ASME
SETTING THE STANDARD
STANDARDS & CERTIFICATION

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To: SOS_RFI@nist.gov

Subject: Standardization Feedback for Sub-Committee on Standards

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[Docket No. 0909100442-0563-02]

Dear Colleague:

On behalf of ASME, it our my pleasure to submit the following comments in response to the recent Request for Information submitted by NIST on the "*Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for National Science and Technology Council's Sub-Committee on Standardization*".

Sincerely,

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Introduction

Founded in 1880, ASME has been a leading developer of internationally accepted standards and conformity assessment programs for over 125 years. Its roots include the development of standards necessary to ensure the interoperability of fasteners as well as the safe and reliable design and operation of machinery ranging from boilers, pressure vessels and piping, to cranes and elevators. With over 125,000 members worldwide (including approximately 4,700 standards development volunteers), a portfolio of over 500 standards, and ASME certified manufacturers located in over 70 countries, ASME serves as a resource for mechanical engineers and other technical professionals throughout the world.

In fulfilling its mission of "advancing, disseminating and applying engineering knowledge for improving the quality of life", ASME not only embraces technological innovations - in many instances, it has enabled them. When the United States began its commercial nuclear power program, ASME rapidly adapted its standards used within the fossil power industry to suit the needs of the nuclear industry. As industries were moving from two dimensional drafting to three dimensional computer aided design, ASME developed a first-of-a-kind standard that established requirements for preparing, organizing and interpreting three dimensional digital product images. ASME continues to meet the demand for standards that are technically rigorous as well as market relevant, and which promote continued innovation and competition. Recent innovations enabled by ASME include processes governing the performance of industrial energy assessments; provisions for risk-informed decision-making; the groundwork for supporting hydrogen infrastructure; and criteria for the verification and validation of computational modeling.

ASME strongly supports the National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119 as key tools for enabling sustained and meaningful partnerships between the private and public sectors by reducing the burdens of government and facilitating cost effective development of consensus standards. Further, as emphasized in the 2010 edition of the *United States Standards Strategy*, ASME believes it is important for organizations (including Federal agencies) engaged in standards development activities to recognize globalization and the need for standards that meet stakeholder needs irrespective of national borders.

We are hereby pleased to provide our insight on Federal agency participation in standards development to NIST and the National Science and Technology Committee's Subcommittee on Standards.

Standards-Setting Processes, Reasons for Participation And the Benefits of Standardization

Who participates in standards-setting activities?

Over 4,700 individuals participate in ASME's standards-setting committees, which are balanced to ensure that a single interest may not dominate the consensus process.[1]

Approximately 350 ASME Standards & Certification volunteers are employed by Federal, state and local agencies, including over 250 individuals from the following Federal agencies:

- Consumer Product Safety Commission
- Department of Defense
- Department of Energy (and its national laboratories)
- Department of Homeland Security
- Department of Interior
- Department of Labor
- Department of Transportation
- Environmental Protection Agency
- Federal Aviation Administration
- International Trade Administration
- National Aeronautics and Space Administration
- National Institute of Standards and Technology
- Nuclear Regulatory Commission

Collectively, these individuals participate on over 500 ASME standards development boards, committees and task groups.

In addition, reflecting the growing global relevance of ASME's standards and certification programs, an increasing percentage of individuals participating in ASME's standards development activities are from outside the U.S. As of January 2011, international stakeholders accounted for approximately 12% of ASME's volunteers.

What are the most important reasons for participation?

Generally, stakeholder participation is driven by one or more of the following reasons:

- to ensure safety, health and welfare
- to ensure reliability, quality, efficiency and/or compatibility
- to ensure market acceptance
- to reduce costs

[1] See Appendix I, Membership Classification for ASME Standards Development Committees

- to advance technology
- opportunities for collaboration

While ASME ensures that all materially affected parties have the opportunity to comment on proposed standards or revisions to standards, individuals who directly participate have the best opportunity to shape the process. This is especially important for stakeholders such as regulators, researchers, suppliers and purchasers whose job functions may require them to make decisions that make use of the latest available technical information.

What are the benefits of developing standards for this sector?

ASME's mission crosses industry sectors and disciplines. Sectors employing ASME standards include:

- Design engineering, such as geometric dimensioning and tolerancing, component specification, measurement and verification/validation
- Material handling machinery, such as elevators, escalators, cranes, conveyors and hoists
- Petroleum refining and transportation, chemical production and natural gas transportation and distribution, particularly with respect to piping and pipelines
- Power generation (including nuclear), particularly with respect to materials, pressure integrity components, processes (including operation, inspection and maintenance), performance measurement and testing, accreditation and certification

Benefits to the respective sectors include:

- improved safety, health and welfare
- improved reliability, quality, efficiency, and compatibility
- improved market acceptance
- reduced costs
- commercialization of new technology

A recent survey of ASME volunteers indicated they spent an average of 175 hours each year on standards committee work, with approximately two-thirds of that time funded by an employer and one-third self-funded. Factoring in the commercial value of a volunteer's time, it is estimated that volunteers involved with ASME's standards development activities contribute approximately 100 million dollars in time each year (not including any related travel expenses).

Sharing the inherent costs in this manner benefits taxpayers by saving Federal agencies millions of dollars each year and by freeing up governmental resources for other important activities.

