

EXECUTIVE OFFICE OF THE PRESIDENT
Office of Management and Budget

OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

AGENCY: Office of Management and Budget, Executive Office of the President

ACTION: Final Revision of OMB Circular A-119

SUMMARY: The Office of Management and Budget (OMB) has revised Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" (hereinafter, Circular A-119, or, the Circular) in light of developments in regulation, standards, and conformity assessment since the Circular was last revised in 1998.

DATES: Effective upon publication

ADDRESSES: Direct any comments or inquiries to the Office of Information and Regulatory Affairs, Office of Management and Budget at CircularA-119@omb.eop.gov.

SUPPLEMENTARY INFORMATION:

- I. Existing OMB Circular A-119
- II. Discussion and Responses to Significant Comments
- III. Section-by-Section Discussion

Existing OMB Circular A-119. The vibrancy and effectiveness of the U.S. standards system in enabling innovation depends on continued private sector leadership and engagement. Our approach—reliance on private sector leadership, supplemented by Federal government contributions to discrete standardization processes as outlined in OMB Circular A-119—remains the primary strategy for government engagement in standards development.

The policies of Circular A-119 are intended to encourage Federal agencies to benefit from the expertise of the private sector, promote Federal agency participation in standards bodies to support the creation of standards that are useable by Federal agencies, and minimize reliance on government-unique standards where an existing standard would meet the Federal government's objective.

The National Technology Transfer and Advancement Act of 1995 (Public Law 104-113; hereinafter known as "the NTTAA") codified pre-existing policies on the development and use of voluntary consensus standards in OMB Circular A-119, established additional reporting requirements for agencies, and authorized the Department of Commerce's National Institute of Standards and Technology (NIST) to coordinate conformity assessment activities.

Revision of OMB Circular A-119. OMB is revising this Circular in light of developments in regulation, standards, and conformity assessment since the Circular was last revised in 1998. These revisions reflect the experience gained by U.S. agencies in implementing the Circular since 1998, and concluding and implementing U.S. trade agreements, as well as developments in domestic and

international regulatory, standards, and conformity assessment policies.

The revised Circular reflects and supports the regulatory policies and principles set out in relevant executive orders. OMB notes, in particular, the requirements of four executive orders, three of which were issued after 1998:

- Executive Order 12866 (“Regulatory Planning and Review”) states that regulations must be consistent with law; regulations must identify the nature and significance of the problem; agencies must identify and assess alternatives to address the problem along with the costs and benefits of each alternative; and the approach selected should maximize net benefits to society;
- Executive Order 13563 (“Improving Regulation and Regulatory Review”) emphasizes that the U.S. regulatory system “must protect public health, welfare, safety, and [the] environment while promoting economic growth, innovation, competitiveness, and job creation,” and stresses the importance of public participation and careful consideration of both benefits and costs;
- Executive Order 13609 (“Promoting International Regulatory Cooperation”) directs Federal agencies to better coordinate U.S. priorities and positions with respect to international regulatory cooperation efforts across U.S. Federal agencies. This includes promoting good regulatory practices both in the United States and internationally, as appropriate, and considering reforms that address unnecessary differences in regulatory requirements between the United States and its major trading partners; and
- Executive Order 13610 (“Identifying and Reducing Regulatory Burdens”) institutionalizes the retrospective review mechanism set out in Executive Order 13563 and calls on agencies to reduce the cumulative effects, including the cumulative burdens, of regulation.

In addition to the above Executive Orders, on January 17, 2012, OMB’s Office of Information and Regulatory Affairs (OIRA), the Office of Science and Technology Policy (OSTP), and the Office of the United States Trade Representative (USTR) released a Memorandum to Federal agencies on “Principles for Federal Engagement in Standards Activities to Address National Priorities” (see <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08>).

The revisions to Circular A-119 inform agencies of their statutory obligations in standards-setting activities. Specifically, 19 U.S.C. § 2532 provides that “[n]o Federal agency may engage in any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States” and specifies four requirements for agencies’ standards-related activities:

1. Ensuring that imported products are not treated less favorably than like domestic products or imported products from other countries;
2. Taking into consideration international standards – and basing standards upon them if appropriate;
3. Developing standards based on performance criteria rather than design criteria when appropriate; and
4. Ensuring foreign suppliers have access to conformity assessment procedures on the same

basis as other domestic and foreign suppliers of like products.

In order to gather relevant information for this revision, OMB published a Request for Information (RFI) in the Federal Register on March 30, 2012 (77 Fed. Reg. 19357) on “whether and how to supplement Circular A-119.” The notice also announced OMB would be holding a public workshop at NIST on May 15, 2012.

The RFI and public workshop allowed interested stakeholders to provide valuable input to OMB, NIST, Federal regulators, and other relevant agencies on how the Federal government should address regulatory, standards, and conformity assessment issues that have emerged or moved to the forefront since the Circular was last promulgated in 1998. OMB received approximately 70 comments from a wide range of stakeholders, including companies, trade associations, academics, public interest groups, standards developing bodies, conformity assessment bodies, and private citizens.¹

In response to those comments from 2012, OMB issued a Request for Comment on a Proposed Revision of OMB Circular A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,” on February 11, 2014 (79 Fed. Reg. 8207). OMB received over 80 comments from a wide range of stakeholders including companies and trade associations, academics, public interest groups, standards development bodies, conformity assessment bodies, and private citizens.²

Discussion and Responses to Significant Comments

Although some commenters were critical of specific aspects of the proposed revision, the majority of commenters expressed support for the overall revisions to the Circular and the approaches taken. The more substantive comments are summarized below, along with OMB’s responses.

While OMB carefully considered the proposals and concerns of all commenters, many comments were not germane, given the scope of the Circular. The purpose of the Circular is only to provide guidance on agency use of standards at a level that is practical and useable for all agencies.

For example, OMB received particularly detailed or individualized comments regarding conformity assessment requirements (OMB defers to NIST and its anticipated revisions to its Guidance on Federal Conformity Assessment), country-specific standards policy (OMB defers to USTR), and the publishing requirements for guidance and regulations for agencies (OMB defers to the Office of the Federal Register). The most current version of NIST’s conformity assessment guidance is available at <http://www.nist.gov/standardsgov/>.

Based on OMB’s consideration and responses to these public comments, as well as developments in regulatory, standards, conformity assessment, and trade policy described above, the revised Circular A-119:

¹ Public comments submitted in response to OMB’s RFI can be found at <http://www.regulations.gov/#!documentDetail;D=OMB-2012-0003-0001>.

² Public comments submitted in response to the Proposed Revisions can be found at <http://www.regulations.gov/#!documentDetail;D=OMB-2014-0001-0001>.

- provides additional guidance for agency participation in standards development activities, including with respect to serving on standards technical committees as well as the boards of standards developing bodies;
- provides factors for agencies to consider when evaluating whether to use a standard to meet agency needs;
- strengthens the role of agency Standards Executives to encourage better internal coordination and training on standards;
- updates the provisions on how the U.S. Government manages and reports on the development and use of standards;
- sets out factors for agencies to consider when assessing the effectiveness of conformity assessment options and determining the type(s) of conformity assessment program(s) to employ;
- provides guidance to agencies on how they should implement provisions of the Circular in their rulemakings and guidance documents;
- encourages each agency to alert the public through the Federal Register or the agency's webpage when the agency is considering whether to participate in the standards development process of a particular body. Such notification would give the public notice that the agency may use the resulting standard in support of significant regulatory action, international regulatory cooperation activities or to otherwise address issues of national priority;
- provides guidance to agencies on what factors to consider when incorporating standards by reference in regulation;
- requires agencies to utilize the retrospective review mechanism set out in Executive Orders 13563 and 13610, to ensure, among other things, that regulations incorporating standards by reference are updated on a timely basis;
- encourages agencies to work together to reference the same version of standards in regulation and procurements and coordinate on conformity assessment requirements, where feasible;
- incorporates references to trade-related statutory obligations on standards-related measures and directs Federal agencies to consult with USTR on how to comply with international obligations with regard to standards, technical regulations, and conformity assessment; and
- maintains a strong preference for using voluntary consensus standards over government-unique standards in Federal regulation and procurement.

The Circular does not preclude the use of standards other than voluntary consensus standards in rulemaking, procurement or other program activities in cases where: voluntary consensus standards do not exist or where use of existing voluntary consensus standards would be inconsistent with law or otherwise impractical, including where use of a voluntary consensus standard would not be as effective at meeting the agency's regulatory, procurement, or program needs. The Circular also recommends that the agency consider allowing the use of other standards as alternative means for complying with agency regulatory, procurement, or program requirements based on voluntary consensus standards where such other standards are also found to be suitable under the agency's analysis.

Promoting Voluntary Consensus Standards: Comments received overwhelmingly supported a continued preference for Federal agencies' use of voluntary consensus standards in lieu of developing their own standards, in line with the existing Circular and the requirements of Section 12(d) of the NTTAA.

There was also significant support among the commenters for providing Federal agencies the flexibility to choose among standards developed in the private sector, particularly standards developed for emerging technologies that may or may not precisely follow the traditional voluntary consensus standards development process. As such, and in order for agencies to choose the best standards for their mission needs, this policy maintains flexibility for agencies to use standards developed in the private sector that best meet agencies' regulatory, procurement, or program needs, whether or not those standards are developed by voluntary consensus standards bodies. To assist agencies in deciding which standards to use, the Circular identifies factors to consider including, among others, the effectiveness and suitability of the standard for meeting agency regulatory, procurement, or program needs, the extent to which a standard meets the definition of a "voluntary consensus standard," and whether the standard is reasonably available.

Along these lines, many respondents provided valuable comments regarding the revised definitions in the Circular. The revised Circular incorporates a number of these suggestions intended to clarify the qualifications for a voluntary consensus standards development process.

Several commenters asked for clarification on how the Circular addresses "leadership standards" (a term used to describe standards that exceed minimum threshold requirements). The Circular does not view leadership standards as different from other types of standards. As always, the Circular will indicate a preference for voluntary consensus standards over government-unique standards, and agencies may build on those standards as necessary to fulfill their obligations.

In addition, the Circular does not indicate a preference for one type of conformity assessment procedure (*e.g.*, supplier's declaration of conformity, third-party certification) over others. Agencies must have flexibility to determine the most appropriate conformity assessment program to meet agency needs, consistent with law (see Section 7 of the Circular).

OMB further notes the Circular serves as a floor—not a ceiling—for when and how an agency should use standards. Agencies can, and in many cases will, have additional guidance for agency components or programs based on mission needs and other factors.

