOs can meet WTO TBT principles and, in fact, develop international standards. In reviewing the extent to which ASTM standards are accepted and used worldwide as international standards, it is important to note that over 4000 ASTM standards are accepted and used by regulation or adoption in 110 countries around the world. And today, nearly 50 percent of the global distribution of ASTM standards takes place outside of the U.S. In summary, ASTM standards can be valuable tools to help U.S. companies accomplish their global business objectives.

In 2005-2006, the ASTM International board of directors funded a qualitative study conducted by the independent research firm Market Measurement Incorporated focused on the impact of standards participation as identified by participants in the standards development process. It aimed to document the expected benefits, costs, risks of standards participation by gauging the views of senior level executives on the value,

application and impact of standards in the business environment. Over 1,000 executives were contacted, and 250 in-depth telephone interviews were completed among C-level (CEO, COO and CFO) and technical executives. Participating companies were selected using a scientifically developed random sample covering Fortune 1000 companies, as well as companies of various sizes.

The survey findings show that, within the executive community, there is clear recognition of the contribution of standards to business vitality and ongoing growth. The research also showed that standards have both a direct and often significant impact on business operations. Among those surveyed 75% report that standards have a "high impact" upon their organization and 95% describe standards as having at least a "moderate impact." When asked to rate their sentiment toward standards when considering specific business-related issues, executive decision-makers gave the highest proportion of "very favorable" ratings to "enhancing product quality and performance" and "improving customer receptivity." Other important attributes of standards that were viewed most favorably were: "serve as a resource for product liability challenges," "enhance coordination with suppliers," and "support product development."

Positive executive viewpoints on standards were brought further into light when participants were asked, in an unaided manner, to identify "the most important benefit of standards" to their organization. While executives continued to acknowledge benefits such as "produce consistency and uniformity" and "foster higher levels of customer satisfaction and retention," some of the other notable responses of the executives surveyed were: "all competitors held to the same standard," "enhance worker safety," "reduce/ control costs," and "increase sales." Ninety percent of the corporate executives and 88 percent of the technical executives rate the return-on-investment of participation in standards development as high or moderate, but no specific financial information is available.

In conclusion, the independent research effort found that companies that use standards and individuals involved in standards development report that standards have a positive impact on corporate profitability.

8. Standards developers are flexible and reasonable in providing government access to intellectual property rights (IPR); patents are effectively addressed in our standards development process; and stronger global enforcement of IPR is needed to 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 standards, we work with them to meet their reasonable needs. For instance, we often provide 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. Regarding patents, most standards developers employ policies that do not encourage embedding patented technology in its standards. If an ASTM technical committee writing

a standard finds it necessary to include a patent, it is permitted, after requesting alternatives, and noting in the final standard that notification of alternatives is requested.

ASTM International standards have never been easier to obtain, more affordable or more efficiently delivered than they are today. They are copyrighted as the original creations of ASTM International technical experts and they are the main source of revenue that drives the continued innovation and success of our organization. In countries where copyright laws are respected, the ASTM International standard is largely protected from illegal reproduction. The WTO's TRIPS 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.

As the use of the Internet increases, so does copyright infringement, and today it occurs on a grand, international scale. Illegal reproduction and sale of digitized intellectual property has risen to new heights. Freewheeling operators in countries such as China and Iran are buying ASTM standards through the Internet, reproducing them and selling them without authorization or permission. Some well-known companies — and some standards organizations — have resorted to the use of digital rights management technology, software that is designed to prevent unauthorized duplication of copyrighted works. In its current state of development, DRM is effective but not foolproof, and it inhibits some uses of digital content. To date, ASTM International has resisted employing DRM out of concern for the inconveniences it would place on legitimate purchasers of ASTM standards.

But the piracy of ASTM International property is a serious issue. Sellers of pirated intellectual property are endangering future trade relations with countries who buy their exports. Buyers of pirated material may or may not get the entire original ASTM standard, which could cause product or testing problems and contracts to fail. Most importantly, the practice of piracy is illegal. To combat the misuse of our intellectual property, we ask that the U.S. government continue to seek greater global awareness and enforcement of protections on standards and related technical information.

9. The Federal Government and private sector need to do more to promote coherency in standards development, both domestically and in international venues.

In today's domestic marketplace, there are 224 organizations that are accredited by the American National Standards Institute (ANSI) to develop standards. While diversity and freedom of choice are important aspects of our national system, the proliferation of accredited standards developers can reach a threshold of diminishing return. The criteria and requirements for ANSI accreditation should be closely examined to avoid 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 SDO's account for 41 percent of all the Standards Incorporated by Reference (SIBR) in the Code of Federal Regulations as complied by

NIST[7]. 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 emerging standardization needs of the future.

Looking globally, 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[8]".

Over the years, ASTM International has experienced examples where our standards development activities have been duplicated in other venues such as the International Organization for Standardization (ISO). ASTM International and ISO are both international standard developers. Our approaches are different. The systems are different. The access is different. 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 standards, harmonize if possible and necessary, respect the intellectual property of developers and allocate the resources to support the standardization strategy.

As an example, consider the emerging multi-disciplined technology known as additive manufacturing of which *The Economist* recently declared "the manufacturing technology that will change the world[9]". ASTM International Committee F42 on Additive Manufacturing was organized in January 2009. At present, the committee has a global membership of over 100 individuals and organizations representing 11 countries, and has (to date) developed 1 standard and 16 registered work items. Recently, a new ISO activity significantly similar in scope to that of the ASTM committee has been created and the stakeholder community, from an organizational and individual perspective, is virtually identical.

Due to the heightened global relevance, the technological advances and market acceptance of this emerging technology, the leadership of ASTM International Committee F42 has observed that the need for coordination between ASTM and ISO in this area is absolutely paramount. Accordingly, ASTM International's leadership has proposed that the two organizations work together and develop a meaningful portfolio of robust and dynamic international standards.

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[7] See: http://standards.gov/sibr/query/index.cfm?fuseaction=rsibr.total_regulatory_sibr

[8] See the USTR TBT Agreement web page for a review of the Agreement, Decisions and Annexes at: http://www.ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade

[9] The Economist, February 12th-18th 2011 edition; see: http://www.economist.com/node/18114327?story_id=18114327&fsrc=rss

As a model for of joint standards development work, ASTM international has pointed to the successful precedent to promote coherency in standards development 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 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 truly collaborative relationships in the global standards development community are rare and ASTM International hopes that ISO will accept our proposal. Early indications have been positive which is welcomed by our global constituencies so as to avoid duplication and speed the time to market of relevant global standards necessary to spur the commercialization of this exciting technology.

Conclusion

ASTM International is pleased for the opportunity to provide comments on this important review conducted by the Subcommittee on Standards. In summary, existing U.S. standards policies promote Public/Private sector standards development efforts that reduce the cost and improve the management and effectiveness of government, while reducing global technical barriers to trade. While ASTM International and other standards developers have demonstrated great success in working cooperatively with governments, consumers, industry and other stakeholders to craft voluntary consensus standards that meet current regulatory needs in the U.S. and elsewhere, it is vital to the competitiveness of U.S. industry and the safety of the public that government agencies continue to engage strategically with SDOs in the development of standards, and to promote the global implementation of technical regulations based on international standards that meet WTO TBT Agreement principles. ASTM International looks forward for opportunities to work with the Subcommittee to ensure that our nation's vital Public/Private collaboration in standards development is positioned to respond to new challenges and opportunities created by advanced technologies of tomorrow.