How do the standards impact organizations and their competitiveness?

In general, organizations that employ standards increase their competitiveness by:

- incorporating state of the art technology and processes
- building confidence in producer/consumer transactions
- improving market acceptance
- reducing costs/improving operational efficiency

As an example, Section XI of the ASME Boiler and Pressure Vessel Code, *In-service Inspection of Nuclear Power Plant Components*, specifies rules for repairs, replacement of equipment, activities for evaluations, and in-service inspection requirements of nuclear power plant components. A single electric utility has estimated that implementation of this code has saved tens of millions of dollars in avoiding unwanted repairs, time delays, outages, and lost revenue. The utility estimates it saves $2.6 million every ten years from a single nuclear safety innovation governing risk-informed in-service inspection for piping welds. Additional code changes, such as a switch to atmospheric leak testing after data was analyzed indicating that hydrostatic testing did not yield better results, have created at least $10 million in savings for the utility.[2]

How has standardization spurred innovation in the technology sector(s) that is the subject of your comment?

The process of standardization provides a sustainable forum for identifying technological gaps as well as for evaluating innovative technology and novel applications of technology.

Recent areas of innovation within ASME include:

- advancement of knowledge of properties and construction techniques for hydrogen infrastructure
- high performance materials for Gen IV nuclear reactors
- new material handling machinery (spurred by performance-based standards)
- risk-based approaches to performance monitoring and inspection
- concentrating solar power plant technology
- steam generators with carbon capture

Frequently, the commercialization of innovative technology presents a chicken-and-egg scenario: unproven technology typically requires a set of standards prior to achieving commercialization; however, it is often not feasible to develop standards without data gathered from wide spread use. In recognition of the value of innovation – as well as its connection to standardization and commercial deployment – ASME established a dedicated entity, ASME Standards Technology LLC (ASME ST-LLC), in 2004 to anticipate the

[2] See Appendix II, Dominion Case Study

standardization needs of industry and government related to emerging technologies. ASME ST-LLC provides a vehicle for obtaining funding and resources required to develop data vital for first-of-a-kind standards and expediting the standards development process.

ASME is actively involved with various other innovative projects – particularly in materials and energy-related areas - such as the investigation and evaluation of advanced nondestructive examination techniques for composite materials; development of training materials for conducting probabilistic risk assessment; development of methods for conducting industrial energy assessments; evaluating materials for Gen IV nuclear reactors, and developing new standards for high temperature gas cooled reactors.

What is the current phase of the standards development process for this technology?

Given ASME's diverse areas of standards development, various technologies are at all phases of standards development, from exploratory research to publication. ASME has observed that standards development can be effectively initiated once technology has advanced beyond the proof of concept stage into demonstration and commercialization. Early identification of standards needs, establishment of sound technical bases, and engagement of stakeholders are keys to timely availability of technically relevant consensus standards.

How has the process worked so far?

ASME supports both ANSI's Essential Requirements and the World Trade Organization Technical Barriers to Trade Committee's Decision on the Principles for the Development of International Standards. Accordingly, it has found that the standards development process is most successful (i.e. incorporates the latest technological advances, meets industry's need for global relevance, and promotes innovation) when it is conducted in an open, transparent, and balanced manner, with due process afforded to all interested parties.

When developing standards, how are the standards-setting processes managed and coordinated?

ASME's standards development processes are typically accomplished jointly via volunteer leadership and technical input and staff management and coordination, in accordance with procedures accredited by the American National Standards Institute (ANSI). To maximize participation, committee business (such as development of drafts, commenting and official voting, and meetings) is accomplished via electronic means whenever possible. Any decision to meet in person (particularly at formative stages or when substantial discussion is needed to achieve consensus on a given issue) is typically left up to the individual committee.

ASME also administers U.S. Technical Advisory Groups (TAGs) to ISO Committees and ISO Secretariats. In such cases, ASME complies with the appropriate ISO Directives and will typically align the TAG as a subordinate group to an existing ASME committee.

Is there a strategic plan that identifies the standards needs and defines the standards development life cycle?

ASME's Board of Governors has established three strategic areas of focus, including energy, engineering workforce development, and global impact. Efforts are made to align with these strategic areas at all levels of the organization, including the Council on Standards and Certification, which establishes annual strategic objectives, targets, and measures. For example, in 2009 the Council established an Energy and Environmental Standards Advisory Board and tasked it with coordinating new standards development addressing global energy and environmental needs. As part of this responsibility, the advisory board has initiated a gap analysis and conducted significant market research. Likewise, each of ASME's supervisory boards (such as the Board on Nuclear Codes and Standards) may elect to develop a strategic plan that in part assesses needs for new standards in their areas.

When undertaking a new standard development activity, a draft scope (and table of contents) is typically distributed for review and comment (including via ANSI's Project Initiation Notice System) to ensure that it is filling a relevant need. A project schedule is generally submitted and maintained by the committee, outlining target deadlines for draft development and publication.

Once published, the majority of ASME's standards are considered to be "living documents". They are continuously maintained by an active committee, are open for further revision and, in most instances, open to official interpretation. Administering standards that are continuously open for revision and interpretation results in frequent, resource intensive inquiries; however, it is an effective way to be responsive to evolving industry needs by resolving practical problems arising from the application of standards and by evaluating the latest technological advances.