Updating Considerations for Conformity Assessment: Commenters who addressed this issue

expressed moderate to very strong support for OMB providing guidance to agencies with respect to conformity assessment. Commenters recommended that the Circular encourage agencies to rely on private sector conformity assessment activities; provide criteria for agencies to utilize when determining how to best meet their needs; and help agencies comply with relevant international obligations regarding conformity assessment. Since the Circular was last published in 1998, the evolution of an increasingly globalized marketplace has induced growth in the scope and importance of conformity assessment. Global supply and distribution chains may mean a greater number of variables for agencies to assess and more complex logistics to account for when conducting assessments of conformity. Accordingly, the revised Circular encourages agencies to consider leveraging existing private sector conformity assessment activities wherever consistent with law and mission.

Ensuring Compliance with International Obligations: Numerous commenters on the RFI and the Proposed Revision support OMB guidance to agencies on how to comply with relevant international obligations, including the WTO Agreement on Technical Barriers to Trade and other trade agreements. Accordingly, OMB in coordination with USTR, which has statutory authority in this area pursuant to 19 U.S.C. § 2171 & 2541, has updated the Circular to reflect this need.

The Circular directs Federal agencies to consult with USTR on how to comply with international trade obligations relating to standards, technical regulations and conformity assessment, including those codified at 19 U.S.C. § 2531. In addition, the revisions direct Federal agencies to consult with the State Department, to the extent international obligations other than trade obligations may be implicated. With respect to the Federal government's formulation of international policies on standards and conformity assessment, regulation, and trade, the revisions would encourage, consistent with Executive Order 13609, greater coordination between the Interagency Committee on Standards Policy, the Regulatory Working Group, the Trade Policy Staff Committee and its subcommittees, and any other relevant interagency groups or committees.

Several commenters to the Proposed Revision voiced concerns over specific issues regarding reciprocity of standards use or recognition by other countries or trade unions. Since these comments fall outside the Circular's scope of providing guidance to agencies about the Federal government's use of standards, OMB encourages parties to address such concerns directly with USTR.

Agency Considerations for Incorporation By Reference: A wide variety of commenters representing public interest groups, individuals, citizens, standards development organizations (SDOs), and companies provided comment on the question of incorporation by reference. Some comments advocated for the maintenance of current law and policy, noting many SDOs already freely publish their standards online in read-only formats, while others urged all standards incorporated by reference be made freely available on the Internet.

The majority of these comments turned on particular interpretations of the "reasonably available" requirement in the Freedom of Information Act (FOIA), which requires that standards incorporated into regulation by reference be made reasonably available to the "class of persons affected." As noted in the Draft Revision, it is not within the purview of the Circular to define reasonable availability. Rather, it is by statute the responsibility of the Office of the Federal Register (OFR) to

address this issue.³ OFR revised its regulations on incorporation by reference in a final rule published November 7, 2014 at 79 Fed. Reg. 66267. In that rule, OFR balanced its statutory obligations regarding reasonable availability of the standards with: (1) U.S. copyright law, (2) U.S. international trade obligations, and (3) agencies' ability to substantively regulate under their authorizing statutes. To address all of these obligations, the OFR rule required that agencies discuss how materials incorporated by reference were made available to parties (and where those materials are located) and to provide a summary of those materials in the preambles of their rulemaking documents. These requirements oblige agencies to provide more information on how they make material incorporated by reference available and a summary of the material, so readers can, if they like, find and review the standards.

The revised Circular provides a non-exclusive set of factors to help agencies assess the availability of specific standards for particular regulatory contexts. These considerations may therefore inform the larger agency decision of whether to request approval for incorporation of those standards in regulation. As explained in the revised Circular, the basis of these factors for consideration is the Administrative Conference of the United States (ACUS) Recommendation 2011-5, *Incorporation by Reference*, 77 Fed. Reg. 2257 (January 17, 2012).⁴ ACUS adopted the Recommendation through a consensus process in which a broad array of stakeholders participated, including standards developing bodies, academics, public interest groups, regulators, and industry. Based on the comments, the revised Circular bases its policy on the ACUS Recommendation, modified to enhance clarity.

In general, the factors based on the ACUS Recommendation were well received, particularly the provision by SDOs of read-only access to their standards. OMB received numerous comments from SDOs highlighting the widespread existence of such a practice. In response to comments, OMB amended the Circular to recommend that agencies also consider the ease of access, registration, and navigation on those sites. OMB also received many comments on the option to provide a “freely available, non-technical summary.” Some commenters expressed the need for greater clarity as to what this might entail. Other commenters questioned the feasibility or utility of a non-technical summary for lengthy, complex, and/or highly technical standards. To clarify, OMB modified this factor to encourage agency discretion and collaboration with SDOs to enhance practical, impactful improvements to availability on a case-by-case basis.

Additionally, OMB made clarifications emphasizing that: (1) the absence of one or more of such factors should not prevent an agency from using a particular standard; (2) agencies should work closely with SDOs to determine appropriate access to the standards for stakeholders; and (3) agencies should explain the reasoning for their choice of standard, including an explanation of how that standard may be accessed by stakeholders.

Strengthening Guidance for Agency Participation in the Standards Development Process and the Role of Agency Standards Executives: Commenters expressed wide support for increased guidance for agency participation, including in standards development voting and standards body governance. As a floor, the revised Circular encourages agencies to participate fully in the standards development process—through voting as well as standards body governance—as equal

³ See 5 U.S.C. §552(a)(1).

⁴ See <http://www.gpo.gov/fdsys/pkg/FR-2012-01-17/html/2012-621.htm>.

parties. OMB, however, defers to individual agencies on their policies for determining to what extent and under what circumstances agency representatives are authorized to engage in particular activities, based on agency requirements and priorities. Additionally, the Circular encourages strong coordination by Agency Standards Executives (ASEs) to allow for effective use of agency resources in the standards development process.

In response to requests for greater notice by agencies of their involvement in the standards development process, the revised Circular provides guidance to agencies on how they should discuss implementation of the Circular in their rulemakings and guidance documents. The revised Circular also encourages each agency to alert the public through the Federal Register and/or its webpage when the agency is considering whether to participate in the standards development process of a particular body, with the intention of using the resulting standard to support significant regulatory action, promote international regulatory cooperation activities, or address issues of national priority. Many of the comments regarding agency participation included agency-specific details that are beyond the scope of the Circular. OMB encourages commenters to contact agencies directly with feedback regarding their voting, travel, or any other policies.

Ensuring the Timely Updating of Regulations and Other Agency Materials Incorporating Standards: Many commenters expressed views on whether the most current version of a standard should always be the one used by an agency. OMB recognizes that agencies may have good reasons for not using the most recent version of a standard. For example, if use of a revised standard significantly increases compliance costs that are not justified by the benefits of using the standard, the agency should be free to decline to adopt it.

To ensure the timely updating of standards, the revised Circular requires agencies to utilize the retrospective review mechanism set out in Executive Orders 13563 and 13610. Many commenters voiced strong support for such periodic review, with many agreeing with the suggested three-to-five year review timeframe. OMB believes the use of retrospective review, as outlined by Executive Orders 13563 and 13610, can help ensure (1) the optimal version of a standard is being used by agencies; (2) agencies minimize the impact of conflicting requirements on their shared regulated entities due to references to different versions of standards; and (3), more broadly, the need for the standard and the regulation referencing it still exists.

Additionally, in response to comments, OMB encourages agencies to work closely with SDOs to ensure agencies are aware of, and thus able to consider, updates and alternatives to existing standards. OMB also encourages agencies to work together to reference the same version of standards in regulation and procurements, consistent with statute and agency mission and objectives.

OMB also received comments on specific provisions of the Proposed Circular. Below are the significant comments OMB received and our responses.

Section-by-Section Discussion

Proposed Section 3e—Definition of Voluntary Consensus Standard. Final Section 2d.

Several clarifications have been made to the definition to increase its technical accuracy (no substantive changes are intended). A commenter suggested that the definition, which states that a voluntary consensus standard needs to be either developed or adopted by a voluntary consensus standards body, be clarified to make clear that the standard at issue was developed or adopted through the use of a voluntary consensus standards development process. OMB agrees and has clarified the final Circular accordingly.

Several other clarifications have been made. We have clarified that it is the voluntary consensus standard bodies, not the standards, which have intellectual property policies. We have also clarified that the Reasonable and Non-discriminatory (RAND) license obligations extend to “implementers of the standard” (this replaces the term “all interested parties,” which is a term of art in the rulemaking context).

Lastly, the Federal government does not make a distinction between standards bodies based on where they are domiciled, but rather with respect to the attributes that characterize their processes for standards development. Thus, we have deleted the phrase “both domestic and international.” This edit is not intended to make a change in terms of coverage (the Circular includes a discussion of “international standards” at Section 5h and 5i).

Proposed Section 3f(i)—Definition of Openness. Final Section 2e(i).

Many commenters expressed concern with the potential burden of the “at all stages” part of the clause requiring SDOs to provide meaningful opportunities to participate. Several commenters noted that, as a practical matter, this need is already covered by the requirements for transparent procedures or processes and for due process. In response, OMB modified the final Circular to omit the reference to “at all stages” and clarify that opportunities to participate in standards development be on a non-discriminatory basis.

Proposed Section 3f(ii)—Definition of Balance of Representation. Final Section 2e(ii)—Definition of Balance.

Several commenters questioned the utility of changing this element from “balance of interest,” found in the current version of Circular A-119 as well as the American National Standards Institute’s (ANSI) Essential Requirements, to “balance of representation.” OMB intended for the definition to be consistent with the concepts of both those documents and has simplified the term to “balance” to avoid confusion and to allow for flexibility in how balance is determined during the consensus phase of the development or adoption of the standard.

Additionally, some commenters expressed concern with the ambiguity of “sectors” in this definition. Others commented that a key objective of “balance” is preventing a single interest from dominating the decision-making process. OMB agrees and modified the final Circular, adapting suggested insertions to the text of the definition.

Proposed Section 3f(iii)—Definition of Due Process. Final Section 2e(iii).

Several commenters expressed concern with the burden and practicality of requiring “full access” to the views and objections of other participants in standards development. Commenters noted the risks of micromanagement and unnecessary overreach. OMB’s intention is to ensure an adequate record of proceedings for the purpose of resolving objections and appeals, so we have modified the final Circular to reflect this intent.

Proposed Section 6e—When deciding to use a standard, what are some of the factors my agency should consider? Final Section 5a.

Several commenters expressed a desire for greater clarity in the relationship between agency missions and the preference for voluntary consensus standards over government-unique standards. OMB agrees, and therefore the Circular maintains the preference for voluntary consensus standards, per the NTTAA, while still maintaining flexibility for agencies to best meet their missions.

