April 30, 2012

Hon. Cass R. Sunstein, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Re: Request for Information 2012-7602, 77 Fed. Reg. 19,357

Dear Mr. Sunstein:

On behalf of Office of the Chairman of the Administrative Conference of the United States, we submit these comments in response to your recent request for information (RFI) regarding “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.”

At its Plenary Session on December 8-9, 2011, the Administrative Conference adopted two recommendations relevant to your request. Recommendation 2011-5, "Incorporation by Reference," which you noted in the RFI, addresses a variety of issues agencies face with respect to regulations that incorporate by reference. This recommendation identifies principles and best practices that can help agencies ensure public access to incorporated materials, keep regulations up-to-date as new versions of incorporated materials become available, comply with procedural requirements for incorporating by reference, and appropriately draft incorporating regulations. A second recommendation adopted during the same plenary session, Recommendation 2011-6, "International Regulatory Cooperation," may also be relevant as you consider the international consequences of Circular A-119 and government use of standards. The Conference has long been interested in the important subjects addressed in these two recent recommendations.

These recommendations reflect consensus positions of the Assembly of the Administrative Conference that were reached through an open, committee-based process. Each recommendation began with a research report delivered to the Committee on Administration and Management (Recommendation 2011-5) and Committee on Regulation (Recommendation 2011-6). The report underlying Recommendation 2011-5, for example, was based on extensive

2 Id. at 2,259.
research that included interviews with employees at eleven federal agencies, as well as representatives of seven standard-development and public interest organizations. The Committee on Administration and Management held two meetings on the project that were open to the public. The committee considered public comments on the draft report and recommendation, including comments from standard development organizations and advocates of open government. Its discussions were lively and thorough. The committee approved the public access provisions of the draft recommendation on a vote of 5-2 and unanimously approved the remainder of the draft recommendation. Following significant debate and consideration of public comments and proposed amendments that would have taken a more aggressive approach on public access, Recommendation 2011-5 was adopted by the Assembly without modification. Recommendation 2011-6 was crafted through a similar process.

These comments analyze the relevance of Recommendations 2011-5 and 2011-6 to several of the questions posed in the RFI. In some places, we provide additional detail to explain the basis of the recommendations and their relation to your inquiries. To the extent that these comments go beyond the text of the cited recommendations, they should be understood to reflect the considered views of the Conference’s Office of the Chairman, informed by the research conducted by the Conference’s staff attorney, Emily Bremer. These views may not reflect the views of the Conference or its members.

I. Ensuring Public Availability of Incorporated Materials

The RFI asks several questions regarding the public availability of standards incorporated by reference. The first section of Recommendation 2011-5 embraces the principle that incorporated materials, including those protected by copyright, should be available to regulated and other interested parties during the rulemaking process and following promulgation. This section of the recommendation further identifies best practices for agencies seeking to facilitate
such public availability, particularly when the issue is complicated by copyright. This part of the recommendation is thus responsive to several of your inquiries, including:

- *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.*

- *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?*

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

As an initial matter, the first paragraph of Recommendation 2011-5 urges agencies to ensure that incorporated materials are reasonably available to both regulated and other interested parties.\(^\text{12}\) This speaks to the provision of the Freedom of Information Act (FOIA) that permits incorporation by reference in federal regulations.\(^\text{13}\) To enforce a regulation, agencies must publish it in the *Federal Register* for codification in the Code of Federal Regulations (CFR).\(^\text{14}\) FOIA provides that “matter reasonably available to the class of persons affected thereby is deemed published in the *Federal Register* when incorporated by reference therein with the approval of the Director of the Federal Register.”\(^\text{15}\) In context, “class of persons affected” might reasonably be interpreted to refer only to regulated parties. In the age of e-rulemaking and amid efforts by this Administration to promote transparency and public participation in rulemaking, however, the recommendation urges agencies to take a broader view that values access for regulated and non-regulated parties alike.\(^\text{16}\)

As the recommendation recognizes, facilitating the public availability of incorporated materials is relatively easy when those materials are not copyrighted. In such circumstances, the best practice is for agencies to make the materials broadly available electronically. Paragraph two of the recommendation accordingly provides that “[i]f an agency incorporates by reference material that is not copyrighted or subject to other legal protection, the agency should make that material available electronically in a location where regulated and other interested parties will be able to find it easily.”\(^\text{17}\)

Many organizations that develop voluntary consensus standards, however, claim copyright in their standards, making it more difficult for agencies to ensure broad public

