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OFFICE OF MANAGEMENT AND BUDGET

Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

ACTION: Request for Information and Notice of public workshop

SUMMARY: The Office of Management and Budget (OMB) invites interested parties to provide input on current issues regarding Federal agencies' standards and conformity assessment related activities. Input is being sought to inform OMB's consideration of whether and how to supplement Circular A-119 (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities). In addition, OMB is announcing a public workshop at the Department of Commerce's National Institute of Standards and Technology (NIST) on May 15, 2012. A complementary NIST workshop, "Conformity Assessment: Approaches and Best Practices," will take place on April 11, 2012 to seek input from individuals on the planned update of *Guidance on Federal Conformity Assessment Activities*, issued by NIST in 2000. The NIST workshop was announced separately by NIST at <http://www.nist.gov/director/sco/ca-workshop-2012.cfm> (see also 77 FR 15719; March 16, 2012).

DATES: *Comments:* Comments are due on or before April 30, 2012.

Public workshop: In addition to providing written comments, interested parties are invited to attend the public workshop on May 15th. The workshop will include presentations from key government officials, industry, and experts on standards and conformity assessment issues, and time will be allotted for participant input and discussions. There is no registration fee for the workshop.

Registration: To gain access to the NIST campus, located at 100 Bureau Drive in Gaithersburg, MD, 20899, all participants must register in advance no later than 5 pm EST on May 8, 2012. Non-U.S. citizens must register no later than May 1, 2012. There will be no onsite registration. To register online, visit the “Register Now” link on the conference web site at https://www-s.nist.gov/CRS/conf_disclosure.cfm?conf_id=5262.

ADDRESSES: All comments should be submitted via <http://www.regulations.gov> or faxed at 202-395-5167. Please submit comments only and include your name, company name (if any), and cite “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities” in all correspondence. All comments received will be posted, without change or redaction, to www.regulations.gov, so commenters should not include information they do not wish to be posted (*e.g.*, personal or confidential business information).

FOR FUTURE INFORMATION CONTACT: Jasmeet Seehra, Office of Information and Regulatory Affairs, at jseehra@omb.eop.gov.

SUPPLEMENTARY INFORMATION: In the "National Technology Transfer and Advancement Act of 1995" (P.L. 104-113; hereinafter "the NTTAA"), Congress stated that Federal agencies "shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities," except when an agency determines that such use "is inconsistent with applicable law or otherwise impractical." As amended by Section 1115 of P.L. 107-107, Section 12(d) provides that:

(d) UTILIZATION OF CONSENSUS TECHNICAL STANDARDS BY FEDERAL AGENCIES; REPORTS.—

(1) IN GENERAL.—Except as provided in paragraph (3) of this subsection, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.

(2) CONSULTATION; PARTICIPATION.—In carrying out paragraph (1) of this subsection, Federal agencies and departments shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget

resources, participate with such bodies in the development of technical standards.

(3) EXCEPTION.—If compliance with paragraph (1) of this subsection is inconsistent with applicable law or otherwise impractical, a Federal agency or department may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies if the head of each such agency or department transmits to the Office of Management and Budget an explanation of the reasons for using such standards. Each year, beginning with fiscal year 1997, the Office of Management and Budget shall transmit to Congress and its committees a report summarizing all explanations received in the preceding year under this paragraph.

(4) EXPENSES OF GOVERNMENT PERSONNEL. - Section 5946 of title 5, United States Code, shall not apply with respect to any activity of an employee of a Federal agency or department that is determined by the head of that agency or department as being an activity undertaken in carrying out this subsection.

(5) DEFINITION OF TECHNICAL STANDARDS.—As used in this subsection, the term “technical standards” means performance based or

design-specific technical specifications and related management systems practices.

Section 12(d) is found as a “note” to 15 U.S.C. 272.

In response to the enactment of the NTTAA, OMB prepared a proposed set of revisions to Circular A-119 (entitled “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”) and issued a Federal Register notice seeking public comment on the proposed revisions. 61 FR 68312 (December 27, 1996). After consideration of the comments, OMB issued the final revision of the Circular. 63 FR 8546 (February 19, 1998). In the preamble to the final notice, OMB responded to the public comments and provided explanatory background regarding the revised Circular. A copy of the Circular is on OMB’s website at http://www.whitehouse.gov/omb/circulars_a119/.