In order to ensure their continued relevance, standards not managed under continuous maintenance are subject to periodic reaffirmation by industry stakeholders at periods not exceeding five years.

Are there barriers to developing high level strategies for standard-setting activities?

There are several potential barriers to developing (and executing) high level strategies for standards-setting activities. These include:

- a lack of information/understanding of industry dynamics
- a lack of participation by all stakeholders
- uncertainty of policies set on local, federal, and international levels
- conflicting stakeholder objectives
- intellectual property concerns, particularly associated with emerging technologies
- perception that standards may stifle innovation

Perspectives on Government's Approach to Standards Activities

What methods of engagement are used by Federal agencies to participate in private sector-led standards development?

1. Direct Participation. Volunteers who participate on ASME Standards & Certification standards development committees – including those employed by Federal agencies - do so as individuals rather than as representatives of their employer. ASME recognizes the value of Federal agency participation and has developed several methods to facilitate their engagement in standards development activities. These include:

    - Standards Committee/Working Group Membership
    - Council on Standards and Certification and Supervisory Board Membership
    - Regulatory-Focused Committees
    - National Interest Review Groups
    - Guest Participation
    - ANSI Public Review

    Recognizing the benefits of participation by all materially affected parties, attempts are made to minimize financial and geographic barriers to participation; all phases of ASME's standards development process are managed online.

2. Incorporation of Regulatory Specific Requirements. In certain instances ASME will accommodate the unique needs of Federal agencies by incorporating specific provisions into an appendix. For example, the HST standards on the *Performance of Hoists* and the B40 standards on *Thermometers* include an appendix as the basis for satisfying the procurement needs of the Department of Defense. Incorporating these provisions eliminated the need for separate Federal standards and provides a vehicle to ensure continued harmonization with industry standards.

3. Convener. In the area of standardization of nuclear power plants, NIST and ANSI jointly established the Nuclear Energy Standards Coordination Collaborative, which is intended to bring together the various standards developers in the area, among which ASME plays a prominent role.

4. Funding of Expedited Process. By providing direct funding, Federal agencies can catalyze standards development without waiting for work to be fully completed by committee volunteers. This was the case in the development of ASME's Energy Assessment standards, which, due in part to funding from the Department of Energy's Industrial Technologies Program and staff participation from various DOE offices, were developed, approved by ANSI, and published in 24 months.

5. Funding Pre-Standardization Research and Development. In many instances, the creation of viable standards relies on technical data which is incomplete or altogether lacking. ASME Standards Technology LLC (ASME ST-LLC) provides a means for ASME to work with many partners – including Federal agencies – on R&D projects that support standards development and the commercialization of innovative technologies. ASME ST-LLC has developed flexibility to serve as either the primary contractor (such as with various cooperative agreements with the DOE and NRC on high temperature

gas cooled reactor (HTGR) advanced materials research) or as a subcontractor (such as cooperative agreements with the National Center for Manufacturing Sciences on non-destructive testing and evaluation methods, the National Energy Technology Laboratory (NETL) on the design of fuel cells, the National Renewable Energy Laboratory (NREL) for hydrogen infrastructure, and the Oak Ridge National Laboratory (ORNL) for fusion reactors). These mechanisms allow partners to serve at their desired level of participation.

How transparent is each method?

Regardless of the method of engagement, ASME aims to maximize transparency and ensure due process.

Prior to undertaking a standards activity, Information related to potential standards development is distributed through ANSI's Project Initiation Notification System and other media. All ASME consensus committees have publicly accessible web pages to facilitate the dissemination of information. Once under development, information on meetings, committee membership, and public review drafts are available online to the general public; documentation regarding draft development, such as meeting minutes, technical comments, and voting is maintained online and accessible to members.

How effective is each method?

Each method has proven effective; however, the method chosen depends on the specific industry and goals of the standardization effort. For mature technologies/industry sectors, direct participation is highly effective. For more innovative technologies and emerging industry sectors, funding models may be preferable in order to catalyze development (rather than relying on a volunteer-driven process). Direct funding for ASME project management services is rare, and special care is taken to preserve the integrity of the consensus process. Since ASME develops standards with the intent that they be internationally relevant, developing stand-alone criteria for a single stakeholder is a least preferred solution.

How could the methods be improved?

Regardless of the method of engagement, Federal agency participation is most effective when the agency:

- has a shared objective with industry
- supports the concept of private sector standards development
- engages early in the process
- provides sustained input
- provides sponsorship and support for technology basis development

Additionally, it is beneficial when Federal agencies approach standardization from a global perspective, rather than from a purely national one.

What other methods should the Federal agencies explore?

While regulated at a state rather than Federal level, a model that has been very successful for ASME is the standardization and regulation of boilers and pressure vessels. Within the framework of a committee comprising each state's Chief Inspector, all jurisdictions participate in developing the standards, and thereby develop both a broad understanding of the technical requirements as well as a sense of ownership. The result is a very coherent regulatory framework and adoption of the Boiler and Pressure Vessel Code in all 50 states. Additionally, the development and employment of accompanying conformity assessment programs has been a useful bridge between consensus-driven standardization and regulatory enforcement.

What impact have Federal agencies had on standards activities?

