



James A. Thomas
President

Address 100 Barr Harbor Drive
PO Box C700
W. Conshohocken, PA
19428-2959 | USA

Phone 610.832.9598
Fax 610.832.9555
e-mail jthomas@astm.org
Web www.astm.org

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Office of Management and Budget
725 17th Street NW
Washington, DC 20503

RE: Proposed Revisions to OMB Circular A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”; Docket Number: 2014-02891

Dear Sir/Madam:

ASTM International (ASTM) is pleased to submit these comments in response to the Office of Management and Budget’s (OMB) request for comments on the proposed revisions to Circular A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.”

ASTM, a not-for-profit organization, is dedicated to developing and publishing international voluntary consensus standards. For more than 115 years, ASTM has served society by providing a global forum to develop and publish voluntary consensus standards for materials, products, systems, and services that are utilized by ninety industrial sectors in the United States and most geographic regions of the world.

Over 30,000 individuals from 150 countries serve on ASTM’s 144 technical committees to develop over 12,000 quality standards. Over 1,400 representatives from Federal agencies are actively engaged in 93 percent of ASTM’s technical committees. ASTM is accredited by the American National Standards Institute (ANSI) and Standards Council of Canada (SCC) and meets the World Trade Organization’s (WTO) six principles¹ for the development of international standards.

Overall, ASTM largely supports OMB’s revisions as they would continue to promote and recognize the importance of the public-private partnership embedded in the current U.S. system of standardization. This thriving public-private partnership contributes to the advancement of innovation, competition, international trade, and the public’s interests in health, safety, and the environment. ASTM’s comments about the proposed revisions and certain issues are detailed below.

¹ G/TBT/1/Rev. 10, Annexes to Part 1.B, para. 1; WTO’s *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*. This framework for quality, international technical standards consists of six principles: transparency, openness, impartiality and consensus, relevance and effectiveness, coherence and developing country interests.

1. ASTM Supports OMB's Recommendation that Federal Agencies Should Prefer and Use Voluntary Consensus Standards that are Developed Under Certain Principles and Processes. (Sections 2, 3(f), 6(a), and 6(f))

ASTM supports OMB's preference and encouragement to Federal agencies in Sections 6(a) and 6(f) to use voluntary consensus standards given the valuable principles and processes under which such standards are developed. Regardless of whether an agency uses a voluntary consensus, voluntary non-consensus, or government-unique standard, ASTM supports that a Federal agency should report its use of the standard to improve tracking and transparency.

ASTM supports OMB's outline of attributes in Section 3(f) that define the development processes of "voluntary consensus standards bodies" to include openness, balance of representation, due process, appeals process, and consensus. A Federal agency's consideration on whether a standards development body meets these valuable principles and adopts the processes will help ensure that high quality, market relevant standards are used in regulation. The attributes and definitions in Section 3(f) appropriately reflect some of the same principles and processes set out in the WTO TBT Committee's Decision. These parallels may aid the Federal agencies in considering whether a voluntary consensus standards body also develops "international standards."

The Circular also provides important guidance to Federal agencies about the value in using voluntary consensus standards. The Government's use of voluntary consensus standards developed under the principles and processes listed in Section 3(f) allow it to achieve the important goals listed in Section 2 of cost-savings, innovation and efficiency, and reliance on the private sector for quality, efficient goods and services. The making of a voluntary consensus standard is a complex process that involves, among many other things, professional staff, housing and administration of the process, technology to allow for broad and virtual participation, and publication and distribution of the documents. ASTM, like other standards development organizations (SDOs), supplies all of the necessary resources and bears much of the costs for developing and providing access to the standards. Given that the Government would unlikely be able to supply all the necessary resources if standardization was based in the public sector, OMB's guidance on the use of voluntary consensus standards remains increasingly relevant.

Unlike federal law and policy, state law and policy do not exist that provide guidance to state agencies on the use of voluntary consensus standards, participation in the development processes, and respect and protection of copyright holders. OMB should provide recommendations to the states or begin educational initiatives that address these issues so states better understand the importance and value of private-sector standardization and the public-private partnership.