The policies in the Circular are intended to reduce to a minimum the reliance by agencies on government-unique standards. In accordance with Section 12(d) of the NTTAA, Circular A-119 directs Federal agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. The Circular also provides guidance for agencies participating in the work of bodies that develop voluntary consensus standards and describes procedures for satisfying the NTTAA’s agency-reporting requirements. In addition, consistent with

Section 12(b) of the NTTAA, the Circular directs the Secretary of Commerce to issue guidance to agencies in order to coordinate conformity assessment activities.

On January 17, 2012, the Office of Information and Regulatory Affairs, the Office of Science and Technology Policy, and the United States Trade Representative built on the Circular and issued guidance on Federal engagement in standards activities to address national priorities.¹ We note more generally the requirements of Executive Order 13563, which emphasizes that our regulatory system “must protect public health, welfare, safety, and our environment while *promoting economic growth, innovation, competitiveness, and job creation*” (emphasis added), and which stresses the importance of public participation and of careful consideration of both benefits and costs.

Purpose: The purpose of this Request for Information (RFI) and related public workshop on May 15, 2012, is to allow interested stakeholders to provide input to OMB, NIST, Federal regulators and other relevant agencies on how the Federal government should address issues in standards and conformity assessment that have emerged or moved to the forefront since the Circular was promulgated in 1998. Such input could help improve U.S. agencies’ implementation of the NTTAA and the Circular.

In addition, input received through the RFI and during the workshop could be used to inform OMB’s consideration of whether and how to supplement Circular A-119 to provide additional or more specific guidance on standards and conformity assessment to agencies engaged in rulemaking, procurement, and other activities. Any such

¹ See http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08_1.pdf

supplemental guidance would be developed in conjunction with NIST's effort to update its conformity assessment guidelines, in order to ensure consistency between the two documents. The NIST conformity assessment guidelines are available at http://gsi.nist.gov/global/docs/FR_FedGuidanceCA.pdf. Additional information on the conformity assessment workshop objectives was provided by NIST in a separate Federal Register notice published on March 16, 2012 (77 FR 15719).

If OMB determines, based on the responses to the RFI, discussions at the workshops, and further consideration of the issues, that it would be useful to develop supplemental guidance for the Circular to address some or all of the issues raised, then OMB will publish a draft notice in the Federal Register at a subsequent date and request public comment.

In response to this RFI and at the workshop, OMB is interested in receiving input from interested stakeholders pertaining to one or more of the following issues relating to standards and conformity assessment, specifically with respect to how these issues may affect agencies engaged in rulemaking, procurement, and other activities.

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?

Standardization Activities. OMB A-119 does not establish a preference between consensus and non-consensus standards developed in the private sector. A limited set of foundational attributes of standardization activities are identified in the Circular, focusing on voluntary consensus standard activities. It may also be important to recognize the contributions of standardization activities that take place outside of the voluntary consensus process, in particular certain activities in emerging technology areas.

- 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.

Conformity Assessment. Circular A-119 directs the Secretary of Commerce to issue guidance to Federal agencies on conformity assessment. NIST issued such guidance in 2000 and plans to update the guidance.

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.

Protection of Copyright Associated With Standards. Standards themselves are considered to be intellectual property and are typically copyrighted by the standards

developing bodies that administer the process by which specific standards are developed and maintained. The rights of copyright holders are protected under U.S. law, and standards developers typically charge fees to access their copyrighted materials. Some parties have raised transparency concerns with respect to the availability of copyrighted materials in instances where standards are referenced or incorporated in regulation and compliance with such standards is mandatory.

In this respect, we take note of three recent developments relevant to this issue:

At its Plenary Session on December 8, 2011, the Administrative Conference of the United States (ACUS) considered and adopted a Recommendation on Incorporation by Reference, specifically addressing the place of voluntary consensus standards in that process and how to determine “reasonable availability.” <http://www.acus.gov/wp-content/uploads/downloads/2011/12/Recommendation-2011-5-Incorporation-by-Reference.pdf>.

