



INTERNATIONAL
Standards Worldwide

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Office of the Federal Register
The National Archives and Records Administration
8601 Adelphi Road
College Park, MD 20740

Re: NARA 12-0002, Incorporation By Reference

Dear Sir/Madam:

ASTM International (ASTM) is pleased to submit these comments in response to the Office of the Federal Register's request for public comment on the petition for rulemaking related to incorporation by reference.

ASTM International

ASTM is a leading, non-profit organization devoted to the development of voluntary consensus standards. For more than 100 years, ASTM has served society by providing a global forum for the development and publication of voluntary consensus standards for materials, products, systems, and services that are utilized by ninety industrial sectors in the United States and in most geographic regions of the world. ASTM is accredited by the American National Standards Institute (ANSI) and meets the World Trade Organization's (WTO) six principles for the development international standards.

To best understand ASTM and other standards development organizations (SDOs), one must first understand the nature of standards. Standards are an essential part of the social and economic development of all nations throughout the world. Standards open channels of communication and commerce; they promote the understanding of the products of technology; they form the basis for achieving health, safety and a higher quality of life; they protect property and the environment against hazards due to production, use and disposal of products. Furthermore, standards consolidate scientific and technical knowledge, and are a mechanism to transfer the benefits of scientific research out of laboratories into widespread application so that society may benefit.

Private and Public Collaboration and Utilization of ASTM International's Standards

Over 30,000 individuals representing 135 countries, including manufacturers, retailers, consumers, regulators, academia and researchers, serve on ASTM's 143 technical committees. Within ASTM's technical committees, members develop standards in over 90 sectors, including consumer products, medical services and devices, textiles, metals, paints, plastics, petroleum, construction, aviation, energy, water, and the environment. ASTM's diverse array of standards makes the world a safer and better place.

More than 12,000 ASTM voluntary consensus standards are published each year in the 80 plus volumes of the "Annual Book of ASTM Standards." These standards: (1) promote public health and safety, and the overall quality of life; (2) contribute to the reliability of materials, products, systems and

services; and (3) facilitate national, regional and international commerce. ASTM standards are widely used around the world by business, consumers, and government. ASTM standards are used by scientists and engineers in their laboratories, by architects and designers in their plans, and governments and their agencies use and reference them for a variety of reasons. More specifically, ASTM is aware of 7,000 citations/references to ASTM standards in regulations or laws by international, federal and state governments and their agencies across more than 75 countries worldwide.

The Value of United States' Policies on Standards--National Technology Transfer and Advancement Act (NTTAA) and Office of Management and Budget (OMB) Circular A-119

The OMB Circular A-119 establishes the 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 Advancement Act of 1995 (NTTAA), 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 like ASTM International.

As one part of our nation's vital public-private collaboration in the development of standards, ASTM is pleased to count on over 1,600 individuals from federal agencies who actively engage in 93% of the technical committees. While nearly every federal agency participates, the agencies with the most representation in our standardization work include the Department of Defense, Department of Commerce, Department of Health and Human Services, and the Environmental Protection Agency.

Furthermore, U.S. policies on standards enable federal agencies to choose from a portfolio of SDOs like ASTM for the development of a standard to meet the agency's regulatory needs. For example, in 2005, the Federal Aviation Administration (FAA) adopted a new class of aircraft, light sport aircraft (LSA), made possible through collaboration with the aviation industry in the development of private-sector consensus standards under the auspices of ASTM International. FAA selected ASTM to develop standards because the agency did not have the breadth of expertise, resources, or platform for reaching consensus on the high quality technical standards necessary to spur this burgeoning industry. With the development of a portfolio of ASTM standards and FAA's acceptance of them, the LSA industry has continuously advanced its innovation through increased safety, marketplace acceptance, technology development, and lower costs for manufacturers and consumers.