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availability. As the preamble to Recommendation 2011-5 recognizes, the Fifth Circuit’s en banc decision in Veeck v. Southern Building Code Congress International, Inc.\(^{18}\) created some ambiguity regarding the scope of copyright protection for privately authored materials incorporated into laws and regulations.\(^{19}\) The majority held that once adopted as law, a privately authored code created for that purpose enters the public domain and loses its copyright protection.\(^{20}\) But the majority further explained that this holding did not extend to extrinsic standards incorporated by reference into laws and regulations,\(^{21}\) including those incorporated pursuant to Circular A-119.\(^{22}\) Other courts have held that materials incorporated by reference retain their copyright protection.\(^{23}\) The Veeck court acknowledged this precedent, finding it “distinguishable in reasoning and result.”\(^{24}\) In light of this caselaw and the reality that agencies may be liable for copyright infringement,\(^{25}\) Circular A-119’s provision urging agencies to “observe and protect the rights of the copyright holder and any other similar obligations”\(^{26}\) remains prudent. Respecting standard developers’ interest in protecting their intellectual property also protects the valuable private-partnership in standards that is furthered by the National Technology Transfer and Advancement Act and Circular A-119.\(^{27}\)

Recommendation 2011-5 thus urges a collaborative approach to facilitating the public availability of copyrighted materials that are or may be incorporated by reference. Paragraph three urges agencies to reach out to standards developers and work with them to make standards freely available both during rulemaking and following promulgation. If the copyright owner does not consent to free publication, the recommendation urges agencies to work with copyright owners and use available technological tools such as read-only access to make the material available without violating or devaluing the copyright.\(^{28}\) Paragraph four of the recommendation articulates a variety of factors agencies should consider in evaluating what constitutes “reasonable availability” in the circumstances and determining the measures to take to ensure such availability.\(^{29}\) These factors acknowledge that greater public access may be required during

\(^{18}\) 293 F.3d 791 (5th Cir. 2002) (en banc).
\(^{20}\) Veeck, 293 F.3d at 796, 802.
\(^{21}\) See id. at 804 and n.20.
\(^{22}\) See id. at 804 n.20 (citing CIRCULAR A-119).
\(^{23}\) See Practice Mgmt. Info. Corp. v. Am. Med. Ass’n, 121 F.3d 516 (9th Cir. 1997), opinion amended by 133 F.3d 1140 (9th Cir. 1998); CCC Info. Servs. v. Maclean Hunter Mkt. Reports, Inc., 44 F.3d 61 (2nd Cir. 1994)
\(^{24}\) Veeck, 293 F.3d at 804; see also Memorandum from Brian T. Yeh, Cong. Research Serv., to Hon. Carl Levin, Potential Copyright Law Issues Concerning Proposals to Require Certain Federal Agencies to Provide Free Online Access to Any Private Sector Materials That Are Incorporated By Reference in Regulations (Oct. 18, 2011) (on file with the Administrative Conference).
\(^{29}\) See id. at 2,258-59.
the rulemaking process, when non-regulated, interested parties need to see the text of a standard to comment meaningfully on a proposed rule that would incorporate the standard by reference.

These public access provisions of Recommendation 2011-5 are also responsive to a related question you pose in the RFI:

- **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?**

While there are a wide variety of factors agencies must consider when determining whether to use a voluntary consensus standard, the availability of the standard ought to be one such factor. Paragraph three, section (c) of Recommendation 2011-5 accordingly provides that “[i]f more than one standard is available to meet the agency’s need, it should consider the availability of the standards as one factor in determining which standard to use.” This provision recognizes that public availability of an incorporated standard may be essential to fulfilling an agency’s regulatory purpose.

An earlier Conference Recommendation, 78–4, provided some more specific guidance on when voluntary consensus standards should be considered by agencies regulating health and safety:

Voluntary consensus standards should be considered with due caution and on a case-by-case basis. Ordinarily, standards which embody judgmental factors should receive greater scrutiny when being considered by agencies for adoption into regulations than standards which specify nomenclature, basic reference units, or methods of measurement or testing, and which are primarily empirical in their formulation. In evaluating a voluntary consensus standard each agency should consider the following factors:

(a) The apparent suitability of the voluntary consensus standard for use as a mandatory standard, including:

   (i) The problems addressed by the standard and changes in the state of knowledge since the standard was prepared or last revised;

   (ii) The extent to which the standard has been complied with, and the reasons for any noncompliance;

   (iii) The extent of injury, accident, or illness known to have resulted from products, materials, processes, practices or services that have conformed with the standard;

30 See CIRCULAR A-119, at ¶ 6(a)(2).
(iv) The clarity and detail of the standard's language; [noting that the wording of a standard may contain too much detail as well as too little]

(v) The extent to which the standard establishes performance rather than design criteria, where feasible;

(vi) The extent to which a newly developed standard, under which little experience exists, appears adequately to address the hazards considered by the developers of the standard or known to the agency; and

(vii) The enforceability of the standard.