2. ASTM Generally Supports OMB's Recommendations that Federal Agencies Should Consider Multiple and Various Factors When Determining Whether to Use a Standard in Regulation. (Section 6(e))

ASTM generally supports OMB's recommendations in Section 6(e) that a Federal agency should consider multiple and various factors when determining whether to use a standard in a regulation; ASTM provides additional recommendations that OMB should include for an agency's consideration.

ASTM supports a Federal agency's consideration of how the use of the standard may affect laws and regulations on safety and the environment, international trade, and intellectual property. Any use of a standard in regulation should help the agency meet its regulatory objectives while respecting the rights and interests of the standards developer.

Additionally, ASTM supports an agency's consideration under Section 6(e)(iii)(4) of whether there are any barriers to membership and participation in the standards development process. OMB should further recommend to Federal agencies that any alleged barrier to membership or participation in the standards development process should be addressed directly with the SDO and not through the rulemaking process. ASTM strives to keep barriers to entry and participation low in order to promote open participation amongst all stakeholders. Most ASTM members pay 75 USD annually for membership that entitles them to full participation rights and access to standards relevant to their interest. Any interested party - ASTM member or not - can submit technical comments and request revisions to the content of a standard; the appropriate technical subcommittee then addresses those comments. If barriers to membership or participation arise, then ASTM works with those affected on a case-by-case basis. Additionally, through ASTM's global cooperation program, technical experts from about 85 developing countries can receive membership on technical committees at no cost. Therefore, while ASTM membership dues remains low, ASTM's participation by all relevant stakeholders is open and has never been higher.

In Section 6(e), OMB should recommend that Federal agencies consider whether industry or the Federal agency already uses a relevant voluntary consensus standard before the agency uses a different standard or creates its own. This recommendation would help conserve resources, reduce barriers in the marketplace and encourage agencies to avoid duplication of standardization efforts. ASTM also supports the use of more than one standard given different market requirements so long as agencies follow OMB's guidance on this topic in Section 6(i) by "giv[ing] clear and specific guidance so that a hybrid standard is not inadvertently created." A survey of what standards are already used in the marketplace and by agencies reflects similar principles of equivalency embedded in OMB's comments in Section 6(h) about the WTO TBT Agreement's requirements in Article 2.7. Article 2.7 states that the United States and other WTO Members are to "give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfill the objectives of their own regulations." Overall, the use of any standard in a regulation should be based on the agency's needs, the technical quality, market relevance, and attributes of a standard, and how a standard helps the agency meet its needs.

In Section 6(e)(iii)(1)(d), OMB recommends as part of a Federal agency's initial criteria on whether to use a standard in regulation that the agency consider "the costs to the government and the regulated public of the agency for developing its own standard." The National Technology Transfer and Advancement Act (NTTAA) and the current OMB Circular A-119 direct Federal agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with the law or impractical. Thereby, a cost analysis for government-unique standards should only come after the Federal agency has determined that there are no voluntary consensus standards developed in the private sector that would help the agency meet its regulatory needs.

Lastly, under Section 6(e), OMB should recommend that when a Federal agency determines whether to use a standard in regulation that it also considers whether a standard is an "international standard" developed under the WTO TBT Committee Decision's six principles. This additional consideration under Section 6(e) of whether a standard is an "international standard" would help ensure that the agency meets international obligations addressed in Section 6(g) and does not create unnecessary barriers to trade.

3. ASTM Supports OMB's Recommendation and Encouragement for Federal Agency Participation in the Standards Development Processes. (Sections 6(b), 6(n), and 7)

ASTM supports OMB's encouragement in Section 7 for Federal agencies to participate in the SDOs' activities. Federal agency representation and participation in the standards development processes is essential to advancing the public-private partnership and the Federal government has remained a key stakeholder in standards activities. For example, ASTM has over 1,400 representatives of Federal agencies on 93 percent of ASTM's technical committees as well as having representatives serve on the ASTM Board of Directors and as leaders for technical committees. Such active agency participation in the SDOs provides technical expertise, support, and leadership, enhances transparency between the public and private sectors, and eliminates the need for the development of separate government-unique standards.

Additionally, ASTM supports OMB's recommendations in Section 6(b) that an agency "should participate in the activities of the voluntary consensus body or at least monitor the development of the standards so that the agency is in a position to use the standards at an appropriate time." This recommendation recognizes the value of participating in the development of relevant voluntary standards and engaging with other interested stakeholders. This recommendation also saves the Government great resources by preventing unnecessary duplicative efforts.