Second, the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 (the Act) was signed into law on January 3, 2012 (P.L. 112-90). Section 24 of the Act created a new subsection (p) of Section 60102 of Title 49 of the U.S. Code. Section 60102(p) prohibits the Secretary of Transportation from issuing “guidance or a regulation” pursuant to Title 49 of the U.S. Code, Chapter 601 (pipeline safety) “that incorporates by reference any documents or portions thereof unless those documents or portions thereof

are made available to the public, free of charge, on an Internet Web site.” Section 60102(p) takes effect one year from the date of its enactment, i.e., January 3, 2013.

Third, the National Archives and Records Administration, Office of the Federal Register, recently published a petition for rulemaking received on February 13, 2012, to amend its regulations governing the approval of agency requests to incorporate material by reference into the Code of Federal Regulations, and requested public comment. 77 FR 11414 (February 27, 2012). OMB notes that the petition raises issues that are closely related to some of the issues discussed in this RFI and encourages interested stakeholders to provide comments in response to the petition.

Circular A-119 specifically contemplates incorporation by reference of voluntary consensus standards by Federal agencies, defining agency “use” of a voluntary consensus standard as “incorporation of a standard in whole, in part, or by reference for procurement purposes, and the inclusion of a standard in whole, in part, or by reference in regulation(s).” Circular A-119 also directs agencies to respect intellectual property rights that may exist in voluntary consensus standards that are incorporated into regulation by reference: “If a voluntary standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and any other similar obligations.”

Since passage of the NTTAA, major strides have been made by Federal agencies in their use of voluntary consensus standards. The NIST “Standards Incorporated by Reference

Database” includes thousands of such standards incorporated by reference in the CFR -- http://standards.gov/sibr/query/index.cfm?fuseaction=rsibr.total_regulatory_sibr.

- 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?

Voluntary Consensus Standards and Cost-Benefit Analysis. Standards developing bodies, including not-for-profit organizations, use a variety of cost-recovery models as part of their overall way of doing business. OMB believes that it may be helpful for the purposes of the Circular and for the evaluation of costs and benefits of significant regulatory actions pursuant to Executive Orders 12866 and 13563 for Federal agencies to have a basic understanding of the costs associated with the development of private sector standards, in addition to the purchase costs of standards. Similarly, agencies and the public should have an understanding of the overall resources and costs that would be

involved if Federal agencies were to develop government-unique standards. Both of these can be elements in determining when it is practical or impractical to incorporate a voluntary standard into regulation or otherwise adopt a standard in the course of carrying out an agency's mission, as compared to developing a government-unique standard.

- What resource and other costs are involved in the development and revision of voluntary standards?
- 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?
- How often do standards-developing bodies review and subsequently update standards? 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?

Using and Updating Standards in Regulation. Federal agencies have adopted various methods of using standards as a basis for regulation. They have also developed different approaches to updating standards that have been referenced or incorporated in regulations.

- 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)?
- 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?

OMB recognizes that changes in technology and the need for innovation can result in the updating of private sector standards in a turn-around time of two years or even less.

Where such standards are already incorporated into regulations, these changes can suggest a need to update the relevant regulations as well and, in some cases, can result in a need for regulated entities to purchase the newly updated standards on a fairly routine basis. In addition to the costs associated with the continuing purchase of such standards, rapid update cycles may make it difficult for the regulated public to understand the nature and significance of the changing regulations.

- 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?

- How should agencies determine the cost-effectiveness of issuing updated regulations in response to updated standards?
- 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?

Use of More Than One Standard or Conformity Assessment Procedure in a Regulation or Procurement Solicitation. OMB recognizes that, in some instances, it may be best, in terms of economic activity, if a regulation or procurement solicitation sets out a requirement that can be met by more than one standard and more than one conformity assessment procedure. In some cases, however, allowing the use of more than one standard or conformity assessment procedure may not be possible or meet the regulatory or procurement objective. For example, doing so may be precluded by statute, and an alternate standard or conformity assessment procedure may not provide an equivalent level of protection as the standard or conformity assessment procedure selected by the regulator.

- 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?

- 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?

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

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