- In the area of pipelines, the U.S. Department of Transportation, jointly with industry representatives, approached ASME for the development of standards addressing urgent pipeline integrity needs. This effort culminated with the issuance of B31.8S, Managing the System Integrity of Gas Pipelines, in 2001. With active participation from individuals from the DOT's Pipeline Hazardous Material Safety Administration (PHMSA), ASME was able to develop a consensus standard in 9 months, which was subsequently adopted into regulations (49 CFR 192, Transportation of Natural and Other Gas by Pipeline: Minimum Federal Safety Standards). PHMSA also worked with ASME in the development of B31Q, Pipeline Personnel Certification, and Section XII of the ASME Boiler and Pressure Vessel Code, Rules for Construction and Continued Service of Transport Tanks.

- In the nuclear power industry, much like the U.S. Nuclear Regulatory Commission (NRC), ASME is focused on protecting public health and safety. ASME's involvement with the nuclear power industry dates back to 1963 when, in collaboration with the Atomic Energy Commission (the predecessor to the NRC), it developed a standard and conformity assessment program for pressure vessels used in nuclear power plants. The standard was based on ASME's Boiler and Pressure Vessel Code, which played a vital role in reducing the number of boiler explosions in the United States and abroad. ASME has continued to build its relationship with the Nuclear Regulatory Commission, with over 50 NRC staff members currently participating on ASME's many nuclear-focused standards and conformity assessment activities[3], including:

    - Rules for the Construction of Nuclear Facility Components
    - Rules for In-service Inspection of Nuclear Power Plant Components
    - Operations and Maintenance of Nuclear Power Plants
    - Qualification of Mechanical Equipment
    - Nuclear Quality Assurance
    - Nuclear Risk Management
    - Nuclear Air and Gas Treatment

[3] A full listing of NRC representatives on standards development committees may be found at http://www.nrc.gov/about-nrc/regulatory/standards-dev/sdo-comm.html

- Cranes for Nuclear Facilities
- Nuclear Certification[4]

While several of the above nuclear industry standards are heavily cited within federal regulations[5], collectively these standards serve the nuclear power industry – both within the U.S. and globally - by ensuring safety; establishing common criteria for designers, suppliers, operators, purchasers and regulators; responding to emerging issues and technology; and freeing up governmental resources.

- In the area of escalators, the U.S. Consumer Product Safety Commission collaborated with ASME's A17 Committee on Elevators and Escalators by assisting with the development of requirements for skirt panel gap deflection devices, in order to reduce incidents of entrapment.

- In the area of industrial energy efficiency, the U.S. Department of Energy's Office of Energy Efficiency and Renewable Energy (as part of its Superior Energy Performance initiative) requested that ASME develop a suite of standards governing the performance energy assessments of heating, pumping, steam, and compressor systems, and contributed funding towards ASME's management of an expedited standards development process.

- In the area of plumbing and water efficiency, the U.S. Environmental Protection Agency makes reference to ASME's various A112 plumbing standards in its *WaterSense* program.

- In the area of procurement, several Department of Defense MIL standards were the basis for standards intended for industry-at-large and subsequently withdrawn, thereby eliminating the potential for conflicting standards and reducing transactional costs. As an example, in the area of geometric dimensioning and tolerancing, MIL-STD-100, *Engineering Drawing Practices,* spawned Y14.24 -*Types and Applications of Engineering Drawings*; Y14.34 - *Parts, Lists, Data Lists, and Index Lists*; and Y14.35 - *Revision of Engineering and Related Documentation Practices.* Similar transitions from DoD MIL standards to industry standards have occurred with standards for fasteners, surface quality, cutting tools, hand tools, hoists, and gages.

- Other joint projects with Federal agencies have included workshops and other consultations, such as with the U.S. Coast Guard in the promulgation of 49 CFR; the Occupational Safety and Health Administration in the development of updated crane and derrick regulations; and the Bureau of Ocean Energy Management, Regulation and Enforcement in regulating the outer continental shelf.

Numerous national-level agencies of other countries have also recognized ASME standards and conformity assessment programs as a credible mechanisms for improving safety and facilitating trade, and have shown

[4] Includes nuclear vessels, pumps, valves, piping systems, storage tanks, core support structures, concrete containments, and transport packaging; field installation and shop assembly; fabrication for appurtenances and supports; and containment for spent fuel and radioactive waste

[5] Refer to http://www.nrc.gov/about-nrc/regulatory/standards-dev/concensus.html

an increased interest to partner with ASME (in part by referencing ASME standards in their domestic standards and regulations). Examples of foreign agencies that reference ASME standards include:

- China (Institute of Standardization for the Nuclear Industry; China Machinery Industry Federation; Shanghai Power Equipment Research Institute; Shanghai Nuclear Engineering Research & Design Institute; Ministry of Industry & Information Technology; Ministry of Science & Technology; National Nuclear Safety Administration; National Energy Administration; and the China State Nuclear Power Technology Corporation)

- Colombia (Ministry of Social Welfare)

- India (Bureau of Indian Standards; Oil Industry Safety Directorate; Ministry of Power, Central Electricity Authority; Atomic Energy Regulatory Board; and the Petroleum and Natural Gas Regulatory Board)

- South Africa (National Nuclear Regulator)

How well do Federal agencies coordinate their roles in standards activities in the sector of interest?

