STANDARDS & CERTIFICATION

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To: The U.S. Office of Management and Budget (OMB)

Subject: Request for Information on OMB Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (77 FR 19357-19360, March 30, 2012)

The American Society of Mechanical Engineers (ASME) submits this response to the Office of Management and Budget (OMB) request for information published in the Federal Register on March 30, 2012 (77 FR 19357). The information is being sought to inform OMB on whether and how to supplement Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.

Founded in 1880, ASME is a not-for-profit scientific, educational, and technical organization for mechanical engineers, with over 125,000 individual members worldwide. It has no corporate members. ASME serves several important functions, one of which is the development and maintenance of over 500 voluntary consensus standards, used in over 100 countries around the world, associated with the art, science, and practice of mechanical engineering. These include standards for complex machinery such as boilers, pressure vessels, elevators, and escalators and items as ubiquitous as nuts, bolts, and plumbing fixtures. These standards reduce the costs of goods and services; enhance safety, health, and quality of life; and facilitate innovation, trade, and competitiveness while substantially reducing the costs of government by providing a consistent and technically sound basis for regulation.

ASME also provides conformity assessment services to over 6,500 manufacturers in 75 countries in the areas of boiler, pressure vessel, and nuclear power component certification.

The current purpose and goals established by OMB Circular A-119, which permits a flexible approach to the incorporation of standards into regulation by reference, are still relevant and essential to a Federal agency's ability to use the materials that best serve their mission and the public. Following are ASME's responses to the specific questions raised in the notice.

AGENCY IMPLEMENTATION OF CIRCULAR A-119 IN RULEMAKINGS.

Are Federal agencies generally following the guidance set out in the Circular and providing an adequate explanation of how they considered standards and conformity assessment -related issues in the preambles to rulemakings?

Federal agencies considering the incorporation of ASME standards are generally following the guidance set out in Circular A-119 ("the Circular").

STANDARDIZATION ACTIVITIES.

What factors should agencies use in evaluating whether to use voluntary non-consensus standards in regulation, procurement solicitations, or other non-regulatory uses? OMB also invites comments on the respective roles of voluntary consensus standards vs. voluntary non-consensus standards for agency responsibilities in rulemaking, procurement, and other activities.

Agencies should continue to use Para. 6(f) of the Circular with respect to both consensus and non-consensus standards. Other considerations may include: the state of acceptance within industry as a best practice; the openness/inclusiveness of the underlying standards development process (including the agency's ability to participate); the diversity of stakeholders impacted by the standard (class of persons affected/regulated entities); the responsiveness of the standard to advancements in technology and evolving industry needs; the need for harmonization with global markets; and appropriate compliance with principles established by the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement.[1]

CONFORMITY ASSESSMENT.

In conjunction with NIST's efforts to update its conformity assessment guidance, should a supplement to Circular A-119 be issued to set out relevant principles on conformity assessment? If so, what issues should be addressed in such a supplement? The following are among the topics that could be considered:

- **factors agencies should use in selecting the appropriate conformity assessment procedure, including product/sector specific issues and the level of risk of non-fulfillment of legitimate regulatory, procurement , or other mission-related objectives;**
- **guidance for regulatory agencies on compliance with relevant international obligations pertaining to conformity assessment and accreditation activities;**
- **factors agencies should consider in determining whether to recognize the results of conformity assessment and accreditation activities conducted by private sector bodies in support of regulation;**
- **non-regulatory uses of standards (including vendor conformity for purposes of response to procurement solicitations); and**
- **ensuring that agencies consider how to minimize conformity assessment costs and delays for businesses, especially small and medium sized enterprises, subject to statutory and budgetary constraints and the ability of agencies to fulfill their legitimate regulatory, procurement, or other mission-related objectives.**

15 CFR Part 287 adequately addresses Federal agency use of conformity assessment. The need for conformity assessment activities and the level of conformity assessment (first, second, or third party), and the need for accreditation of such activities, should be determined on a sector-by-sector basis.