(b) The nature of the agency's statutory mandate to develop health or safety regulations and the consistency of the provisions of the voluntary consensus standard with that mandate.

(c) The adequacy of the procedures followed by the organization preparing the standard to assure that:

(i) The membership of the technical committee represents a broadly based and balanced array of relevant interests, including, where appropriate, representatives of consumers, labor, small business, and other affected groups, and no single interest has a dominating influence on the committee;

(ii) Reasonable notice that a proposed standard is being considered is given to interested persons and groups;

(iii) Interested persons and groups have an opportunity to participate in the deliberations and discussions relating to the standard;

(iv) Prompt and careful consideration is given to minority points of view and objections to the standard;

(v) Standards are approved by considerably more than a simple majority vote of the technical committee, although unanimity is not necessarily required;

(vi) An adequate opportunity for review is afforded to assure that fairness is protected and that dissenting views are given full consideration;

(vii) Adequate records are maintained to document that the established procedures were actually followed and that the views presented were duly considered in accordance with those procedures; and

(viii) The entire process is open to public scrutiny and review.

(d) The availability of documentation adequately describing the costs and benefits, the rationale for and method of arriving at the critical requirements of the standard, and other factors actually considered by the technical committee in developing or revising the voluntary consensus standard. 33

33 Administrative Conference of the United States, Recommendation 78-4, Federal Agency Interaction with Private Standard-Setting Organizations in Health and Safety Regulation, 44 Fed. Reg. 1,357 (Jan. 5, 1979). The recommendation was supported by a research report by Robert W. Hamilton, The Role of Nongovernmental
Finally, it bears emphasizing that making a copy of a highly technical standard available to the public for free may not be sufficient to facilitate meaningful comments on a proposed rule or full understanding of a final rule’s requirements. Understanding technical standards often requires significant technical, scientific, or other expertise. Moreover, because standards are not typically created for the purpose of being incorporated into regulations, the relationship between an agency’s regulatory purpose and a particular standard may require explanation. Paragraph five of Recommendation 2011-5 recognizes these realities, urging that “[w]hen considering incorporating by reference highly technical material, agencies should include in the notice of proposed rulemaking an explanation of the material and how its incorporation by reference will further the agency’s regulatory purpose.”

II. Updating Regulations That Incorporate by Reference

Paragraphs six through eleven of Recommendation 2011-5 address best practices for keeping regulations up-to-date as incorporated materials are revised. These provisions may shed some light on several additional questions in the RFI, including:

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

  Although practices vary among standard development organizations and with respect to individual standards, most standards developers review standards every two to five years and revise or update them as required by the emergence of new issues or advances in technical knowledge. For example, the National Fire Protection Association (NFPA) requires that standards “shall not be processed through a revision cycle more than once every 3 years and not less than once every 5 years.” In “special circumstances” and with approval, however, “the time interval may be extended to a maximum of 10 years.” ASTM International permits the proposal of revisions at any time, but also requires that each ASTM standard be reviewed at least every five years. Other standard developers may make minor revisions to standards as frequently as every two years.

  As the preamble to Recommendation 2011-5 explains, updating regulations to reflect revisions to incorporated standards has proven to be a challenge for many agencies. The law prohibits agencies from “dynamically” incorporating standards by requiring the inclusion of the

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34 Bremer Report at 32, 45.
38 See id. § 10.5.3.
specific version and date of an incorporated standard in the text of the regulation. This prohibition on dynamic incorporations reflects sound public policy, but the result is that agencies must typically conduct a notice-and-comment rulemaking to update a regulation that incorporates by reference.

Recommendation 2011-5 addresses this challenge and thus provides some guidance on the following questions posed in the RFI:

- Should an OMB supplement to the Circular set out best practices for updating standards referenced in regulation as standards are revised? If so, what updating practices have worked well and which ones have not?

- Is there a role for OMB in providing guidance on how Federal agencies can best manage the need for relevant regulations in the face of changing standards?

Paragraphs six through eleven of the recommendation identify best practices for updating incorporating regulations. Paragraph six encourages agencies to review incorporating regulations periodically and use technical amendments to update contact information for the standard developers, publishers, or resellers that provide copies of incorporated standards. Other provisions encourage several techniques that have proven effective in reducing the burden of updating regulations when incorporated standards are revised. These techniques include leveraging participation in the standard development process (paragraph seven), using equivalency determinations or enforcement discretion to minimize the harm of outdated references (paragraph nine), and using direct final rulemaking to accommodate non-controversial revisions to incorporated standards (paragraph ten). Paragraph eight of the recommendation counsels agencies against addressing the challenge of updating by confining incorporations by reference to non-binding guidance documents. Although this tactic obviates the need to use notice-and-comment rulemaking, it runs contrary to principles of good governance and may prevent an agency from enforcing a standard as a regulatory requirement.