ASTM recognizes that government representatives and other stakeholders may have limited resources to participate in the development of standards. ASTM provides many virtual tools and resources to its members to eliminate barriers to participation in the standards development process. For example, ASTM offers valuable electronic participation tools including an online balloting platform, a customized online member portal, virtual meetings for members and non-member stakeholders, and a series of free online training workshops about the development processes. ASTM provides the free Standards Tracker that tracks and alerts any interested stakeholder about specific standards or interest areas.

Furthermore, ASTM supports OMB's recommendation in Section 6(n) for Federal agencies to alert the public of its potential participation in standards development activities, including information about why the agency is participating and how the public can obtain more information. Such transparency would foster the public-private partnership and educate interested stakeholders about how they can participate in the standards development processes.

4. ASTM Strongly Supports OMB's Recognition that Federal Agencies' Should Respect and Protect Standard Developers' Intellectual Property. (Sections 6(l) and 6(p))

ASTM strongly supports OMB's recognition that Federal agencies should observe, respect, and protect the rights of copyright owners when using and publishing voluntary standards in Federal agencies' documents. Over 1,200 ASTM standards are incorporated by reference in Federal regulations. ASTM, along with many other SDOs, own and control the copyrights in our standards on a fair and flexible basis. The Government's respect and protection of standards developers' copyright in standards incorporated by reference is essential to the continued success of the U.S. system of standardization in meeting the needs of the public and Government.

Federal agencies should duly note OMB's commentary and acknowledgment of the importance of respecting SDO's copyright in standards. Specifically, OMB acknowledges that requiring that standards incorporated by reference be made "free of charge" would be contrary to the public's interest because it

would result in shifting the costs to others, likely to the Government, or depriving SDOs of the necessary funding to meet the needs of their stakeholders.

There are many costs in the process of developing, publishing, and maintaining voluntary consensus standards. ASTM receives no Federal or State funding to underwrite such costs. The model that ASTM has chosen to pay for our standards development activities is one that requires payment by end users of our documents, rather than front-loaded standards development fees charged to industry, governments, and other important stakeholders such as consumer and environmental advocacy organizations. Because the costs of developing our standards are spread out among thousands of users who buy standards on a reasonable basis, ASTM is able to keep the barriers to participation in the process very low. As a result, over 50 percent of participants in our standards development activities come from small and medium sized companies. This well balanced participation is vital to producing technically credible and market relevant standards.

The revenue ASTM receives from the distribution of our standards is invested to meet commitments to our members and stakeholders, and to ensure the long-term vibrancy of our standards development activities. ASTM has looked at other systems and we continue to find that our current model of standards development and distribution is the most effective way to protect the public, meet the needs of government, and ensure that ASTM can continue to provide value and innovate to meet new challenges of the future.

5. ASTM Generally Supports OMB's Recommendation and Flexible Approach that Federal Agencies Should Use When Considering Whether a Standard Incorporated by Reference is "Reasonably Available." (Section 6(p))

Respect and protection of intellectual property goes hand-in-hand with the issue that standards incorporated by reference are to be made "reasonably available" and not "free of charge." ASTM generally supports OMB's recommendation in Section 6(p) that Federal agencies should consider multiple factors to determine whether a standard is "reasonably available" for purposes of incorporation by reference. A "one-size-fits-all" solution does not exist when addressing the issue of access to standards incorporated by reference. OMB's recommendation complements the Office of Federal Register's proposal that Federal agencies should consult and work with SDOs to address the best solution to accessing referenced standards while also respecting the SDOs' interest in their intellectual property. OMB's guidance that "the absence of one or more of these factors alone should not be used as the basis for an agency decision not to use the standards" speaks to the need for a flexible approach on the issue of access.

ASTM recommends that OMB consider the language in Section 6(p)(iii) so that the focus is not on "obtaining" a copy of the material, but on accessing and reading the material. Additionally, OMB should make a distinction in the consideration of the costs of accessing a standard to the public compared to the costs to those that are using the standard for commercial purposes.