In many instances, standards and conformity assessment programs gain relevance not through regulatory mandate, but through market acceptance based on their demonstrated ability to provide value. For example, over 100 nations recognize ASME standards and conformity assessment programs in the areas of boiler, pressure vessel, and nuclear power component certification. This is made possible not only by the relevant agency's understanding that ASME standards comply with the WTO TBT principles, but also

[1] World Trade Organization, Agreement on Technical Barriers to Trade (G/TBT/1/Rev.9) *Decision Of The Committee On Principles For The Development Of International Standards, Guides And Recommendations With Relation To Articles 2, 5 And Annex 3 Of The Agreement* (Sept. 8, 2008) http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

through market acceptance via a long track record of being an effective means of enhancing the protection of life and property and establishing trust between producers and purchasers.

Any guidance or best practices should continue to afford Federal agencies, and the general public, the flexibility to benefit from a variety of conformity assessment programs.

PROTECTION OF COPYRIGHT ASSOCIATED WITH STANDARDS.

Is lack of access to standards incorporated by reference in regulation an issue for commenters responding to a request for public comment in rulemaking or for stakeholders that require access to such standards? Please provide specific examples.

The issue of accessibility (and availability) is separate from the issue of cost. However, in terms of both available channels and costs, access to standards by materially affected stakeholders has not been an issue.

ASME publishes its standards for reference and use by any interested entity in a wide variety of channels and formats. For example, ASME provides information about all its standards on its Internet website at www.asme.org, employs the services of numerous resellers, and offers an annual catalog of its publications. Recognizing that some of its standards are voluminous and that many users do not need them in their entirety, ASME offers copies of separate, specialized volumes for sale individually.

While ASME provides physical copies of its standards to agencies for reference and public inspection, it also has worked to provide broadened access. For example, during a recent U.S. Department of Transportation (DOT) rulemaking that involved the proposed incorporation of an ASME standard on transport tanks (ASME Boiler and Pressure Vessel Code, Section XII), a trade association expressed concerns to the DOT and ASME about its members not having access to the standard, which impeded their ability to evaluate the rulemaking. In this instance, ASME worked with the DOT to provide commenters online access to the standard for the duration of the rulemaking.

What are the best practices for providing access to standards incorporated by reference in regulation during rulemaking and during the effective period of the regulation while respecting the copyright associated with the standard?

Standards should be accessible during rulemaking as well as during the effective period of the regulation; however, due to the many differences in industry sectors, technologies, and underlying standards, ASME supports a flexible approach, where appropriate access is determined on a case-by-case basis by the responsible agency, in consultation with copyright holders and materially affected stakeholders.

Any best practices should reinforce that the issue of accessibility (and reasonable availability) is separate from the issue of cost. As stated by the National Science and Technology Council,[2] and subsequently acknowledged by the Administrative Conference of the United States (ACUS),[3] "…the text of standards and associated documents should be available to all interested parties on a reasonable basis, which may include monetary compensation where appropriate."

[2] Subcommittee on Standards, National Science and Technology Council, Executive Office of the President, *Federal Engagement in Standards Activities to Address National Priorities: Background and Proposed Recommendations 11* (Oct. 10, 2011).

[3] Administrative Conference Recommendation 2011-5 *Incorporation by Reference* (Dec. 8, 2011)

What are the best practices for incorporating standards by reference in regulation while respecting the copyright associated with the standard?

Agencies should continue to comply with Para. 6(j) of the Circular, which requires agencies to "observe and protect the rights of the copyright holder." Further, as noted in the ACUS recommendations, "Agencies should ensure that incorporations by reference support, rather than detract from, the usefulness and readability of the Code of Federal Regulations. Incorporated material may provide detail, but a regulation should, by itself, make the basic concept of the rule understandable without the need for the reader to refer to the incorporated material."

ASME encourages referencing of its standards as one means of demonstrating compliance with the safety objectives of the regulations; and not the only means. In many instances, the regulator or enforcement body would have a mechanism for accepting an alternative standard, specification, or methodology. While the referenced standard would carry a presumption of conformity, the regulation should still provide the overriding safety and technical objectives such that the reader would understand the basic concept of the rule and in order to facilitate use of potential alternative means of demonstrating compliance.