Coordination between Federal agencies has not been a major issue in mature technology areas; however, issues periodically arise due to a lack of coordination between state, federal and foreign agencies.

In emerging technology areas, such as new clean energy technologies, ASME has observed that multiple government agencies serve as key stakeholders and there is an opportunity to better coordinate and optimize the application of federal resources toward commercialization of these technologies. For example, ASME is aware of the Climate Change Technology Program, however, many partner agencies are not active in ASME standards development and may not fully understand the important role consensus standards can play in commercializing emerging technologies.

When Federal agencies have been involved in standards setting efforts in a technology sector, how has the progress of standards setting efforts in this technology sector changed after Federal agencies became involved?

In many instances, participation by Federal agencies in standards setting efforts is stimulated by adverse events that fall under their purview, specifically events dealing with safety and public welfare. Such events (whether a component or system failure, operational incident, or security issue) are typically also a concern of other industry stakeholders, and trigger both an increased awareness and a shared sense of urgency. In general, ASME has not observed any negative impacts on the progress of standards development when federal agencies become involved, provided they have a shared vision with other industry stakeholders.

Are Federal agencies generally receptive to input from other participants in standards-setting activities?

Yes, however, occasionally a regulator (state or federal) will look at issues solely from the perspective of jurisdictional enforceability, rather than as drivers for improvements in safety, technology, performance, or global relevance.

Does receptiveness tend to depend on whether the Federal agency is a regulator or a customer?

There are some differences in receptiveness depending on whether an agency is a regulator or a customer.

For example, Federal OSHA displayed a reluctance to fully cooperate within the framework of ASME's B30 *Standards on Cranes and Related Equipment* during its recent Cranes and Derricks Negotiated Rulemaking process, since the B30 standards include recommendations in addition to requirements. OSHA was singularly focused on promulgating enforceable requirements, and therefore chose to work outside the existing process and establish its own rulemaking committee. This created the potential for duplication of effort and the promulgation of conflicting information.

On the other hand, regulators such as the NRC, USCG and PHMSA, and non-regulatory agencies, such as DOE and NASA, have a long track record of being receptive to input from others and working within the established standards frameworks.

In those sectors where Federal agencies play a significant role in standards activities, how valuable and timely is the work product associated with this effort?

From ASME's perspective, all of its work products are valuable and timely, whether or not a Federal agency plays a significant role; however, ASME believes a given work product can only benefit when all stakeholder interests are represented and directly involved in its development.

The value of a standard can be measured by its use and continued relevance; ASME conducts regular reviews of its standards to ensure that they are still considered relevant by industry and governmental stakeholders.

The timeliness of a standard depends on the nature of the issues involved and the willingness of stakeholders to participate in the process.

Issues Considered During the Standards Setting Process

Has Federal agency participation in standards-setting impacted the consideration and resolution of these issues, and the standards setting processes?

In many areas, such as the regulation of pipelines, pressure equipment, and nuclear power plant components, Federal agency participation is vital and ASME has a long history of working in tandem with the public and private sectors. However, in some instances, the focus of a regulatory authority – whether on a local or federal level – is limited to obtaining outcomes beneficial for their specific jurisdiction rather than the greater global community. In such instances, there is the potential for a public sector stakeholder to feel as though their concerns are superordinate to other stakeholders.

Are efforts made to determine whether there is potential for overlap or duplication with existing international standards?

Yes. Like many US-domiciled standards developers, many of ASME's standards - developed via a consensus process compliant with WTO TBT provisions - are internationally relevant (and therefore do not need to be transferred to ISO to become "international"). In sectors where there is a significant potential for overlap with other consensus standards, ASME is active in ISO and other standards developing organizations around the world to minimize duplication and facilitate coherence.

Domestically, ANSI attempts to avoid duplication through its Project Initiation Notification System (PINS) tools and through formation of standards panels.

ASME has also observed some efforts at voluntary coordination by Federal agencies, most notably in Hydrogen & Fuel Cells (DOE EERE/NREL), Nuclear Codes and Standards (DOE/NIST), Smart Grid (NIST), and Nanotechnology (NIST).

How are other appropriate international standards that may be of interest identified?

Environmental scanning is performed by volunteers and staff, either prior to or during the course of standards development. In instances where potential overlap is detected, committees may elect to establish a formal liaison and periodically report on the activities of the other standards developing organization, or consider other means for coordination (such as joint standards development).

Are efforts made to identify existing or planned regional or national standards that may be considered for use as the basis for foreign technical regulations, rather than the international standard being considered by the committee?

ASME attempts to identify the existing body of knowledge, including regional or national standards, prior to initiating/revising a standard. While a systematic approach has not been established, in many instances, overlapping specifications being developed elsewhere are discussed.

Ultimately, ASME supports industries having the ability to select standards that they believe will best serve their needs, irrespective of its source, provided they are developed in a manner compliant with the WTO's Principles for the Development of International Standards.

How does the need for access to intellectual property rights by Federal agencies factor into the use or development of standards?

Because ASME standards development activities are open, holders of intellectual property are sometimes reluctant to introduce information and data that potentially affords them a competitive advantage, creating a barrier to early initiation of standards actions. In such instances, they may elect to pursue a performance-based approach (such as with standards dealing with reliability) which does not reveal data that could be used to gain a competitive advantage. Alternatively, they may make a business decision which leads them to conclude that establishing an industry standard is preferable to retaining proprietary information.