Additionally, some commenters highlighted the utility of considering the extent to which a standard is already used by a Federal agency, by State and local governments, as well as the prevalence of the standard in the national and international marketplace. These are important considerations precisely aligned with Executive Orders 13563, 13609, and 13610, discussed above. Accordingly, OMB agrees, and modified the Circular to include these considerations.

Proposed Section 4g—How should my agency determine whether a voluntary standard is “reasonably available” in a regulatory or non-regulatory context? Final Section 5f -- What factors should my agency consider to aid the determination of whether a standard is “reasonably available” in a regulatory or non-regulatory context?

In general, the factors based on the ACUS Recommendation were well received, particularly SDO provision of read-only access to standards. OMB received numerous comments from SDOs noting they already provide such access. One commenter, however, brought to OMB’s attention the disparate capabilities and requirements of various read-only standards websites. OMB agrees that this should be a consideration, and has amended the text to recommend agencies also consider the ease of access, registration, and navigation on those websites.

As referenced above, OMB also received many comments on the option to provide a “freely available, non-technical summary.” Some commenters expressed the need for greater clarity as to what this might entail. Other commenters questioned the feasibility or utility of providing a non-technical summary for lengthy, complex, and highly technical standards. To clarify, OMB modified this factor and potential option to encourage agency discretion and cooperation with SDOs to enhance practical, impactful improvements to availability on a case-by-case basis.

Additionally, in response to several comments asking for greater agency consideration of the accessibility of standards incorporated by reference, OMB revised the Circular to recommend that agencies provide, in the preamble of a Notice of Proposed Rulemaking (NPRM) or final rule or guidance document, an explanation of the incorporated materials;

how such incorporated standards may be accessed; and how the agency's incorporation by reference of the standard would further the agency's regulatory objective.

Proposed Section 7—What is the Policy for Federal Participation in Voluntary Standards Bodies?
Final Section 6 -- What is the Policy for Federal participation in Voluntary Consensus Standards Bodies?

Several commenters questioned the reformatting of this section from the existing Circular, specifically the absence of explicit authorization to provide "direct financial support" to standards development activities. Many agencies do so, consistent with applicable law, and here OMB defers to agency policy. To provide agencies with flexibility to meet their missions, the Circular maintains the existing language.

Proposed Section 8a—What considerations should my agency make when it is determining the type of conformity assessment procedure(s) to use? Final Section 7a—What considerations should my agency make when it is addressing the need for conformity assessment?

In response to comments, OMB simplified this section. OMB has incorporated the previous Section 8a, "Should my agency consider relying on private sector conformity assessment activities in conjunction with, or where appropriate, in lieu of governmental conformity assessment?" into one question which is now Section 7a, "What considerations should my agency make when it is addressing the need for conformity assessment?"

Additionally several commenters expressed concern over the apparent distinction between using "international conformity assessment schemes" or "private sector conformity assessment activities" as was phrased in the proposed revision. OMB agrees that such international conformity assessment schemes are just one example of private sector conformity assessment activity, and modified the Circular accordingly.

Accordingly, OMB Circular A-119 is revised as set forth below.

Howard Shelanski

Administrator, Office of Information and Regulatory Affairs

EXECUTIVE OFFICE OF THE PRESIDENT
Office of Management and Budget

Washington D.C. 20503

[insert date]

Circular No. A-119

Revised

CIRCULAR NO. A-119, Revised

TO THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

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

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BACKGROUND

1. What is the Purpose of this Circular?

This Circular establishes policies to improve the internal management of the Executive Branch with respect to the U.S. Government's role in the development and use of standards and conformity assessment. Consistent with section 12(d) of P.L. 104-113, the "National Technology Transfer and Advancement Act of 1995," as amended (hereinafter "the NTTAA"), and U.S. Government executive orders, this Circular directs agencies to use standards developed or adopted by voluntary consensus standards bodies rather than government-unique standards, except where inconsistent with applicable law or otherwise impractical. The policies in this Circular are intended to facilitate agencies' compliance with obligations under U.S. trade statutes and trade agreements. U.S. Federal law (19 U.S.C. § 2532) specifically prohibits any U.S. Government agency from engaging in standards-related activities that create unnecessary obstacles to the foreign commerce of the United States.

This Circular provides guidance for agencies participating in the work of voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements of the NTTAA. The policies in this Circular are intended to minimize the reliance by agencies on government-unique standards. The Circular also provides policy guidance to agencies on the use of conformity assessment in procurement, regulatory, and program activities. This Circular replaces Office of Management and Budget (OMB) Circular No. A-119, dated February 10, 1998.

Many voluntary consensus standards are appropriate or adaptable for the Federal government's purposes. The use of such standards, whenever practicable and appropriate, is intended to achieve the following goals:

- (i) eliminating the cost to the Federal government of developing its own standards and decreasing the cost of goods procured and the burden of complying with agency regulation;
- (ii) providing incentives and opportunities to establish standards that serve national needs, encouraging long-term growth for U.S. enterprises and promoting efficiency, economic competition, and trade; and
- (iii) furthering the reliance upon private sector expertise to supply the Federal government with cost-efficient goods and services.

This Circular will also help agencies meet the five fundamental strategic objectives for Federal engagement in standards activities set out in Memorandum M-12-08, "Principles for Federal Engagement in Standards Activities to Address National Priorities" (http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08_1.pdf), which was issued on January 17, 2012.

While M-12-08 applies to Federal engagement in standards activities in those exceptional circumstances where the U.S. Government is playing a leading or convening role, OMB believes that the objectives are generally applicable to Federal engagement in standards and conformity assessment activities, absent contrary statutory requirements.

In addition, the Circular seeks to support efforts by the Federal government to ensure that:

- a. the benefits of regulations justify their costs, consistent with Executive Orders 12866, “Regulatory Planning and Review,” and 13563, “Improving Regulation and Regulatory Review,” and OMB Circular A-4, “Regulatory Analysis”;
- b. agencies modify, streamline, expand, or repeal regulations that may be outmoded, ineffective, insufficient, or excessively burdensome through the retrospective review process, consistent with Executive Orders 13563 and 13610, “Identifying and Reducing Regulatory Burdens”;
- c. agencies work with their regulatory counterparts in other countries to address common health, safety, labor, security, or environmental issues, as well as unnecessary differences between the regulatory approaches of U.S. agencies and those of their foreign counterparts that may impair economic growth, innovation, competitiveness, and job creation, consistent with Executive Order 13609, “Promoting International Regulatory Cooperation”; and
- d. agencies consider the cumulative effects, including the cumulative burdens, of regulation, consistent with Executive Order 13610.

DEFINITIONS

2. What is a Standard?

- a. The term “standard,” or “technical standard,” (hereinafter “standard”) as cited in the NTTAA, includes all of the following:
 - (i) common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices;
 - (ii) the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, designs, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; formats for information and communication exchange; or descriptions of fit and measurements of size or strength; and
 - (iii) terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process, or production method.
- b. The term "standard" does not include the following:
 - (i) professional standards of personal conduct; or
 - (ii) institutional codes of ethics.

- c. “Government-unique standard” is a standard developed by and for use by the Federal government in its regulations, procurements, or other program areas specifically for government use (*i.e.*, it is not generally used by the private sector unless required by regulation, procurement, or program participation). The standard was not developed as a voluntary consensus standard as described in Sections 2d and 2e.
- d. “Voluntary consensus standard” is a type of standard developed or adopted by voluntary consensus standards bodies, through the use of a voluntary consensus standards development process as described in Section 2e. These bodies often have intellectual property rights (IPR) policies that include provisions requiring that owners of relevant patented technology incorporated into a standard make that intellectual property available to implementers of the standard on non-discriminatory and royalty-free or reasonable royalty terms (and to bind subsequent owners of standards essential patents to the same terms). In order to qualify as a “voluntary consensus standard” for the purposes of this Circular, a standard that includes patented technology needs to be governed by such policies, which should be easily accessible, set out clear rules governing the disclosure and licensing of the relevant intellectual property, and take into account the interests of all stakeholders, including the IPR holders and those seeking to implement the standard.
- e. “Voluntary consensus standards body” is a type of association, organization, or technical society that plans, develops, establishes, or coordinates voluntary consensus standards using a voluntary consensus standards development process that includes the following attributes or elements:
 - (i) Openness: The procedures or processes used are open to interested parties. Such parties are provided meaningful opportunities to participate in standards development on a non-discriminatory basis. The procedures or processes for participating in standards development and for developing the standard are transparent.
 - (ii) Balance: The standards development process should be balanced. Specifically, there should be meaningful involvement from a broad range of parties, with no single interest dominating the decision-making.
 - (iii) Due process: Due process shall include documented and publically available policies and procedures, adequate notice of meetings and standards development, sufficient time to review drafts and prepare views and objections, access to views and objections of other participants, and a fair and impartial process for resolving conflicting views.
 - (iv) Appeals process: An appeals process shall be available for the impartial handling of procedural appeals.
 - (v) Consensus: Consensus is defined as general agreement, but not necessarily unanimity. During the development of consensus, comments and objections are considered using fair, impartial, open, and transparent processes.

See Section 5h of this Circular for a discussion of “international standards.”

3. What is Conformity Assessment?

Conformity assessment” is a demonstration, whether directly or indirectly, that specified requirements relating to a product, process, system, person, or body are fulfilled. Conformity assessment includes sampling and testing, inspection, supplier’s declaration of conformity, certification, and management system assessment and registration. Conformity assessment also includes accreditation of the competence of those activities.

POLICY

4. To Whom Does This Policy Apply?

This Circular applies to all agencies and agency representatives who use standards or conformity assessment and/or participate in the development of standards. “Agency” means any executive department, independent commission, board, bureau, office, government-owned or controlled corporation, or other establishment of the Federal government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding the use of voluntary consensus standards. It does not include the Legislative or Judicial branches of the Federal government.

5. What is the Policy for Federal Use of Standards?

Consistent with Section 12 (d)(1) of the NTTAA, all Federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. In these circumstances, your agency must submit a report describing the reason(s) for its use of government-unique standards in lieu of voluntary consensus standards as explained in Sections 9-11.

a. When deciding to use a standard, what are some of the factors my agency should consider?