VOLUNTARY CONSENSUS STANDARDS AND COST-BENEFIT ANALYSIS.

What resource and other costs are involved in the development and revision of voluntary standards?

Standards development resource costs include: staff support (including responding to technical inquiries); research and development in support of technical criteria; meeting logistics and travel; process management (including programming, IT support, and auditing); editing; publishing; marketing; outreach; and indirect costs associated with operating a not-for-profit business. Other costs incurred include recruiting, training, and retaining balanced groups of subject matter experts from industry, government, and academia to serve on standards committees and corresponding governance groups.

These cost factors should not be considered by agencies when determining whether the use of a voluntary standard is practical for regulatory or other mission purposes. Agency decisions should be based primarily on technical relevance and safety concerns.

What economic and other factors should agencies take into consideration when determining that the use of a voluntary standard is practical for regulatory or other mission purposes?

Economic and other factors agencies should consider when determining that the use of a voluntary standard is practical for regulatory or other mission purposes include: whether the standard is consistent with the needs of their mission; the relevance of the standard to industry, including the frequency with which it is updated; the cost of developing and updating an alternative governmental standard (including costs associated with increasing the burdens on industry by establishing a potentially conflicting standard); the class of persons affected by the standard; and whether the standard was developed without undue commercial or political interests.

How often do standards-developing bodies review and subsequently update standards?

In order to maintain technical and market relevance, ASME's standards are typically revised or reaffirmed no less frequently than every five years. Many standards – including those incorporated by reference into regulations - are under continuous maintenance with new editions issued every two to three years. In addition, ASME continuously responds to technical inquiries relating to the practical application of its standards and issues formal interpretations to many of its standards as needed.

If standards are already incorporated by reference in regulations, do such bodies have mechanisms in place for alerting the relevant agencies and the public, especially in regard to the significance of the changes in the standards?

Pending revisions to ASME's standards are available for public review and published on a comprehensive ASME website, on the developing committee's webpage, and in ANSI Standards Action, a weekly electronic newsletter. Final approval notifications of updated standards are also announced on ASME's website and in ANSI Standards Action. ASME publishes a free quarterly electronic newsletter, *S&C Update*, which provides information regarding new activities and in-progress publications. ASME also has assigned staff to each of its standards, who are available to address general inquiries.

In addition, ASME has established mechanisms to ensure understanding of the scope and magnitude of changes within its standards, specific to the varying needs of industry sectors and agencies. Examples include the establishment of the Boiler and Pressure Vessel Code Conference Committee, the B30 (Cranes) Regulatory Authority Council, the A17 (Elevators & Escalators) Regulatory Advisory Council, the A112 (Plumbing) Regulatory Authority Committee, and the BPV Section III (Nuclear Components) Special Working Group on Regulatory Interface.

ASME provides consultation with agencies in the process of considering the incorporation of standards by reference upon request, however, the most effective mechanism for alerting relevant agencies to changes in ASME's standards is via direct participation by representatives from relevant agencies in the standards development process; some 250 individuals from Federal agencies serve on ASME's standards development committees.

USING AND UPDATING STANDARDS IN REGULATION.

Should OMB set out best practices on how to reference/incorporate standards (or the relevant parts) in regulation?

The current guidance established by the Circular, which permits a flexible approach to the incorporation of standards into regulation by reference, is still relevant. Agencies should be able to utilize those standards that best meet its objectives and needs. Any best practices should continue to respect the copyrights of standards developing organizations and continue to afford Federal agencies, and the general public, the flexibility to benefit from a variety of private sector standards.

Are there instances where incorporating a standard or part thereof into a regulation is preferable to referencing a standard in regulation (or vice versa)?

There may be instances where incorporating a standard or part thereof directly into a regulation, rather than by reference, is preferable. For example, it may be impractical for a regulatory authority to incorporate a voluntary standard by reference that includes recommended practices in addition to enforceable requirements (i.e. a regulatory authority may need to avoid making recommended practices mandatory). Additionally, the scope of a standard may not be fully compatible with the relevant regulation, and hence may not be relevant in its entirety. In some instances, a viable solution has been to reference specific sections, chapters, or subsections of standards. However, as various provisions within standards are interdependent, standards generally should be considered in their entirety and do not lend themselves to partial incorporation.