ASME policy stipulates that patented items should not be referenced explicitly in ASME codes and standards and that whenever possible, requirements of codes and standards be written in performance language in order to enable the use of applicable patented products, materials, etc. When it is necessary to use a patented item in order to conform to a standard, ASME defers to ANSI's patent policy.

It is also important to address the intellectual property rights of the standards developing organizations. While industry-driven standards development relies heavily on the expertise and work of volunteers, costs for development, coordination, and administrative and technical support are frequently born by the standards development organizations (SDOs) themselves. Many SDOs recoup these costs through revenue generated from the copyright-protected sales and licensing of the standards. By funding operations through the sale of standards, rather than through membership, participation fees, or sponsorship, SDOs can minimize barriers to qualified participation and maximize independence from entities seeking to influence the outcome for commercial or political reasons. Under this model, the actual recouped costs through standards sales is but a fraction of what the total production costs would have been if the developers were not volunteers.

Hence, in order to ensure the continued success of the public-private standardization partnership within the U.S., it is imperative that the Federal government continue to support policies established by OMB Circular A-119 by incorporating the usage of privately developed standards within regulatory and other activities and by respecting and protecting the intellectual property of copyrighted works issued by SDOs.

To what extent, if any, has the development, adoption or use of a standard, by Federal agencies in this technology sector been affected by holders of intellectual property?

N/A.

How have such circumstances been addressed?

N/A.

Are there particular obstacles that either prevent intellectual property owners from obtaining reasonable returns or cause intellectual property owners to make IP available on terms resulting in unreasonable returns when their IP is included in the standard?

N/A.

What strategies have been effective in mitigating risks, if any, associated with hold-up or buyers' cartels?

N/A.

Adequacy of Resources

What resources are needed to successfully complete the efforts?

Like other stakeholders, Federal agencies who participate in a standards development activity need to allocate sufficient time, expertise and (in many cases) travel expenses.

Taking into account budget constraints and competing initiatives, have Federal agencies committed adequate resources?

With over 250 representatives from Federal agencies, ASME is pleased with the participation of Federal agencies in its standards development activities and would welcome increased participation.

What resource constraints impact the successful completion of the standards efforts?

ASME has an excellent track record at successfully completing its standards development objectives. However, occasionally, for reasons such as uncertainty in Federal policy, its standards do not attain the envisioned market relevance. QMO-1, *Qualification and Certification of Medical Waste Incinerator Operators* and QHO-1, *Qualification of Hazardous Waste Incinerator Operators*, for example, were initiated in collaboration with the EPA in the early 1990's in anticipation of amendments to the Clean Air Act. However, as enforcement of operator qualifications was not incorporated into regulation, the standards never achieved commercial acceptance.

In order for a Federal agency to maximize the value of private sector standards development, the standard must be incorporated into the appropriate regulation in a timely manner. In many instances, the regulatory adoption process used by many agencies is not able to keep pace with the rate of change of industry-driven consensus standards. A more timely review and adoption process would help ensure that Federal agencies – and stakeholders – receive maximum value from standards activities.

Process Review and Improvement Metrics

What lessons about standards development in complex technologies have been learned so far?

A key lesson in dealing with diverse and complex technologies is to be cognizant that there is no universally applicable approach to standards development. Additionally, in order to ensure market relevance, all stakeholders should be engaged early within the process and have a shared vision as to the scope of the standards activity. Finally, the traditional approach to standardization has included writing prescriptive standards only after technology is fully established and after commercialization has been completed. It has been observed in recent years that the lack of standards in a particular area can actually create a barrier to commercialization. If standards development can be more anticipatory, then useful rules governing the application of technology become available as soon as they are needed.

How have these lessons learned been implemented?

ASME has developed procedures and processes that maximize stakeholder participation, ensure responsiveness to stakeholders needs, and optimize the use of resources. Additionally, ASME has incorporated market research (to investigate the envisioned market relevance of a given standard) and pre-standardization technical analysis (to support standardization criteria) as part of its standards activities. Lastly, ASME has focused efforts to anticipate standards-related training needs to facilitate the practical application of a given standard.

Have there been any impediments to implementing these lessons?

ASME has not encountered any insurmountable impediments in pursuing its standards development objectives.

How has this information been documented or disseminated, and implemented?

ASME has developed online training modules for volunteers which cover the administrative, procedural and legal aspects of standards development. Additionally, strategic and operational objectives established by its Council on Standards and Certification are cascaded to individual boards, committees and subordinate groups. Lastly, a checklist has been developed to assist with the collection of information and the evaluation of potential standards development opportunities.

What kinds of performance metrics are appropriate to measure the effectiveness of the standards-setting process?

While time-to-market is a key metric, once published, ASME's primary metric for measuring the effectiveness of the standards-setting process is market relevance. Indicators of market relevance include sales; committee membership and meeting attendance; proposed revisions; requests for interpretation and training; use within global markets; and use within regulatory frameworks.

If any such performance metrics have been used, what are the results?