- (i) In evaluating whether to use a standard, which should be done on a case-by-case basis, an agency should consider the following factors, where applicable:
 - (1) Whether the standard is effective and otherwise suitable for meeting agency regulatory, procurement, or program needs, including as applicable:
 - (a) the nature of the agency’s statutory mandate and the consistency of the standard with that mandate;
 - (b) the level of protection the standard provides or is expected to provide for public health, welfare, safety, and the environment;
 - (c) the clarity and detail of the standard's language, as the wording of a standard may contain too much detail as well as too little;

- (d) the costs and benefits of implementing other available standards that may also meet the agency's needs;
 - (e) the costs and benefits to the Federal government and the regulated public of the agency developing its own standard;
 - (f) the ongoing use of the standard by other agencies for the same or a similar requirement, the use of which in a particular instance would increase consistency across the Federal government;
 - (g) the ongoing use of the standard by State and local governments for the same or a similar requirement, the use of which in a particular instance would increase consistency across jurisdictions;
 - (h) the prevalence of the use of the standard in the national and international marketplaces;
 - (i) the problems addressed by the standard and changes in the state of knowledge and technology since the standard was prepared or last revised;
 - (j) the extent to which the standard establishes performance rather than design criteria, where feasible;
 - (k) the ability of small- and medium-sized enterprises (SMEs) to comply with the standard; and
 - (l) the agency's ability to use, and enforce compliance with, the standard in its regulatory process.
- (2) The extent to which, when preparing the standard, the standards body reflected the attributes of a voluntary consensus standards body set out in Section 2e of the Circular. The procedures related to these attributes (*e.g.*, openness, balance, due process, appeals process, and consensus) should be easily accessible, clear and unambiguous.
- (3) The extent to which the standard is an international standard (see Section 5h).
- (4) Any barriers to membership and participation in the standards development process, given that fee structures, modes of participation, and other factors can impact the ability of SMEs, public interest groups, and the general public to participate.
- (5) Whether the standard is "reasonably available." See Section 5f of the Circular for additional information.
- (6) The standards maintenance process used by the relevant standards developing body or bodies.
- (ii) If an agency is proposing to use a standard in a proposed or final rulemaking, the agency must comply with the "Principles of Regulation" (enumerated in Section 1(b) of Executive Order 12866, "Regulatory Planning and Review"), the analytical requirements of other relevant executive orders, and other documents as applicable, including those described in Section 1 of the Circular.
- (iii) As a general matter, standards being considered for use in regulation that specify

nomenclature, basic reference units, or methods of measurement or testing, and that are primarily empirical in their formulation, will ordinarily warrant less scrutiny by an agency than standards that embody factors that are less objective.

- (iv) An agency should, to the extent permitted by law, take account of the effect of using the standard on the economy, and of applicable Federal laws and policies, including laws and regulations relating to antitrust, national security, small business, product safety, environment, metrication, technology development, international trade, intellectual property and copyright, privacy and security, and conflicts of interest.
- (v) An agency should take into consideration the standards developer's intellectual property rights (IPR) policies. Many standards developing bodies have policies requiring participating IPR holders to commit to license any relevant patented technology incorporated into a standard on non-discriminatory and royalty-free or reasonable royalty terms and to bind subsequent owners of standards-essential patents to the same terms. Such policies should be easily accessible, set out clear rules governing the disclosure and licensing of the relevant IPR, and take into account the interests of all stakeholders, including the IPR holders and those seeking to implement the standard.

b. Does this policy establish a preference between voluntary consensus standards and other types of standards? Consistent with Section 12(d)(1) of the NTTAA, this policy establishes a preference for the use of voluntary consensus standards in lieu of government-unique standards. The Circular does not preclude the use of other standards in rulemaking, procurement, or other program activities in cases where voluntary consensus standards do not exist or use of existing voluntary consensus standards would be inconsistent with law or otherwise impractical, including where use of a voluntary consensus standard would not be as effective at meeting the agency's regulatory, procurement or program needs. The Circular also recommends that the agency consider allowing the use of other standards as alternative means for complying with agency regulatory, procurement, or program requirements that incorporate voluntary consensus standards, where such other standards are also found to be suitable under the agency's analysis. See Section 51 concerning the selection of multiple standards.

c. When must my agency use voluntary consensus standards? Your agency must use voluntary consensus standards in its regulatory, procurement, and program activities in lieu of government-unique standards, unless use of such standards would be inconsistent with applicable law or otherwise impractical. In all cases, your agency has the discretion to decline to use existing voluntary consensus standards if your agency determines that such standards are inconsistent with applicable law or otherwise impractical, and instead to use a government-unique standard or other standard.

In addition to consideration of voluntary consensus standards, this Circular recognizes the contributions of standardization activities that take place outside of the voluntary consensus standards process. Therefore, in instances where use of voluntary consensus standards would be inconsistent with applicable law or otherwise impracticable (*e.g.*, no voluntary consensus standard would be effective in meeting agency regulatory, procurement, or

program needs), agencies should consider, to the extent consistent with applicable law – as an alternative to using a government-unique standard – other standards that meet the agency’s regulatory, procurement or program needs, deliver favorable technical and economic outcomes (such as improved interoperability) and are widely utilized in the marketplace.

In those circumstances where an agency elects to use or develop a government-unique standard in lieu of using a voluntary consensus standard, Section 12(d) of the NTTAA requires the agency to submit a report describing the reason(s) to OMB. Under the Circular, this report is submitted to OMB through the National Institute of Standards and Technology (NIST). For more information on reporting, see Sections 9 -11 of this Circular.

- (i) “Use” means incorporation of a standard in whole, in part, or by reference for procurement purposes; inclusion of a standard in whole, in part, or by reference in regulation(s); or inclusion of a standard in whole, in part, or by reference in other mission-related activities.
- (ii) “Impractical” includes circumstances in which such use would fail to serve the agency's regulatory, procurement, or program needs; be infeasible; be inadequate, ineffectual, inefficient, or inconsistent with the agency mission or the goals of using voluntary consensus standards; be inconsistent with a provision of law; or impose more burdens, or be less useful, than the use of another standard.

d. What if no voluntary consensus standard exists? In cases where no suitable voluntary consensus standards exist, an agency may use suitable standards that are not developed by voluntary consensus bodies. In addition, an agency may develop its own standards or use other government-unique standards, solicit interest from qualified standards development organizations for development of a standard, or develop a standard utilizing the process principles outlined in Section 2e of the Circular. As explained above (see Section 5c of the Circular), Section 12(d) of the NTTAA provides that an agency may use a government-unique standard in lieu of a voluntary consensus standard if the use of a voluntary consensus standard would be inconsistent with applicable law or otherwise impractical. In such cases, the agency must file the statutorily required report (see Section 10).

e. Should my agency give preference to performance standards? Yes. Pursuant to Section 1(b)(8) of Executive Order 12866 and 19 U.S.C. § 2532(3), your agency should give preference to performance standards where feasible and appropriate. The term “performance standard” refers to a standard that states requirements in terms of required results, but without stating the methods for achieving the required results. A performance standard may define the functional requirements for an item, operational requirements, and/or interface and interchangeability characteristics. A prescriptive standard, by contrast, may specify design requirements, such as materials to be used, how a requirement is to be achieved, or how an item is to be fabricated or constructed. It is important to recognize that, in many instances, a standard may contain both performance and prescriptive elements. In such cases, agencies should select standards that provide the most flexibility for achieving the desired results. In most instances, these will be standards that rely more heavily on performance-based criteria.

f. What factors should my agency consider to aid the determination of whether a standard

is “reasonably available” in a regulatory or non-regulatory context? In determining whether a standard is “reasonably available” to regulated and other interested parties, agencies should take into account the following factors, given that reasonable availability is context-specific. The absence of one or more of these factors alone should not be used as a basis for an agency decision not to use the standard. This section shall also be applied in a manner consistent with U.S. international obligations to use relevant international standards (see Section 5h of the Circular); the “Principles of Regulation” (enumerated in Section 1(b) of Executive Order 12866); and the need to “protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation” (see Section 1 of Executive Order 13563).

Factors to consider include:

- (i) whether the standards developer is willing to make read-only access to the standard available for free on its website during the comment period to facilitate more effective access, because access may be necessary during rulemaking to make public participation in the rulemaking process effective;
- (ii) the cost to regulated and other interested parties to access a copy of the material, including the cumulative cost to obtain incorporated materials, and their ability to bear the costs of accessing such materials in a particular context;
- (iii) the extent particular access is needed to achieve agency policy or to subject the effectiveness of agency programs to public scrutiny; and
- (iv) whether the standards developer can provide a summary that explains the content of the standard in a way that meets agency needs and is understandable to a member of the public who lacks relevant technical expertise.

When considering incorporation by reference, agencies should include in the preamble of an NPRM, final rule, or guidance document an explanation of the incorporated materials, and how the agency’s incorporation by reference of the standard would further the agency’s regulatory objective (see 79 FR 66267 published November 7, 2014 entitled Incorporation by Reference).

If an agency incorporates by reference material that is already freely available, the agency should ensure that the material is available electronically in a location where regulated and other interested parties will be able to find it easily by, for example, providing a link to the website of the standards body. If an agency incorporates by reference material that is copyrighted or otherwise subject to legal protection and not freely available, the agency should work with the relevant standards developer to promote the availability of the materials, consistent with applicable law, such as through the use of technological solutions, low-cost-publication, or other appropriate means, while respecting the copyright owner’s interest in protecting its intellectual property. To this end, the agency should explain, in the preamble of an NPRM, final rule, or guidance document how such incorporated standards may be accessed consistent with OFR’s regulations in 1 CFR Part 51.

- g. How should my agency reference standards?** Where your agency seeks to incorporate a standard by reference, your agency should reference the standard, along with sources from

which a copy of the standard may be obtained, in relevant publications, regulations, and related internal documents. The Office of the Federal Register's regulations at 1 CFR Part 51 govern the use of incorporation by reference in regulation. For all other uses, your agency must determine the most appropriate form of reference. If a standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and meet any other similar obligations, such as those relating to patented technology that must be used to comply with the standard.

- h. Are there standards-related international trade obligations that agencies must adhere to regarding the use of standards?** Yes. There are statutory and international obligations governing "standards-related activities." In particular, agencies should be aware of the obligations in 19 U.S.C. § 2532, which provides that "[n]o Federal agency may engage in any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States..." and that "[e]ach Federal agency shall ensure, in applying standards-related activities with respect to any imported product, that such product is treated no less favorably than are like domestic or imported products..." "Standards-related activity" is defined in 19 U.S.C. § 2571 and covers certain standards and technical regulations as well as conformity assessment procedures. These statutory requirements reflect U.S. international obligations under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement). Specifically, Articles 2.1 and 2.2 and Annex 3 of the Agreement commit the United States, with respect to standards and technical regulations, to provide no less favorable treatment to imported products than like domestic products and to avoid unnecessary obstacles to trade.