Another way to quantify the success of such policies and public-private engagement is to the extent by which voluntary consensus standards are accepted and utilized by U.S. federal agencies to meet regulatory and procurement needs. According the NIST Standards Incorporated by Reference Database, over 2,229 ASTM standards have been incorporated by reference in the U.S. Code of Federal Regulations, which makes ASTM the single most federally referenced standards development organization in the U.S. The incorporation of standards by reference demonstrates the value and need to protect and enhance the public-private partnership in standards development, which the federal policies on standards require. Additionally, the federal government recognizes 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.

Through the government's participation in ASTM's standards development process and its incorporation of standards by reference, the government benefits from the reduced costs of standards development and the ability to turn to SDOs, like ASTM, to develop standards that meet the agency's regulatory needs and benefit society.

U.S. Government's Commitment to the U.S. Policies on Standards and Copyright Protection of Standards

Advances in technology through the Internet do not equate to the right to supersede the protection of intellectual property. More so, the Administration and Congress, when adopting the policy on standards, did not intend the federal government to transfer or void an organization's copyright over the standards when they are incorporated by reference in regulation. ASTM encourages the Office of the Federal Register and other federal agencies to work with SDOs to reference voluntary consensus standards in an agency's document under the direction of the OMB Circular A-119, which requires that federal agencies "must observe and protect the rights of the copyright holder and any other similar obligations."

Additionally, ASTM's approach to making standards incorporated by reference available to the public is reflected in the Administrative Conference of the United States' (ACUS) Recommendation 2011-5 part 3(b) :

When an agency is considering incorporated copyrighted material by reference, the agency should work with the copyright owner to ensure the material will be reasonably available to regulated and other interested parties both during rulemaking and following promulgation...

(b) If copyright owners do not consent to free publication of incorporated materials, agencies should work with them and, through the use of technological solutions, low-cost publication, or other appropriate means, promote the availability of the materials while respecting the copyright owner's interests in protecting its intellectual property.

The White House National Science and Technology Council's report Federal Engagement in Standards Activities to Address National Priorities also reflects ASTM's recommendation. The report states that federal agencies should consider certain attributes in SDO's processes that maximize the impact of standards development activities while helping the agency to meet its mission, including:

Access and Availability: 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.**

Therein, ASTM strongly urges the Office of the Federal Register to acknowledge the value of SDO's intellectual property and that monetary compensation may be necessary to ensure that standards are reasonably available to the public and interested stakeholders. The Office of the Federal Register should refrain from amending its regulation in 1 CFR § 51 to define "reasonably available" as free to anyone as such definition would conflict with the Administration's current guidance on standards and it would be detrimental to SDOs' ability to achieve their mission. Federal agencies as well as any members of the public should work with SDOs on a case-by-case basis if there are any issues relating to accessibility.

The copyright protection and commercial distribution of standards support the mission and purpose of valued U.S. standards development organizations.

"Reasonably available" in 1 CFR § 51 should not be defined as free because such policy would be detrimental to the existing U.S. system for standards development. Not all standards developers are full consensus organizations. Some are trade associations or professional organizations whose members pay substantial fees for memberships, registrations and projects — fees that are large enough to support their organizations. In contrast, ASTM, a non-profit organization, relies on the copyright protection and the commercial distribution of our standards to sustain our mission and serve the public through the development of technical standards - the majority of which have very little or no

commercial value. At best, roughly 20 percent of ASTM standards development activities break-even or generate revenues exceeding costs while the remaining 80 percent of our activities do not and are absorbed as part of our mission.

The idea of free standards across the board is not in the public interest, nor is it based in reality, because nobody's standards are free. Standards development organizations support the making of a technical standard, which is a complex process that involves, among other things, a professional staff, the housing and administration of the process, and cutting edge technology for broad participation and for the publishing and distribution of the documents. Standardization requires resources; it costs money. The U.S. system, recognizing that the standards community is diverse, leaves it to the individual organization to choose the method by which it will pay for the production of its standards. Therefore, mandating that standards developers provide free access to standards would lead to many unintended costs and harmful consequences for the standards development organizations and the public's health, safety, protection of the environment, product quality and reliability, domestic and international trade, and competition in the marketplace.

