



James A. Thomas
President

Address 100 Barr Harbor Drive
PO Box C700
W. Conshohocken, PA
19380-2959 | USA

Phone 610.832.9596
Fax 610.832.9555
e-mail jthomas@astm.org
Web www.astm.org

September 14, 2011

Administrative Conference of the United States
Committee of Administration and Management
1120 20th Street, NW, Suite 706
Washington, DC 20036

RE: Comments on “Incorporation by Reference in Federal Regulations,” Committee of Administration and Management

To Whom It May Concern:

ASTM International (ASTM) is pleased to submit these comments to the Committee of Administration and Management in response to the report entitled, “Incorporation by Reference in Federal Regulations”.

ASTM is a leading non-profit organization devoted to the development of voluntary consensus standards that are utilized by ninety industrial sectors in the US and in most geographic regions of the world. For more than 100 years, ASTM has served society as a leading venue for consumers, industry and regulators to work together in the development of voluntary consensus standards that promote health, safety, the environment, and that improve the overall quality of life. ASTM is accredited by the American National Standards Institute and meets World Trade Organization principles for the development of international standards.

National Technology Transfer and Advancement Act of 1995 (NTTAA) and Office of Management and Budget (OMB) Circular A-119

As noted in the report, the February 10, 1998 Memorandum from Office of Management and Budget (OMB) Director Franklin D. Raines, OMB Circular A-119 establishes existing federal policy and guidance regarding “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”. Consistent with the National Technology Transfer and Advancement Act of 1995, the Circular directs federal agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical. Additionally, the Circular provides guidance for agencies participating in voluntary consensus standards bodies such as ASTM International.

ASTM finds that OMB A-119 continues to be an extremely effective policy that benefits the federal government and the regulated community alike. The Circular affirms and ensures that the US has a decentralized system of standardization that is driven by the needs of stakeholders. Such a system of standardization eliminates or significantly reduces the cost to the federal government for developing its own standards. For consumers, the US system of standardization reduces the costs of most goods that

are purchased and increases consumer confidence. Most importantly, the system allows stakeholders – technical experts, consumer advocates and regulators - to engage directly under an open, transparent and balanced process in the development of voluntary consensus standards that can be utilized to meet regulatory objectives.

Furthermore, OMB A-119 promotes successful public-private sector standards development efforts that help reduce the cost and improve the management and effectiveness of the Executive Branch. For example, in support of the principles set forth in NTTAA and OMB Circular A-119 that support the public-private collaboration, the US government is a key stakeholder in ASTM's standards development process, with active participation from a broad range of federal agencies in 93% of ASTM's 140 technical committees. Federal agencies should establish practices that promote the Circular as a model of regulatory policy that establishes the intrinsic purpose and principles of the US standards system.

ASTM Standards and the Code of Federal Regulations

The federal government's commitment to the policies set forth in the NTTAA and OMB Circular A-119, through incorporation by reference, has led to an increased use of voluntary standards in the US and has made government regulation and procurement more efficient and globally relevant. ASTM has a long history of working in partnership with federal agencies to develop standards that meet evolving regulatory and procurement needs. The report reflected ASTM's work with federal agencies through the high volume of voluntary consensus standards incorporated by reference in the CFR. ASTM is the single most federally referenced standards development organization in the US, which demonstrates the importance of enhancing the public-private partnership and collaboration in standards development.

Additionally, incorporation by reference demonstrates the federal government's recognition that consensus standards provide uniformity across the public-private sectors, help maintain product quality, reliability and performance, allow for enforcement measures, improve market access, and develop consumer confidence.

Copyright Protection and Reasonable Accessibility for Standards Incorporated by Reference

ASTM encourages federal agencies to work with standard development organizations to reference voluntary consensus standards in an agency document under the direction of Circular A-119, which requires that federal agencies "must observe and protect the rights of the copyright holder and any other similar obligations."

When a federal agency has demonstrated a need for access to intellectual property contained in ASTM's standards, ASTM works with the agency to meet reasonable needs. ASTM appreciates that the report recognizes that ASTM strives to be flexible and reasonable when working on access issues with federal agencies. While the report's references are generally correct, some of the terms of the agreements with trade associations, such the Hand Made Toys Alliance, and federal agencies, such as DHS, are more nuanced than explained in the ACUS report. Agency representatives seeking to discuss agency and regulated public access to ASTM standards are encouraged to contact John Pace (jpace@astm.org) or Jeff Grove (jgrove@astm.org) for more information.

Additionally, as noted in the ACUS report, 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. However, ASTM often waives the 75 USD membership fee for interested consumers and

general interest participants. Through ASTM's global cooperation program, technical experts from roughly 70 developing countries can receive membership on technical committees at no cost. Furthermore, any interested party - ASTM member or not - can submit technical comments on standards development issues. Therefore, ASTM membership revenue maybe low, but participation in the process by all relevant stakeholders has never been higher.

Updating Standards Incorporated by Reference

ASTM asks that federal agencies develop a means to update, frequently, all consensus standards incorporated by reference. ASTM standards, known for the high technical quality, provide reliable physical and chemical requirements. ASTM's standards have titles with year designations, which refer to a specific edition of the standard. ASTM reviews each ASTM standard at least once every five years to ensure that its technical documents continue to meet industry and consumer needs and reflect the "state of the art." ASTM committees can also revise standards more frequently in response to new information or technologies.

Incorporating by reference the most updated version of a consensus standard is important for the federal government, the consumer, and industry. The US government fosters and supports public-private collaboration, clarifies legal uncertainty, and reduces confusion in the market place by incorporating by reference the most recent standards. Additionally, US companies of all sizes invest their technical resources in the development of standards that match their interest, business objectives, and advancing technologies. Barriers to the acceptance of current consensus standards, like regulations incorporating by reference outdated standards, impair industry's ability to develop and employ them. As a result, the companies are most affected by outdated standards that are incorporated by reference because of the need for additional product testing or product redesign to achieve their desired market access.

The Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, provides an example of how a federal agency, no less than every two years, is directed to effectively review and modify standards through a FR notice. The statute's language allows for efficient regulation, prompt review, and increased flexibility for updating the most recent standards on medical devices. The Food and Drug Administration (FDA)'s mechanism for updating standards incorporated by reference through a review cycle allows them to maximize the efficiency of their regulatory and guidance documents and reduces confusion by those needing to comply with agency requirements.

Conclusion

In conclusion, ASTM and other standards developers have demonstrated great success in working cooperatively with federal agencies, consumers, industry and other stakeholders to craft voluntary consensus standards that meet current regulatory needs. Enhanced public-private cooperation and federal participation remains crucial to ensure that regulatory challenges of the future continue to be met. ACUS's recommendations should promote principles, embodied in the OMB A-119 and NTTAA, that enhance the competitiveness of industry and the safety of the public, as well as, protect standards developers' technically superior standards that allow for the overall effectiveness of the federal government.

Committee on Administration and Management
PG 4

ASTM International is pleased for the opportunity to provide these comments about regulating through the utilization of consensus standards incorporated by reference. Please contact Jeff Grove in the ASTM Washington Office at 202-223-8505 for any additional information.

Sincerely,

A handwritten signature in black ink that reads "Jim Thomas". The signature is written in a cursive style with a large, stylized initial "J".

James A. Thomas
President, ASTM International