In addition, the United States is obligated under the TBT Agreement to use relevant international standards, except where such standards would be an ineffective or inappropriate means to fulfill the legitimate objective pursued. In particular, the TBT Agreement, Article 2.4, provides that: "Where technical regulations are required and relevant international standards exist or their completion is imminent, [WTO] Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems." In addition, 19 U.S.C. § 2532 directs Federal agencies, in developing standards, to base the standards on international standards if appropriate.

The WTO TBT Agreement defines "technical regulation" as a document which sets out product characteristics or their related processes and production methods, including applicable administrative provisions, with which compliance is mandatory, and states that the definition may include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process, or production method. The WTO TBT Agreement excludes services, sanitary and phytosanitary measures, and government procurement from its scope. These areas are covered by other WTO agreements discussed later in this section.

The WTO TBT Agreement does not provide a list of bodies that develop international standards. However, in 2000, the WTO Committee on Technical Barriers to Trade adopted

a decision setting out principles that standards bodies should follow when developing international standards (the Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the WTO Agreement on Technical Barriers to Trade, hereinafter the Committee Decision). Please see the annex to this Circular for additional information.

In addition, certain U.S. free trade agreements commit the United States to determine whether an international standard exists based on the principles set out in the Committee Decision. Agencies should, therefore, pay close attention to the Committee Decision and consult with USTR when questions arise as to evaluating whether a standard developed by a particular standards body is “international.” A voluntary consensus standard may be an international standard under the WTO TBT Agreement or provisions of U.S. trade agreements applying to technical barriers to trade, if it was developed in accordance with the Committee Decision principles.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which applies to sanitary and phytosanitary measures (*e.g.*, food safety regulations), also addresses the use of relevant international standards. Article 3.1 of the WTO SPS Agreement states: “To harmonize sanitary and phytosanitary measures on as wide a basis as possible, [WTO] Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular paragraph 3.” Article 3.3 of the SPS Agreement also provides that:

Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraph 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provisions of this Agreement.

The WTO SPS Agreement includes a detailed definition of “sanitary or phytosanitary measure” and generally covers measures related to food safety and the spread of disease or pests. Unlike the WTO TBT Agreement, the WTO SPS Agreement identifies three bodies, among others, that develop international standards, guidelines and recommendations for purposes of implementing the WTO SPS Agreement. In particular, the SPS Agreement identifies the following as international standards, guidelines and recommendations: for food safety, those established by the Codex Alimentarius Commission; for animal health and zoonoses, those developed under the auspices of the International Office of Epizootics; for plant health, those developed in the framework of the International Plant Protection Convention; and “for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all [WTO] Members, as identified by the [SPS] Committee.”

The United States also has procurement obligations under the WTO Agreement on Government Procurement (GPA) and a number of Free Trade Agreements (see FAR Subpart 25.4) to base the technical specifications on international standards, where available. Article X.2 of the WTO GPA provides:

In prescribing the technical specifications for the goods or services being procured, a procuring entity shall, where appropriate:

- (i) set out the technical specification in terms of performance and functional requirements, rather than design or descriptive characteristics; and
- (ii) base the technical specification on international standards, where such exist; otherwise, on national technical regulations, recognized national standards or building codes.

Agencies should consult with USTR on questions regarding international trade obligations relating to regulations, standards, conformity assessment procedures, or procurement or with respect to any requests from countries regarding the establishment of mutual arrangements with respect to standards-related activities. Pursuant to 19 U.S.C. § 2171 and 2541, USTR has statutory authorities and responsibilities in these areas including “for coordinating United States discussions and negotiations with foreign countries for the purpose of establishing mutual arrangements with respect to standards-related activities.” Agencies should consult with the Department of State on questions regarding the application of international agreements other than trade agreements.

- i. **When should my agency consider using or recognizing a standard used by a trading partner?** To the extent a standard used by a trading partner is an international standard or voluntary consensus standard, agencies should consider and use them as described in this Circular (see, *e.g.*, Sections 5a and h). In addition, agencies should consider and use a standard used by a trading partner, where, pursuant to an international agreement, the United States has agreed to do so (*e.g.*, pursuant to a mutual recognition agreement). Agencies should also examine how recognition or use of a standard used by a trading partner would impact the policy objectives set out in Section 1 of Executive Order 13609, “Promoting International Regulatory Cooperation.” An agency may have additional obligations to consider a standard used by a trading partner pursuant to Section 3(d) of Executive Order 13609.

In addition, the United States is obligated to adhere to certain international agreements with respect to accepting as equivalent standards used in the regulations of U.S. trading partners. In particular, the WTO TBT Agreement, Article 2.7, requires the United States and other WTO Members 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.”

The WTO SPS Agreement also contains obligations regarding equivalence determinations with respect to foreign country sanitary and phytosanitary measures (SPS measures). Article 4 of the SPS Agreement provides:

- (i) Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
- (ii) Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures. Agencies should consult with USTR regarding entering into any such consultations.

U.S. Federal law, as codified at 19 U.S.C. § 2578a, provides that an agency may not determine that a foreign country's sanitary or phytosanitary measure is equivalent to a sanitary or phytosanitary measure established under the authority of Federal law unless the agency determines the foreign country measure provides the same level of sanitary or phytosanitary protection as the U.S. measure.

See SPS Agreement, Annex A, for the definition of SPS measure.

j. How does this policy affect my agency's regulatory authorities and responsibilities?

This policy does not preempt or restrict agencies' authorities and responsibilities to make regulatory decisions authorized by statute. Such regulatory authorities and responsibilities include determining the level of acceptable risk and risk-management, and due care; setting the level of protection; and balancing risk, cost, and availability of alternative approaches in establishing regulatory requirements. However, agencies should consider using voluntary consensus standards, as described in this Circular, to achieve their regulatory, procurement, and program needs, including for test methods, sampling procedures, and protocols, if applicable.

k. How does this policy affect my agency's procurement authority? This policy does not preempt or restrict agencies' authorities and responsibilities to identify the capabilities that they need to obtain through procurements. Rather, this policy establishes a preference for using a voluntary consensus standard, to the extent a suitable one exists, instead of pursuing an identified capability through reliance on a government-unique standard.

l. What factors should my agency consider when determining whether to allow the use of more than one standard? In considering whether to allow the use of more than one standard for suppliers to demonstrate that they meet a particular program, procurement, or regulatory requirement, your agency should consider whether doing so meets your agency's regulatory, procurement, or program needs (see, *e.g.*, Section 5a). It may be appropriate for the agency to allow the use of multiple standards in order, for example, to permit greater flexibility for producers and service providers in meeting program, procurement, or regulatory requirements, enhance competition in the marketplace, provide greater choice to consumers, and enable new innovative solutions to be developed. Allowing the use of more

than one standard may also allow producers and service providers to meet both U.S. requirements and requirements in different markets simultaneously, thereby reducing burdens for manufacturers and service providers while effectively addressing agency objectives.

m. How should my agency ensure that references to standards incorporated in regulation are updated on a timely basis? Consistent with Executive Orders 13563, “Improving Regulation and Regulatory Review,” and 13610, “Identifying and Reducing Regulatory Burdens,” agencies should, on a regular basis, review and if necessary update references to standards that have been incorporated by reference. Each agency should undertake a standards-specific review of such incorporated standards every three-to-five years, or when stakeholders otherwise provide adequate information that a standards-specific review is necessary due to urgent matters of health and safety, the need to remain current with technological changes, or for other compelling reasons. For example, regulated entities may petition agencies to update incorporated standards.

In accordance with the retrospective review provisions of Executive Orders 13563 and 13610, an agency should also consult with stakeholders prior to issuance of an NPRM, for example through an Advanced Notice of Proposed Rulemaking (ANPRM) or an RFI. Such consultations will help the agency identify which updated or new standards would potentially be controversial (if incorporated by reference in regulation) and which ones would not, and also whether incorporation of new or updated standards may warrant substantive changes to the underlying regulation.

- (i) In the case of standards for which updating or substituting a new standard or standards would not be controversial, the agency should, to the extent permitted by law, consider issuing a standards-specific direct final rule.
- (ii) In the case of other standards for which an agency may wish to update or substitute a new standard or standards, the agency should publish a standards-specific NPRM.
- (iii) To promote efficiency, and to the extent feasible and appropriate, an agency is encouraged to consolidate proposals to update or substitute standards, rather than conducting separate rulemakings for each standard the agency wants to update or substitute.
- (iv) In the case of standards for which updating or substituting a new standard would require a substantial re-opening of a rule, such revisions should be addressed in the context of a broader-scope “look-back” NPRM (rather than through a standards-specific NPRM), where such re-opening meets the objectives and criteria set out in Executive Orders 13563 and 13610.
- (v) If an agency decides not to adopt the most recent version of a standard, the agency should explain its reasons in the final rule.
- (vi) Except in urgent circumstances, and where consistent with law and international obligations, agencies must allow a reasonable interval between the publication of final rules and their effective dates, in order to provide affected stakeholders sufficient time

to adapt their products and methods of production to comply with the updated or new standard.

6. What is the Policy for Federal Participation in Standards Bodies?

Consistent with Section 12(d)(2) of the NTTAA, agencies must consult with voluntary consensus standards bodies and must participate with such bodies in the development of standards when consultation and participation is in the public interest and is compatible with their missions, authorities, priorities, and budgetary resources. In voluntary consensus standards development processes, agency participation can be an important contribution to ensuring balance is achieved.

The WTO TBT and SPS Agreements also contain obligations regarding participation in international standards developing bodies:

- (i) TBT Agreement, Article 2.6: “With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.”
- (ii) TBT Agreement, Article 5.5: “With a view to harmonizing conformity assessment procedures on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures.”
- (iii) SPS Agreement, Article 3.4: “Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.”

Each agency should arrange for qualified representatives to participate in standards development activities, as appropriate. The representatives’ function should be to participate in the standards writing and/or, as appropriate, act as a liaison, provide information and expertise, and communicate the views of the agency concerning the standards being developed and the procedures being followed.

- a. Must agency participants be authorized?** Agency representatives who, at Government expense, participate in activities of standards bodies on behalf of the agency must do so as specifically authorized agency representatives. Agency support for, and participation by, agency representatives in standards bodies must be in compliance with applicable laws and regulations. For example, agency support is subject to legal and budgetary authority and availability of funds. Similarly, participation by agency representatives (whether or not on behalf of the agency) in the activities of standards bodies is subject to the laws and regulations that apply to participation by Federal employees in the activities of outside organizations.