ASTM strives to be flexible and reasonable when working with Federal agencies on issues of access. ASTM works with a Federal agency on a case-by-case basis to provide the public with read-only access to a standard during the agency's comment period of rulemaking. Upon promulgation, ASTM provides the public with free, read-only access in ASTM's electronic reading room to our standards incorporated by reference and mandated in Federal regulation. Commercial interests can access our standards on a reasonable basis and through a variety of flexible business models. Overall, reasonable access to a

standard incorporated by reference at any stage of the rulemaking process should be made on a case-by-case basis between the regulating agency and the standards developer.

6. ASTM Supports OMB's Recommendation that Federal Agencies Update Standards Referenced in Regulations on a Timely Basis. (Section 6(o))

ASTM supports OMB's recommendation in Section 6(o) that Federal agencies review and update its regulations on a timely basis that incorporate by reference private-sector standards. ASTM's technical committees review each ASTM standard on a regular basis, which helps ensure that they reflect the "state of the art" by meeting industry's innovating needs, responding to new research and scientific information, materials, or technologies, or addressing emerging hazards or threats in the marketplace. Therein, referencing a recent version of an ASTM standard in an agency's regulation is valuable to the public, consumers, businesses, and the Government as it increases public-private collaboration, ensures a higher level of protection of public health and safety, clarifies legal uncertainty, and reduces confusion in the marketplace.

Additionally, ASTM agrees that Federal agencies should verify with NIST the accuracy of the standards included in the Standards Incorporated by Reference (SIBR) Database. OMB should consider recommending that each agency's Standards Executive help facilitate these efforts. The SIBR Database can be a useful tool for the public and SDOs to determine what standards are used in Federal regulations.

7. ASTM Supports OMB's Guidance to Federal Agencies About Compliance with International Obligations on International Standards and Technical Regulations. (Sections 6(g), 6(h) and 6(i))

ASTM supports OMB's recognition in Sections 6(g) and 6(h) of the international obligations and implications arising from the use of standards in Federal regulations. ASTM's standards development process is designed in accordance with the WTO TBT Decision's six principles: transparency, openness, impartiality and consensus, relevance and effectiveness, coherence, and developing country interests. This successful framework provides for the development of ASTM's high technical quality international standards that are used in the global marketplace and in regulations in 75 countries around the world.

As required under the WTO TBT Agreement² and found by the WTO Appellate Body³, standards developed under the principles outlined in the WTO TBT Decision are considered "international standards" and should be used as the basis for technical regulations whenever possible. When U.S. regulators look to reference international standards as part of Federal regulations, they fulfill their WTO commitments. Furthermore, by the U.S. Government looking to the WTO principles as a framework for the development of international standards, the U.S. promotes the use of standards based on technical merit and encourages choice in both the public and private sectors given that there are multiple sources of international standards. 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 cooperation, and legislative and regulatory approaches. In particular, this is an important consideration when promoting international regulatory cooperation as a part of the Transatlantic Trade and Investment Partnership.

² Uruguay Round Agreement: Agreement on Technical Barriers to Trade, 1868 U.N.T.S. 120, Section 2.4.

³ Appellate Body Report, *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS381/R (May 16, 2012).

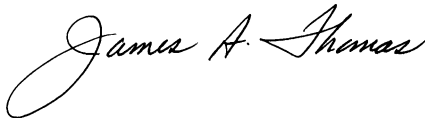
8. ASTM Supports OMB's Recommendations that Would Strengthen the Role of Federal Agencies' Standards Executives. (Section 15)

ASTM supports OMB's revisions that would strengthen the role of Federal agencies' Standards Executive so that they have sufficient authority to ensure proper use of standards and encourage participation by the agency's representatives in the standards development processes. Each Federal agency treats the participation in SDOs and the use of standards differently, so the Standards Executive should serve in a key role of collaborating, coordinating, and resolving issues with standards developers.

Conclusion

Overall, ASTM supports OMB's proposed revisions to the OMB Circular A-119 that help advance the current system of private sector standardization based on a public-private partnership. The public and private sectors depend on this collaborative and flexible system for high quality and affordable standards that help promote innovation, competition, international trade, and protect the public's health and safety and the environment. Please feel free to contact Jeff Grove in the ASTM Washington Office at 202-223-8505 to discuss ASTM's comments.

Sincerely,

A handwritten signature in cursive script that reads "James A. Thomas". The signature is written in black ink and is positioned above the printed name.

James A. Thomas