It would be useful for OMB to disseminate the best practices identified in Recommendation 2011-5. Indeed, we would welcome the opportunity to work with OMB to implement these and other provisions of the recommendation.

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40 See 1 C.F.R. § 51.1(f); CIRCULAR A-119, at § 6(j); Nat’l Archives & Records Admin., Federal Register Document Drafting Handbook, Chapter 6: What is Incorporation by Reference, and How do I do it? (Jan. 2011), http://www.archives.gov/federal-register/write/handbook/chapter-6.pdf. It is possible of course, that an agency regulation may appropriately incorporate a private standard that has since been revised or updated. In some such circumstances, the agency may be satisfied with the earlier private standard. In such situations, the standard-setting organization may be (and perhaps should be) more willing to make its older version available without charge.

41 See Bremer Report at 33-34.


43 See id. at 2,259.

44 See id.

45 See Bremer Report at 37-38.
The updating provisions of Recommendation 2011-5 are relevant to one final question posed in the RFI:

- 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?

As noted above, paragraph seven of the recommendation identifies federal agency participation in the standard development process as one way for agencies to keep abreast of emerging revisions to incorporated standards. The research underlying this recommendation suggests that some agencies are more engaged in the standard development process than others. Among other factors, scarce resources and a lack of available personnel often prevent agencies from participating consistently and fully in standard development processes. More active participation can only facilitate updating if agencies adopt internal policies to ensure the information gleaned through that participation is communicated to the agency personnel responsible for rulemaking. The National Institute of Standards and Technology provides assistance to agencies as they navigate the standard development process. OMB guidance in this area could build upon NIST’s work and the foundation of Recommendation 2011-5 to improve agency practices further.

III. Drafting Regulations That Incorporate by Reference

- Should OMB set out best practices on how to reference/incorporate standards (or the relevant parts) in regulation? If so, what are the best means for doing so? Are the best means of reference/incorporation context-specific? Are there instances where incorporating a standard or part thereof into a regulation is preferable to referencing a standard in regulation (or vice versa)?

Further guidance from OMB on these issues may be warranted. Agencies often incorporate voluntary consensus standards with additions or modifications to make the standard conform better to the agency’s particular regulatory needs. If the standard is incorporated by reference, such changes must be explained in the text of the regulation. This can make it more difficult to determine what the regulation actually requires. Such difficulties may be avoided by printing a modified version of the standard in the text of the regulation rather than incorporating by reference. If the agency uses only a small portion of a copyrighted standard, reprinting a modified version in the text of the regulation may be a noninfringing fair use. But if the agency is using all or a substantial portion of a standard, reprinting it with modifications in the text of

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47 See Bremer Report at 35-37.
49 See, e.g., 16 C.F.R. § 1219.2(b) (explaining modifications to incorporated ASTM standard for crib testing).
the regulation may not constitute a fair use. Guidance from OMB regarding how agencies can best navigate these legal issues and improve the clarity of incorporating regulations may be helpful.

IV. International Regulatory Cooperation

A second recommendation adopted at the December 2011 Plenary Session may be of interest to you in connection with the following inquiry:

- 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?

Recommendation 2011-6, International Regulatory Cooperation, deals with regulatory cooperation between United States agencies and foreign authorities, including their counterparts in other nations, international organizations, and standard-setting bodies. The recommendation urges agencies to examine their legal authority for cooperating with such foreign authorities and, where appropriate, to seek additional legal authorization to enable such interactions. It also sets forth a number of strategies agencies may wish to pursue in interacting with foreign authorities, and it urges agencies to ensure transparency in the process, apprising the public of interactions with foreign authorities and seeking public input on international cooperation efforts. OMB might consider these principles in crafting a possible supplement to the Circular.

V. Conclusion

We applaud your efforts to improve the implementation of Circular A-119 by issuing the RFI and engaging the public on these important and complex issues of federal policy. We believe that the Conference’s recent research and recommendations on incorporation by reference and international regulatory cooperation can be a significant resource to you as you work with federal agencies to implement federal standards policy and encourage international regulatory harmonization. We look forward to working with you and your staff as you move forward on these issues.

Sincerely,

Paul R. Verkuil
Chairman

Emily S. Bremer
Attorney Advisor

50 See Bremer Report at 15-20; see also Office of Legal Counsel, Dep’t of Justice, Whether and under what Circumstances Government Reproduction of copyrighted Materials Is a Noninfringing “Fair Use” under Section 107 of the Copyright Act of 1976 (1999).