Additionally, in considering the applicability of 18 U.S.C. § 208, which addresses Federal participation in outside organizations, the Office of Legal Counsel (OLC) of the Department of Justice has determined the following: “When the board of an outside organization plays an integral role in the process of setting standards, it would therefore frustrate the statute [NTTAA] to forbid Federal employees from being on the board. They could not then take the “active” role that Congress mandated. To carry out the statute, therefore, employees may serve on these outside boards without running afoul of 18 U.S.C. § 208, if the boards are engaged in the standard-setting activities in which Congress directed Federal agencies to participate.”⁵

Furthermore, in the 2001 amendment to the NTTAA (in Section 1115 of Public Law 107-107 (which enacted a new paragraph of Section 12(d)), Congress expressly exempted application of 5 U.S.C. § 5946 (which prohibits payments for membership and conference fees) with respect to activities of Federal agencies and personnel in carrying out Section 12(d) of the NTTAA (see 15 U.S.C. § 272 note). As noted in the previous Section, active agency technical involvement and leadership in standards activities is encouraged by this Circular and the NTTAA. However, agency representatives should avoid the practice or the appearance of undue influence relating to their participation in standards bodies and activities.

b. Does agency participation indicate endorsement of any decisions reached by standards bodies? Agency participation in standards bodies does not connote agency endorsement or agreement with decisions by such bodies.

c. What forms of support may my agency provide to standards development? The forms of agency support may include:

- (i) direct financial support (*e.g.*, grants, memberships, and contracts);
- (ii) administrative support (*e.g.*, travel costs, hosting of meetings, and secretarial functions);
- (iii) technical support (*e.g.*, cooperative testing for standards evaluation and participation of agency personnel in the activities of standards bodies);
- (iv) joint planning with standards bodies to promote identification and development of needed standards; and
- (v) participation of agency personnel.

Federal agencies should give adequate priority in their budgets to the need for agency officials to participate in standards development.

d. Do agency representatives participate equally with other members? Consistent with agency regulation and policy, agency representatives should participate actively and on an equal basis with other members, consistent with the procedures of standards bodies, particularly in matters such as establishing priorities, developing procedures for preparing, reviewing and approving standards, and developing or adopting new standards. Active participation includes full involvement in discussions and technical debates, registering of opinions and, if selected,

⁵ See OLC’s opinion of August 24, 1998, on “Application of § 208 to Service by Executive Branch Employees on Boards of Standard-Setting Organizations,” <http://oge.gov/DisplayTemplates/ModelSub.aspx?id=1826>.

serving as chairpersons (or other leadership positions) or in other official capacities. Agency representatives may vote, in accordance with the procedures of the standards body, at each stage of the standards development process, unless prohibited from doing so by law or their agencies.

- e. **How should my agency alert the public of its potential participation in standards development activities that could be used as a basis for rulemaking or other mission-related activities?** In the interest of enhancing transparency and information-sharing, agencies should advise the public about ongoing or planned participation in standards development activities, when, for instance, doing so to address issues of national priority, or in support of significant regulatory action or international regulatory cooperation activities. Methods could include publication of a notice in the Federal Register, providing notice on the agency's public website, or using other appropriate mechanisms. The information provided could include, for example:

- (i) which body or organization is developing the standard;
- (ii) why the agency's participation is relevant to the public; and
- (iii) methods by which the public can obtain more information.

When an agency is unsure of the nature and extent of standards activity that may be relevant for an upcoming regulation, procurement, or non-regulatory action, the agency is encouraged to request information on standards development through, for example, an RFI or an ANPRM. Agencies could also use more informal means, such as contacting relevant bodies directly.

Note that agency participation in the standards development process is not a prerequisite for incorporating or otherwise using a standard.

- f. **What if a voluntary consensus standards body is likely to publish a suitable standard in time for an agency to use it?** If a voluntary consensus standards body is in the process of developing or adopting a voluntary consensus standard that would likely be practical for an agency to use, and would likely be developed or adopted on a timely basis, an agency should not develop its own standard and instead should participate in the activities of the voluntary consensus standards body (or at least monitor the development of the standard) so that the agency is in a position to use the standard at the appropriate time.

7. **What is the Policy on Conformity Assessment?**

Section 12(b) of the NTTAA requires the NIST to coordinate Federal, State, and local standards activities and conformity assessment activities with private sector standards development and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. The Secretary of Commerce, through NIST, issues guidance to the agencies on conformity assessment (see www.standards.gov).

Building upon the NTTAA, U.S. statutory and international obligations, and NIST's previous guidance to agencies on conformity assessment, agencies may develop and use conformity assessments procedures that:

- (i) are effective and appropriate in carrying out agency missions;
- (ii) minimize the regulatory and/or conformity assessment burden on regulated entities;
- (iii) are in accordance with statutory and international obligations;
- (iv) conserve and leverage agency resources; and
- (v) increase acceptance of U.S. products in domestic and foreign markets.

Agencies should be aware that conformity assessment procedures and systems can be used in many different ways to support their missions. Conformity assessment procedures and systems may be integral to a regulatory agency's compliance and enforcement system, or the results of conformity assessment may be an input to the regulatory system. The agency may have roles and responsibilities related to the development and maintenance of conformity assessment system requirements and/or the conduct of specific activities in these systems. Flexibility is essential when devising an optimal conformity assessment system tailored to the missions of regulatory agencies.

Agencies should also design conformity assessment programs with the objectives of furthering outcomes that are closely aligned with market dynamics and otherwise maximize net benefits to society. In this context, agencies should recognize the possible contribution of private sector conformity assessment activities. When properly conducted, conformity assessments conducted by private sector conformity assessment bodies can increase productivity and efficiency in government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment.

Working closely with NIST and OMB, agencies are encouraged to identify their conformity assessment needs in such areas as regulatory compliance and enforcement, procurement, and other programmatic contexts and to assess whether the use of private sector conformity assessment mechanisms in lieu of or in conjunction with government conformity assessment procedures would be beneficial, where such use is feasible and appropriate and not otherwise prohibited by law. Agencies should also consider whether reliance on international conformity assessment schemes would meet their conformity assessment needs.

Agencies will continue to have the flexibility of choosing conformity assessment programs, whether private, public, or some combination thereof, to best achieve the objectives above.

- a. What considerations should my agency make when it is addressing the need for conformity assessment?** Agencies should consider appropriate agency roles and responsibilities to carry out their missions in a way that protects health, safety, welfare, and the environment, while promoting economic growth, competitiveness, and job creation, and reducing costs and burdens, including the cumulative effects of regulation, on the affected public and the U.S. economy. When an agency is evaluating whether to put in place a conformity assessment program, it should, consistent with statute, resource constraints, and the instruments set out in Section 1 of this Circular, consider certain factors when assessing the effectiveness of conformity assessment options and determining the type(s) of conformity assessment to employ. These include:

- (i) the objective(s) of the underlying regulation, procurement, or program activity;
- (ii) the level of confidence required by the agency to ensure that the agency objective(s)

- has/have been achieved, weighing the risk of non-compliance and its associated consequences with the anticipated costs of demonstrating compliance (including time and resources) to the producers, suppliers, consumers, and the agency;
- (iii) whether there are existing private sector conformity assessment activities, acceptance schemes or arrangements, that may work in conjunction with or, where appropriate, in lieu of governmental conformity assessment activities, except where such activities are inconsistent with law, unfit for regulatory or other agency purpose, or otherwise impractical;
- (iv) their consistency with statutory and international obligations;
- (v) consideration of the available scientific and technical information, as relevant to the selection of the appropriate conformity assessment program;
- (vi) relevant industry practice and experience, and the industry's history of compliance;
- (vii) the need to reduce duplication and complexity, and ensure consistency and coordination with the conformity assessment approaches of other agencies, where feasible, appropriate, and consistent with law;⁶
- (viii) the appropriateness of recognizing the results of private sector conformity assessment programs being utilized in State, local, and/or foreign government regulation, consistent with subsection (iii); and
- (ix) the degree of transparency to stakeholders and the public of the conformity assessment activity.

b. Are there statutory and international obligations concerning conformity assessment?

There are statutory and international obligations governing standards-related activities, which include conformity assessment procedures. In particular, agencies should be aware of the obligations in 19 U.S.C. § 2532, which provides that “[n]o Federal agency may engage in any standards-related activity that creates unnecessary obstacles to the foreign commerce of the United States...” and that “[e]ach Federal agency shall ensure, in applying standards-related activities with respect to any imported product, that such product is treated no less favorably than are like domestic or imported products...” Additionally, “[e]ach Federal agency shall, with respect to any conformity assessment procedure used by it, permit access for obtaining an assessment of conformity and the mark of the system, if any, to foreign suppliers of a product on the same basis as access is permitted to suppliers of like products, whether of domestic or other foreign origin.” 19 U.S.C. § 2532(4). Conformity assessment requirements and procedures are also subject to the WTO TBT Agreement, which requires the United States to ensure it does not prepare, adopt, or apply conformity assessment procedures with a view to, or with the effect of, creating unnecessary obstacles to international trade. Articles 5 through 9 of the WTO TBT Agreement set out detailed obligations on conformity assessment procedures falling within the scope of the WTO TBT Agreement, including the need to use relevant guides or recommendations issued by international standardizing bodies as a basis for conformity assessment procedures, except where ineffective or inappropriate, and to ensure that the conformity assessment procedures are not more strict or applied more strictly than necessary to give adequate assurance that products conform to applicable “technical regulations” or

⁶ Pursuant to 15 C.F.R. § 287.1, your agency should work with NIST to “coordinate conformity assessment activities with those of other appropriate government agencies and with those of the private sector to reduce unnecessary duplication....This will help ensure more productive use of the increasingly limited Federal resources available to conduct conformity assessment activities...” Consistent with 15 C.F.R. § 287.4, agencies should also “consider using the results of other agencies’ conformity assessment procedures (see also Section 7e).”

standards, taking into account the risks non-conformity would create. Article 9.1 of the WTO TBT Agreement provides:

Where a positive assurance of conformity with a technical regulation or standard is required, Members shall, whenever practical, formulate and adopt international systems for conformity assessment and become members thereof or participate therein.

The United States has also undertaken additional commitments on conformity assessment in U.S. free trade agreements (FTA). These include a commitment not to discriminate against conformity assessment bodies located in the territories of U.S. FTA partners when it comes to accrediting, approving, licensing or otherwise recognizing conformity assessment bodies. Agencies are urged to consult with USTR on questions regarding international obligations regarding conformity assessment.