Free access to standards that are incorporated by reference would fundamentally shift burdensome costs to the federal government and could raise new barriers to participation in standards development.

The costs of developing standards and making them available for free online would shift to the federal government if the Office of the Federal Register or any other federal agency requires that "reasonably available" means that standards are free to any interested member of the public. Such a change in policy would dramatically alter the current U.S. standards system that has effectively served the public for over 100 years. This burden would cost taxpayers millions of dollars and would force the federal government to shift its limited resources away from other valuable programs. More so, such a shift in costs would be detrimental because of the value of the current U.S. standards development process, which brings together all stakeholders—public and private bodies—to develop the most relevant, quality, and consensus standards. This system of public/private partnership in the collaborative development of voluntary consensus standards is the envy of the world and would be threatened by such a fundamental shift in approach.

ASTM International's business model and policies ensure that any standards, regardless of whether incorporated by reference, are reasonably accessible to the public.

ASTM strives to be flexible and reasonable when working on access issues, including the price of ASTM's intellectual property. Generally, any member of the public can purchase a single ASTM standard at a cost of 36-70 USD. The cost of ASTM standards as compared to the value of the technical information they convey to intended end-users is well-accepted by industry as acknowledged by the fact that over 250,000 customers access ASTM standards.

When a federal agency or any member of the public has demonstrated a need for access to intellectual property contained in ASTM's standards, ASTM works with the agency or public member on a case-by-case basis to meet their reasonable needs. ASTM has works with Federal agencies, such as the EPA and CPSC, to provide public access to ASTM standards included in proposed regulations during the public review and comment period of the proposed rule. In instances where Federal agencies, like the Department of Homeland Security, have sought to provide our nation's first responders with enhanced access to certain ASTM standards, ASTM has entered into a flexible distribution agreement to support that objective. Flexibility and reasonableness are incorporated in ASTM's case-by-case approach to access issues.

Additionally, ASTM strives to keep barriers to the entry and participation in the standards development process and the accessibility of our standards 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 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.

Additionally, the thriving participation level by small and medium-sized companies in ASTM's technical committees demonstrates ASTM's success and commitment to keeping barriers to participation low, so that all stakeholders—no matter what size of an enterprise—can participate in the standards development process. Small and medium size enterprises comprise more than half of the individuals participating in the development of standards. Such participation is crucial to ensuring that all stakeholders' interests and knowledge are considered in the process. ASTM's web-based resources enable participation regardless of a company's travel, time or budgetary restrictions. Committee members can use a suite of online standards development tools, including online forums, virtual meetings, electronic balloting and more if they are unable to attend in person technical meetings.

Furthermore, any interested party—ASTM member or not—can submit technical comments on standards development issues. Therefore, while ASTM membership revenue remains low, the participation in the process by all relevant stakeholders has never been higher because of ASTM's business model and the current system of standards development. As demonstrated, with such low participation barriers, the commercial distribution of ASTM's standards is at a high value to cost ratio, which remains a vital part of ASTM's mission.

Conclusion

In conclusion, defining "reasonably available" in 1 CFR part 51 as requiring that standards development organizations make their technical standards free to anyone would erode the current U.S. standards system and conflict with the objectives and principles embodied in the U.S. policies on standards. The Office of the Federal Register's response to the petition should foster the objectives and principles embodied in the OMB A-119 and NTTAA. Current policies on standards remain strongly beneficial by helping to ensure the competitiveness of industry and the safety of the public. Additionally, such policies protect standards developers' copyright over their technically superior standards, which contribute to the advancement of government needs and the overall effectiveness of the federal government. 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 various industry and regulatory needs. Enhanced public/private cooperation and federal participation remains crucial to ensure that regulatory challenges of the future continue to be met.

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 cursive script that reads "James A. Thomas". The signature is written in black ink and is positioned below the "Sincerely," text.