ASME's standards are used in over 100 countries worldwide, with sustained growth in international conformity assessment services; there are 563 references to ASME standards in the U.S. Code of Federal Regulations.[6]

[6] http://standards.gov/sibr/query/index.cfm

Recommendations

1. Policy makers should be aware that the dynamics impacting innovation and standards development vary by industry sector. ASME recognizes the value of having a coordinated national strategy (such as the US National Standards Strategy) in order to maximize benefits to stakeholders and citizens alike. However, factors such as the availability and maturity of technology, workforce competencies, competitive advantages, and evolving political and economic landscapes (at both the domestic and global level) will ultimately impact strategies for innovation and standardization. Hence, while theoretically appealing, a "one size fits all" approach to standards development is not feasible in practice.

2. Clearly defined protocols for determining when the Federal government should assume the role of convener of private sector standards development should be established. Such protocols will assist industry and standards developers with strategic and operational management.

3. Federal agencies should continue to support the National Technology Transfer and Advancement Act and OMB-A119. Agencies should be encouraged to directly participate in voluntary standards and conformity assessment committees and should take measures to ensure that regulations reference the most recent edition of voluntarily developed consensus standards.

4. Federal agencies should have a long-term strategy for participation in standards development activities. The most effective standards development occurs when there is a shared vision and early and sustained engagement of all stakeholders. Late stage or inconsistent engagement by materially affected stakeholders typically delays development and results in additional costs. Many standards developers have taken measures to facilitate governmental participation while minimizing inherent costs to participate.

5. Federal agencies should support private sector standards developers that meet the WTO TBT Committee Decision on the Principles for the Development of Internationals Standards. Supporting such standards developers will ensure that concerns raised by Federal agencies receive due process. Supporting standards that are promulgated in order to establish monopolistic or competitive advantages goes against the spirit of the WTO Principles.

6. Federal agencies and regulatory authorities should recognize the benefits of standardization beyond their jurisdictional mandates. Agencies should recognize multiple objectives of consensus standards development, including the protection of public health and welfare, trade facilitation, and innovation. The promulgation of inconsistent standards and regulations – whether on a local, federal or global level – not only drives up transactional costs, but also creates the potential for barriers to trade and retaliation by trade partners. The use of performance based standards, whenever possible, is encouraged.

7. Federal agencies should recognize the important role of consensus standards in the commercialization of new technologies. The adoption of technically relevant consensus standards helps overcome barriers to commercialization by establishing public confidence, permitting rapid and transportable workforce

development, removing impediments to business, and enabling global trade. Key to anticipatory standards development is the availability of a sound technical basis. National Laboratories should coordinate with standards developing organizations to help ensure that research programs are relevant to the anticipated new standards. Standards committees could then help steer the direction of research and development programs toward priority areas that can make the largest and most immediate impact, and research results could more likely to be utilized and adopted to expedite standards development.

Appendix I – Membership Classification for ASME Standards Development Committees

(Excerpted from Procedures for ASME Codes and Standards Rev. 14 Development Committees August, 2010)

3.2.5 Classification of Members. In order to establish balanced representation for developing evidence of consensus on standards, consensus committee members shall be classified in accordance with the business interests of their primary source of support for committee participation. Alternates shall not be counted in determining the balance of the consensus committee. The classification system and the classifications assigned to members shall be proposed by the consensus committee, shall be subject to approval by the cognizant board, and shall be included in the supplement to the procedures. Not more than one-third of the membership of consensus committees dealing with safety codes and standards shall come from any single category without the recorded approval of the other classifications and the approval of the cognizant board.

No single category shall have a majority on consensus committees dealing with product standards except with the recorded approval of the other classifications and the approval of the cognizant board.

If a member's classification changes because of a change in employment or another reason, action shall be taken by the consensus committee to:

(a) reaffirm the member to complete the present term, or
(b) reappoint the member for a full term, or
(c) terminate the membership

The effects of the member's changed classification on the balance of interest for the consensus committee shall be considered.

(Excerpted from "Guide to Procedures for ASME Codes and Standards Development Committees" Rev. 9, November, 2010)

Membership Classification There are two generally accepted membership classification systems.

(a) The members on standards committees dealing with safety codes and standards are generally classified in accordance with their major interests from among the following categories.

1) Manufacturers of the product, product component, or material

2) Purchasers or owners of the product

3) Employees affected by the safety code or standard

4) Governmental bodies having regulatory power or influence over the field in question

5) Specialists having expert knowledge

6) Designers

7) General interests

8) Insurance interests

9) Installers and erectors

10) Utilities

11) Independent distributors and retailers

12) Consumer interests

13) Labor

(b) The members on standards committees dealing with product standards are generally classified from among the following categories:

1) Producer or manufacturer interests

2) Distributor and retailer interests

3) Consumer or user interests

4) Federal, state or local government

5) General interest

Other classification systems which appropriately classify interested parties may be used.

Appendix II – Dominion Case Study on Utilization of ASME Standards

One Code to Save Millions: ASME codes and standards guide Dominion in efficiency, cost savings and safety

Efficiency, production costs and safety are priorities for any business, with many following specific guidelines to help increase overall production. In engineering, these guidelines are communicated in the form of codes and standards, which are developed to support consistency of production and operations, while helping to prevent accidents, thus saving companies millions of dollars. ASME (the American Society of Mechanical Engineers) has developed codes, standards and conformity assessment programs for over 125 years to guide engineers and regulators in creating more efficient and safer production and work environments. One code in particular, the ASME Boiler and Pressure Vessel (BPV) Code, is often utilized at nuclear power plants and contributes to safer, cleaner and more profitable energy production. By following the ASME BPV Code, many companies, including Dominion Resources, have saved millions of dollars by enhancing safety protocols and keeping their equipment running at high efficiencies.