- c. **What obligations does my agency have when considering whether to use a conformity assessment procedure used by a trading partner?** Agencies should use voluntary consensus standards and international guides and recommendations issued by international standardizing bodies in their conformity assessment procedures, as described in this Circular, including where such standards, guides and recommendations are used by a trading partner. In addition, Article 6.1 of the WTO TBT Agreement obligates the United States (and other WTO members) to accept the results of conformity assessment procedures in other WTO member countries, provided it is satisfied that those procedures offer an assurance of conformity equivalent to its own procedures. U.S. free trade agreements may also have obligations with respect to recognition of trading partners' conformity assessment procedures. Agencies should consult with USTR regarding compliance with these obligations. Agencies should consult with the Department of State in the case of other international obligations or to consider what other relevant international agreements may apply. Agencies should also examine how such use or recognition would impact the policy objectives set out in Executive Order 13609, "Promoting International Regulatory Cooperation." An agency may have additional obligations to consider such procedures under Section 3(d) of Executive Order 13609.
- d. **How does this policy affect my agency's regulatory authorities and responsibilities?** This policy does not preempt or restrict agencies' authorities and responsibilities to make regulatory decisions authorized by statute.
- e. **When should my agency utilize the retrospective review mechanism with respect to conformity assessment?** Pursuant to Executive Orders 13563, "Improving Regulation and Regulatory Review," and 13610, "Identifying and Reducing Regulatory Burdens," and 15 C.F.R. § § 287.1 and 287.4, your agency should integrate meaningful review of its conformity assessment activities into its retrospective review plans on a periodic basis. Consistent with the NTTAA, this Circular (particularly Section 1), and NIST guidance, the review should evaluate alternative approaches to ensure that current conformity assessment schemes are effective and the burden on regulated entities is minimized.

Agencies are encouraged to consider joint rulemaking to reduce redundancy, complexity, and the cumulative effects on the regulated public of needing to comply with different conformity assessment procedures where (1) agencies have the same or similar requirements for

conformity assessment for the same product/service attributes and (2) demonstrating compliance with one agency's requirement is sufficient to demonstrate that a product or service attribute conforms to other agencies' requirements for the same product or service attribute. Consistent with law and the need for agencies to maintain appropriate levels of protection, for example, in regulations affecting health, safety, and the environment, agencies should engage the regulated public and other stakeholders in public consultation as part of the retrospective review process described above before initiating such rulemakings.

8. How will the U.S. Government Coordinate Regulatory Policy with Standards and Conformity Assessment Policy?

The Interagency Committee on Standards Policy (ICSP) shall coordinate with the Trade Policy Staff Committee (TPSC), its subcommittee on Technical Barriers to Trade, and the designees, or "Seconds," of the Regulatory Working Group (Working Group) created by Executive Order 12866, "Regulatory Planning and Review," with a view to encouraging more strategic and coordinated Federal participation in the development and use of standards and in conformity assessment activities, in accordance with the objectives of the executive orders set out in Section 1 of this Circular. USTR has responsibility under 19 U.S.C. §§ 2171 and 2541 for coordinating the consideration of international trade policy issues with respect to standards-related activities.

While a primary focus of this Circular is to encourage agency reliance on voluntary consensus standards, OMB recognizes Federal agencies also participate in the development of other standards with standards bodies that do not have all of the attributes described in Section 2(e), as well as in regulatory collaboration initiatives and encourages such participation. Under Section 2(a) of Executive Order 13609, "Promoting International Regulatory Cooperation," and subject to Section 6 of that order, the Working Group serves "as a forum to discuss, coordinate, and develop a common understanding among agencies of U.S. Government positions and priorities with respect to: (A) international regulatory cooperation activities that are reasonably anticipated to lead to significant regulatory actions; . . ." Moreover, under Section 3(a) of Executive Order 13609, "if required to submit a Regulatory Plan pursuant to Executive Order 12866, [each agency shall] include in that plan a summary of its international regulatory cooperation activities that are reasonably anticipated to lead to significant regulations, with an explanation of how these activities advance the purposes of Executive Order 13563 and [Executive Order 13609]." Regular discussions between the Working Group Seconds and the ICSP, as well as the TPSC, its subcommittee on Technical Barriers to Trade, and any other relevant interagency groups or committees, will help to coordinate U.S. Government activities relating to standards and conformity assessment, as well as regulation.

MANAGEMENT AND REPORTING OF STANDARDS USE

9. How Does My Agency Manage and Report on the Implementation of the Circular?

Your agency should establish a process to identify, manage, and review your agency's activities pursuant to the guidance in this Circular. At minimum, your agency must have the ability to provide to OMB, through NIST, (1) a report on the agency's use of government-unique standards in lieu of voluntary consensus standards, along with an explanation of the reasons for such

usage, as required by Section 12(d) of the NTTAA and as described in Section 5c of this Circular; and (2) a summary of your agency's activities undertaken to carry out the provisions of this Circular. The summary should contain a link to the agency's standards-specific website(s) where this information is available. This policy establishes two ways – category based reporting and transaction based reporting – for agencies to manage and report their use of standards. Your agency must report uses of government-unique standards in lieu of voluntary consensus standards in one or both ways, pursuant to the following guidance.

As required by the NTTAA, your agency must report to NIST, no later than December 31 of each year, the decisions by your agency in the previous fiscal year to use government-unique standards in lieu of voluntary consensus standards. Your agency must include an explanation of the reason(s) why use of such voluntary consensus standards would be inconsistent with applicable law or otherwise impractical, as described in Sections 5c, 10a(ii), and 11b(ii) of this Circular. Your agency must report in accordance with the instructions issued by NIST.

NIST must maintain the reports received on <http://www.nist.gov/standardsgov/> and will report the use of government-unique standards in lieu of voluntary consensus standards, along with the agency's explanations for such use, to OMB on an annual basis.

10. What are the Procedures for Reporting My Agency's Use of Standards in Regulations?

Your agency should use transaction based reporting – that is, report on each use of a government-unique standard in lieu of a voluntary consensus standard – in your annual report to NIST if your agency issues regulations that use or reference standards. If your agency is issuing or revising a regulation that contains a standard, your agency should follow these procedures:

- a. Publish in the preamble of rulemaking notices what steps the agency is taking to follow and implement the Circular. Such information should include the following elements if applicable:
 - (i) When your agency is proposing or has decided to use a standard, provide a statement which identifies such standard and any alternative standards which have been identified.
 - (ii) When your agency is proposing or has decided to use a government-unique standard in lieu of a voluntary consensus standard, provide a statement that identifies such standards and provide an explanation for why using the voluntary consensus standard would be inconsistent with law or otherwise impractical. Such explanation must be also included in the annual report.
 - (iii) When your agency is proposing or has decided to use a government-unique standard and has not identified a voluntary consensus standard, your agency should include a statement to that effect in the preamble of the final rule or guidance document. For other rulemaking notices, your agency should invite the public to identify any standard and explain why your agency should use such a standard.
- b. For significant regulatory actions, agencies are also encouraged to include in their rulemaking notices a discussion in the regulatory preamble of the following elements:

- (i) which bodies or organizations the agency consulted with to determine whether there are relevant standards in use in the marketplace (or completion of relevant standards is imminent) or if standards that are currently incorporated by reference have been revised;
- (ii) whether agency officials are participating in the work of such bodies or organizations, along with a description of their roles;
- (iii) whether the agency has worked with relevant bodies or organizations to try to ensure that the standards meet agency needs, and a description of the agency's interactions with the technical committees and/or technical advisory groups involved; and
- (iv) whether the agency has coordinated its positions in technical advisory groups or technical committees of such bodies or organizations with (1) other interested agencies that are or should be participating in such work and, (2) where appropriate, foreign regulatory agencies that are participating in such work, where the work is relevant to regulatory cooperation council work plans described in Section 3(d) of Executive Order 13609, "Promoting International Regulatory Cooperation."

11. What are the Procedures for Reporting My Agency's Use of Standards in Procurements?

Your agency must report on either a categorical basis or on a transaction basis to identify, manage, and review the standards used in your agency's procurements.

- a. How does my agency report the use of standards in procurements on a categorical basis?** Your agency must use categorical based reporting when your agency identifies, manages, and reviews the use of standards by group or category. Category based reporting is especially useful when your agency either conducts large procurements or large numbers of procurements using government-unique standards, or is involved in long-term procurement contracts that require replacement parts based on government-unique standards. To report use of government-unique standards on a categorical basis, your agency must:
 - (i) maintain a centralized standards management system that identifies how your agency uses government-unique, voluntary consensus, and other standards;
 - (ii) systematically review your agency's use of government-unique standards for conversion to voluntary consensus standards and, where appropriate, other standards;
 - (iii) maintain records on the groups or categories for which your agency uses government-unique standards in lieu of voluntary consensus standards, including an explanation of the reasons for such use, which must be transmitted according to Sections 5c and 9; and
 - (iv) enable potential offerors to suggest voluntary consensus standards and, where appropriate, other standards that can replace government-unique standards.
- b. How does my agency report the use of standards in procurements on a transaction basis?** Your agency should report on a transaction basis when your agency identifies, manages, and reviews the use of standards on a transaction basis rather than a category basis. Transaction-based reporting is especially useful when your agency conducts procurement involving mostly commercial products and services, but is occasionally

involved in a procurement involving government-unique standards. To report use of government-unique standards on a transaction basis, your agency must follow the following procedures:

- (i) in each solicitation that references government-unique standards, the solicitation must identify such standards and provide potential offerors an opportunity to suggest alternative voluntary consensus standards (or, where appropriate, other standards) that meet the agency's requirements; and
- (ii) if such suggestions are made and the agency decides to use government-unique standards in lieu of voluntary consensus standards, the agency must explain in its annual report to OMB through NIST, as described in Sections 5c and 9, why using such voluntary consensus standards is inconsistent with applicable law or otherwise impractical.

The requirements in this Section do not apply to those solicitations that are for: (1) commercial-off-the-shelf products (COTS), (2) products or services that rely on voluntary consensus standards or other standards, or (3) products that otherwise do not rely on government-unique standards.

AGENCY RESPONSIBILITIES

12. What are the Responsibilities of the Secretary of Commerce?

The Secretary of Commerce:

- a. coordinates and fosters executive branch implementation of this Circular and, as appropriate, provides administrative guidance to assist agencies in implementing this Circular, including guidance on identifying voluntary consensus standards bodies and voluntary consensus standards;
- b. sponsors and supports the ICSP, chaired by NIST, which considers agency views and advises the Secretary and agency heads on the Circular;
- c. reports to the Director of OMB concerning the implementation of the policy provisions of this Circular; and
- d. issues guidance to the agencies to improve coordination on conformity assessment in accordance with Section 7 of this Circular.