In summary, agencies should continue to be encouraged to incorporate standards by reference and to take exceptions or make additions as needed rather than incorporating all or part of the text of a standard into a regulation. However, there are cases where this is not the best approach.

Should an OMB supplement to the Circular set out best practices for updating standards referenced in regulation as standards are revised?

Federal agencies may benefit from best practices for updating standards referenced in regulation as standards are revised. In general, the latest edition of a standard will incorporate the best available practices.

Do agencies consult sufficiently with private sector standards bodies when considering the update of regulations that incorporate voluntary standards, especially when such standards may be updated on a regular basis?

It is ASME's observation that agencies vary in their capacity to update regulations that incorporate voluntary standards. Guidance consistent with ACUS recommendations 6-11[4] may help level the capacity of various agencies.

USE OF MORE THAN ONE STANDARD OR CONFORMITY ASSESSMENT PROCEDURE IN A REGULATION OR PROCUREMENT SOLICITATION.

Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions?

Allowing the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions will provide flexibility to those impacted by regulations, including producers, suppliers, and users. However, agencies should be aware that acceptance of alternative standards should be based on technical relevance and may necessitate supplemental regulatory requirements in order to establish equivalency.

Where an agency is requested by stakeholders to consider allowing the demonstration of conformity to another country's standard or the use of an alternate conformity assessment procedure as adequate to fulfilling U.S. requirements, should OMB provide guidance to agencies on how to consider such requests?

Standards and conformity assessment systems used in other countries or regions may not have the same basis as those in the U.S. For example, the European New Approach Directives are developed primarily to regulate the movement of goods throughout the European Union. In the case of the European Commission's Pressure Equipment Directive, the requirements for the safety of the covered equipment are overlaid on that fundamental principle, whereas in the U.S., pressure equipment regulations consider the safety of the equipment as the foremost concern. Therefore, consideration of another country's or region's standards and conformity assessment procedures must entail a rigorous analysis of the business and regulatory environment in which they were developed; their intended goals; and the legal infrastructure that supports enforcement of compliance with those programs.

[4] Administrative Conference Recommendation 2011-5 *Incorporation by Reference* (Dec. 8, 2011)

Any guidance provided by OMB to agencies on how to consider such requests should include a requirement to ensure technical relevance, which may necessitate supplemental regulatory requirements in order to establish equivalency; consideration of the agency's ability to participate in the development of the standards they adopt; an understanding that acceptance of products designed and used in accordance with another country's or region's standards or conformity assessment procedures will enhance that country's or region's access to the U.S. market; and a requirement to ensure reciprocal market acceptance of products designed and used in accordance with standards or conformity assessment procedures accepted within the U.S.

OTHER DEVELOPMENTS.

Have there been any developments internationally -- including but not limited to U.S. regulatory cooperation initiatives -- since the publication of Circular A-119 that OMB should take into account in developing a possible supplement to the Circular?

A general global desire to harmonize standards has been observed and there is a growing demand, particularly in emerging technology areas, for globally relevant standards.

There remains a perception that standards must be developed under the auspices of ISO or IEC to become adoptable internationally. U.S. agencies must keep in mind that ISO and IEC standards provide good solutions in some cases, but not so in many others. Further, the "one country, one vote" delegate process utilized by ISO and IEC creates the potential for de facto regional voting blocs (e.g., the European Union, which has a centralized monetary currency, a single free market, and a centralized standards system - but still retains 27 individual votes in ISO and IEC). Such voting blocs may put countries that are most materially affected at a disadvantage and impede access to global markets. Additionally, such systems create the opportunity for multi-national companies to disproportionately influence the development of a given standard by providing representatives to more than one country's voting committee.