Overview

Dominion is one of the nation's largest producers and transporters of energy, with a portfolio of more than 27,500 megawatts of generation, 12,000 miles of natural gas transmission, gathering and storage pipeline and 6,000 miles of electric transmission lines. Dominion operates the nation's largest natural gas storage system with 942 billion cubic feet of storage capacity and serves retail energy customers in 12 states.

Dominion‘s resources include gas and electric facilities, wind farms, fossil-fueled power stations, hydro power stations and nuclear power plants. Nuclear energy is the core of Dominion’s business, with four plants in Virginia, one in Wisconsin, and two in Connecticut. For Dominion, it is a top priority to run at the highest of efficiencies and operate with the most current production and safety procedures available.

The Challenge

As an energy provider and distributor, Dominion has a unique set of challenges concerning safety and efficiencies. New technologies and programs, including Risk Informed Inservice Inspection (ISI) and updated weld overlay applications, that contribute to overall plant efficiency and the output of energy production are being introduced into the industry at a rapid pace, making it a challenge for some energy providers to stay current on their own. This is another area where the ASME codes and standards become an important resource. Codes and standards help engineers by providing accurate, reliable, and leading edge guidelines for the design, manufacture, inspection, testing, operation, maintenance, and certification of a myriad of power plant equipment. In many cases, the resulting codes and standards are the basis for regulatory enforcement.

Keeping up with new technology isn’t the only challenge for an energy provider. The mix of old and new equipment creates logistical issues for any manager concerned with equipment efficiency and regulatory compliance. Each piece of equipment requires specific efficiency and safety tests scheduled at particular intervals, depending on age and model. With over 3,000 items that need to be tracked and tested at each of Dominion’s plants, this can become overwhelming.

The Solution

In order to stay on track with technology and provide the safest and most efficient working environment at their nuclear power plants, Dominion follows the codes and standards developed by ASME. ASME has been developing codes and standards for over 125 years; the mission of its Standards & Certification organization is "to develop the preeminent, universally applicable codes, standards, conformity assessment programs, and related products and services for the benefit of humanity." These codes and standards have a significant impact on the industry and save companies millions of dollars per year as well as assist in accident prevention and the development of more efficient production and operational practices. Key technical staff from Dominion are among the over 4,000 volunteers from around the world who contribute to this important effort.

To help interpret and apply the codes and standards and keep the company updated on any changes, Dominion supports the Code by sending several employees to the quarterly meeting. One of these employees is Viki Armentrout, an engineer at the corporate office in Richmond, Virginia. Viki is the Chair of the Task Group Alloy 600, Secretary of the Working Group on Inspections of Systems and Components, and member of Subgroup Industry Experience for New Plants (BPV III/XI), Subgroup Water Cooled Systems, and Subcommittee XI.

One of the codes that Armentrout focuses on is Section XI of the ASME BPV Code, In-service Inspection of Nuclear Power Plant Components. This section of the code includes rules for repairs, replacement of equipment, activities for evaluations and in-service inspection requirements. Implementation of this code alone has saved Dominion tens of millions of dollars in avoiding unwanted repairs, time delays, outages, and lost revenue.

For example, every ten years Dominion saves $2.6 million from a nuclear safety innovation called Risk-Informed ISI that was generated for the code specific to piping welds. Section XI has changed the way inspections are performed on piping welds, making the process more efficient and less time consuming. This has not only saved Dominion millions of dollars, but has enhanced productivity and safety throughout the nuclear industry.

In addition to establishing rules and guidelines, many of ASME's codes and standards are under continuous review, which facilitates the incorporation of technical revisions based on advances in technology and changes in the industry. "ASME codes are designed to allow engineers to evaluate new concepts, new techniques and new ways to do things through code cases," says Armentrout. "They are living documents."

Code cases provide a particularly expeditious means of addressing new technologies, materials, and processes and allow ASME to make amendments to the code without changing the code itself. This process enables engineers to keep current with new technologies and to develop new techniques without being limited by prescriptive code requirements. Without the flexibility of code cases, the industry would fall behind, and use of new techniques as well as possible safety issues would take longer to address.

Nuclear Code Cases N-498 and N-416-1 and their revisions for example, helped to eliminate the practice of hydrostatic testing when it was discovered that the value of this test was no better than a leakage test conducted at normal operating pressure and temperature. These BPV Section XI code cases have created at least $10 million in savings for Dominion.

Dominion has seen significant cost savings, increased efficiencies and improved safety measures through its use of the ASME BPV code. By following these requirements and guidelines, Dominion is able to help keep their employees safe and provide a more efficient work environment.

Through their codes and standards, ASME has increased the quality of life and safety for millions of people around the world. Celebrating 125 years of codes and standards, ASME now has over 4,000 volunteers who create and oversee the development of more than 500 codes and standards, which are in use in over 100 countries around the world. Public safety is a top priority for ASME and, through the development of codes and standards, a reality worldwide.