Providing preference to standards that adhere to the WTO TBT *Principles for the Development of International Standards* ensures that the best standards solutions are available to U.S. agencies, including international standards developed by U.S.-based standards development organizations (SDOs). OMB guidance may be helpful to explain the multiple paths and processes for standardization and to underscore/incorporate the WTO TBT principles with respect to international standardization.

Does the significant role played by consortia today in standards development in some technology areas have any bearing on (or specific implications for) Federal participation?

Federal agencies charged with regulatory oversight should have an understanding of the various principles under which both consensus and non-consensus standards are developed, including the agency's ability to participate in the standards development process.

Are there other issues not set out above that OMB might usefully seek to address in a supplement?

As previously noted, SDOs incur substantial costs in order to develop standards that are technically sound and commercially relevant. One question that was not asked is, "Who should ultimately bear the costs of standards development?"

The first goal cited in support of the Federal policy endorsing voluntary consensus standards within the Circular is to "eliminate the cost to the Government of developing its own standards[.]" The scenario of the Federal government assuming responsibility for the development and update of tens of thousands of

standards each year is neither practical nor desirable. Further, proposals calling for Federal agencies that incorporate standards to bear the cost of making them available to the public for free will impose additional – and substantial - costs on U.S. taxpayers.

While some trade associations, consortia, and other groups collectively underwrite the cost of standards development and have determined it is in their organizational interest to make their respective standards available for free, other models - such as that used by ASME - rely on the sale of standards in order to recoup the costs of standards development. ASME does not impose a participation fee on its members nor does it receive contributions from companies or government for the development and maintenance of standards. This model strengthens ASME's ability to provide a neutral, inclusive, and transparent environment and precludes specialized commercial or political interests from dominating the standards development process. It results in a sustainable system in which costs are borne principally by the business entities utilizing the standard in the production of their products and work; burdens of government are lessened by the availability of sound technical standards; and the public derives the greatest benefit from enhanced safety.

ASME's standards are intended for and used by manufacturers and contractors, not by lay individuals. Those businesses routinely purchase relevant standards, independent of their incorporation by a particular jurisdiction, in their interest in benefiting from the technical experience of others as captured through standards. For them, the cost of purchasing a standard is simply a recognized, accepted, and worthwhile cost of doing business. The cost of purchasing standards is not exorbitant to those businesses and is negligible when compared to the cost of goods sold. By contrast, the cost to the government could be enormous if it were to try to supplant all revenue from licensing and sale in order to make standards free to the public.

Lastly, costs associated with developing standards fluctuate depending on economic trends and technological advancements within the respective industry —both of which can be unpredictable. A market-driven approach in which the development of new standards is spurred by industry need and commercial demand, rather than an approach that is subject to the availability of taxpayer revenue and the politics of Federal budgeting and congressional appropriation processes, is better suited to accommodate such fluctuations.

In sum, as noted in the ACUS recommendations, agencies should consider "The types of parties that need access to the material, and their ability to bear the costs of accessing such materials" when incorporating standards by reference. The current model used by ASME fairly places the cost of consensus standards on those who must comply with them and efficiently distributes those costs across all affected industries and all jurisdictions where they are adopted.

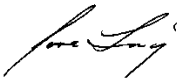
CONCLUSION

As a not-for-profit organization, ASME has long supported the relationship between the public and private sectors through the continued development of voluntary consensus standards. These standards reduce the costs of goods and services; enhance safety, health, and quality of life; and facilitate innovation, trade, and competitiveness while substantially reducing the costs of government by providing a consistent and technically sound basis for regulation.

Laws such as P.L. 112-90 (the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011), which prohibits the reference of any standard in a guidance document or regulation promulgated under the Pipeline Bill "unless the documents or portions thereof are made available free of charge on an Internet

Website", place practical barriers on the ability of Federal agencies to rely on the state of the art technical standards written by SDOs, and set a precedent that severely undermines the financial ability of standards developing organizations to develop and make their standards available for government use. The purpose and goals of the original OMB Circular A-119 still hold true; any supplements or other modifications should continue to respect the copyrights of standards developing organizations and continue to afford Federal agencies, and the general public, the flexibility to benefit from a variety of private sector standards.

Respectfully submitted,



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