13. What are the Responsibilities of the Heads of Agencies?

The Heads of Agencies:

- a. implement the policies of this Circular in accordance with the procedures described;
- b. ensure agency compliance with the policies of the Circular is a top priority and implement appropriate organizational changes as necessary to achieve such compliance;
- c. in the case of an agency that uses standards for regulatory, procurement, or other mission-related activities, designate a senior level official as the Agency Standards Executive who

- will be responsible for the agency's implementation of this Circular, including the responsibilities outlined in 15 C.F.R. 287.5; represent the agency on the ICSP; and be situated in the agency's organizational structure such that he or she is kept regularly apprised of the agency's regulatory, procurement, and other mission-related activities and has sufficient authority within the agency to ensure compliance with the Circular; and
- d. transmit the annual report prepared by the Agency Standards Executive as described in Section 9 of this Circular.

14. What are the Qualifications and Responsibilities of Agency Standards Executives?

An Agency Standards Executive, consistent with applicable law:

- a. Should be a senior level official; have demonstrated knowledge of, and experience in, the areas of standards, standardization processes and procedures, and conformity assessment; be broadly engaged in the agency's standards and conformity assessment related activities so as to ensure intra-agency coordination; and be broadly familiar with how the agency uses standards and conformity assessment in its mission and how it participates in activities of standards bodies and conformity assessment systems, including international systems of conformity assessment.
- b. Promotes the following goals in the context of agency participation in the work of standards bodies and in conformity assessment activities:
 - (i) effective use of agency resources and participation in standards bodies;
 - (ii) the development of agency positions that are in the public interest and are coordinated across units;
 - (iii) the development of agency positions that are consistent with Administration policy;
 - (iv) the development of agency technical and policy positions that are clearly defined and coordinated with other Federal participants in a given standards activity; and
 - (v) the development of agency policies on conformity assessment to implement the provisions of Section 7 of this Circular, consistent with 15 C.F.R. § 287.
- c. Coordinates the agency's participation in standards bodies by:
 - (i) establishing procedures to ensure that agency representatives who participate in standards bodies will, to the extent possible, ascertain the views of the agency on matters of paramount interest and express views and positions that are not inconsistent or in conflict with established agency views and positions;
 - (ii) consulting other relevant agencies, as appropriate, to avoid to the extent practicable expressing views or positions in standards bodies that are inconsistent or in conflict with established views or positions of such other agencies;
 - (iii) ensuring that the agency's participation in standards bodies is consistent with agency missions, authorities, priorities, and budget resources;
 - (iv) coordinating with standards bodies, and notifying such bodies when the agency has incorporated their standards by reference in regulation;
 - (v) ensuring, when two or more agencies participate in a given standards activity, that they coordinate their views on matters of paramount importance so as to present, whenever

- feasible, a single, unified position and, where not feasible, a mutual recognition of differences;
- (vi) cooperating with the head of the agency or his or her designee in carrying out his or her responsibilities under this Circular;
 - (vii) consulting with the head of the agency or his or her designee, as necessary, in the development and issuance of internal agency procedures and guidance implementing this Circular;
 - (viii) preparing, as described in Sections 9 through 11 of this Circular, a report on uses of government-unique standards in lieu of voluntary consensus standards, and a report on the status of agency standards policy activities;
 - (ix) establishing a process for ongoing review of the agency's use of standards for purposes of updating or substituting, pursuant to Section 5m;
 - (x) coordinating with appropriate agency offices (*e.g.*, budget and legal offices) to ensure that effective processes exist for the review of proposed agency support for, and participation in, standards bodies, so that agency support and participation will comply with applicable laws and regulations;
 - (xi) making agency employees aware of available standards training opportunities and providing training (consistent with an agency's budgetary and other considerations) for agency employees participating in standards and conformity assessment activities so that participation is effective, efficient, and in keeping with the rules of the organizations in which they are participating;
 - (xii) providing ongoing assistance and policy guidance to agency employees and managers on significant issues in standardization and conformity assessment; and
 - (xiii) coordinating with the TPSC TBT Subcommittee or other relevant TPSC subcommittees on the trade implications of standardization.
- d. Ensures that agency rulemaking, procurement, and other programmatic activities are consistent with this Circular by, for example:
- (i) providing ongoing assistance, training, and policy guidance to agency employees and managers on the Circular;
 - (ii) being engaged in the development of the agency's rulemakings, procurements, and other programmatic activities that have a standards and/or conformity assessment component and providing advice on compliance with the Circular; and
 - (iii) participating in the ICSP and consulting on a regular basis with NIST, other Agency Standards Executives, USTR (and, if applicable, your agency's representatives to the relevant subcommittee of the TPSC), and the desk officer for your agency in OMB's OIRA.

SUPPLEMENTARY INFORMATION

15. When Will This Circular Be Reviewed?

This Circular will be reviewed for effectiveness no later than five years from the date of issuance.

16. What Is the Legal Effect of This Circular?

This Circular is not intended to delay the administrative process, and this Circular does not provide new grounds for judicial review, or create new rights or benefits, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, or its officers or employees. Authority for this Circular is based on 31 U.S.C. § 1111, which gives OMB broad authority to establish policies for the improved management of the Executive Branch. This Circular is intended to implement section 12(d) of the NTTAA (15 U.S.C. § 272 note) and other instruments set out in Section 1 of the Circular; establish policies that will improve the internal management of the Executive Branch; and, in so doing, improve regulatory and other policy outcomes.

17. Do You Have Further Questions?

For information concerning this Circular, contact the Office of Management and Budget, Office of Information and Regulatory Affairs at CircularA-119@omb.eop.gov.

ANNEX A

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

Decision⁷

The following principles and procedures should be observed, when international standards, guides and recommendations (as mentioned under Articles 2, 5 and Annex 3 of the TBT Agreement for the preparation of mandatory technical regulations, conformity assessment procedures and voluntary standards) are elaborated, to ensure transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and to address the concerns of developing countries.

The same principles should also be observed when technical work or a part of the international standard development is delegated under agreements or contracts by international standardizing bodies to other relevant organizations, including regional bodies.

Transparency

All essential information regarding current work programmes, as well as on proposals for standards, guides and recommendations under consideration and on the final results should be made easily accessible to at least all interested parties in the territories of at least all WTO Members. Procedures should be established so that adequate time and opportunities are provided for written comments. The information on these procedures should be effectively disseminated.

In providing the essential information, the transparency procedures should, at a minimum, include:

- (a) The publication of a notice at an early appropriate stage, in such a manner as to enable interested parties to become acquainted with it, that the international standardizing body proposes to develop a particular standard;
- (b) The notification or other communication through established mechanisms to members of the international standardizing body, providing a brief description of the scope of the draft standard, including its objective and rationale. Such communications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;
- (c) Upon request, the prompt provision to members of the international standardizing body of the text of the draft standard;
- (d) The provision of an adequate period of time for interested parties in the territory of at least all members of the international standardizing body to make comments in writing

⁷ G/TBT/9, 13 November 2000, para. 20 and Annex 4.

and take these written comments into account in the further consideration of the standard;

- (e) The prompt publication of a standard upon adoption; and
- (f) To publish periodically a work programme containing information on the standards currently being prepared and adopted.

It is recognized that the publication and communication of notices, notifications, draft standards, comments, adopted standards or work programmes electronically, via the Internet, where feasible, can provide a useful means of ensuring the timely provision of information. At the same time, it is also recognized that the requisite technical means may not be available in some cases, particularly with regard to developing countries. Accordingly, it is important that procedures are in place to enable hard copies of such documents to be made available upon request.

Openness

Membership of an international standardizing body should be open on a non- discriminatory basis to relevant bodies of at least all WTO Members. This would include openness without discrimination with respect to the participation at the policy development level and at every stage of standards development, such as the:

- (a) Proposal and acceptance of new work items;
- (b) Technical discussion on proposals;
- (c) Submission of comments on drafts in order that they can be taken into account;
- (d) Reviewing existing standards;
- (e) Voting and adoption of standards; and
- (f) Dissemination of the adopted standards.

Any interested member of the international standardizing body, including especially developing country Members, with an interest in a specific standardization activity should be provided with meaningful opportunities to participate at all stages of standard development. It is noted that with respect to standardizing bodies within the territory of a WTO Member that have accepted the Code of Good Practice for the Preparation, Adoption and Application of Standards by Standardizing Bodies (Annex 3 of the TBT Agreement) participation in a particular international standardization activity takes place, wherever possible, through one delegation representing all standardizing bodies in the territory that have adopted, or expected to adopt, standards for the subject-matter to which the international standardization activity relates. This is illustrative of the importance of participation in the international standardizing process accommodating all relevant interests.

Impartiality and Consensus

All relevant bodies of WTO Members should be provided with meaningful opportunities to contribute to the elaboration of an international standard so that the standard development process will not give privilege to, or favour the interests of, a particular supplier/s, country/ies or region/s. Consensus procedures should be established that seek to take into account the views of all parties concerned and to reconcile any conflicting arguments.

Impartiality should be accorded throughout all the standards development process with respect to, among other things:

- (a) Access to participation in work;
- (b) Submission of comments on drafts;
- (c) Consideration of views expressed and comments made;
- (d) Decision-making through consensus;
- (e) Obtaining of information and documents;
- (f) Dissemination of the international standard;
- (g) Fees charged for documents;
- (h) Right to transpose the international standard into a regional or national standard; and
- (i) Revision of the international standard.

Effectiveness and Relevance

In order to serve the interests of the WTO membership in facilitating international trade and preventing unnecessary trade barriers, international standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions. Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics.

Accordingly, it is important that international standardizing bodies:

- (a) Take account of relevant regulatory or market needs, as feasible and appropriate, as well as scientific and technological developments in the elaboration of standards;
- (b) Put in place procedures aimed at identifying and reviewing standards that have become obsolete, inappropriate or ineffective for various reasons; and
- (c) Put in place procedures aimed at improving communication with the World Trade

Organization.

Coherence

In order to avoid the development of conflicting international standards, it is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential.

Development Dimension

Constraints on developing countries, in particular, to effectively participate in standards development, should be taken into consideration in the standards development process. Tangible ways of facilitating developing countries' participation in international standards development should be sought. The impartiality and openness of any international standardization process requires that developing countries are not excluded de facto from the process. With respect to improving participation by developing countries, it may be appropriate to use technical assistance, in line with Article 11 of the TBT Agreement. Provisions for capacity building and technical assistance within international standardizing bodies are important in this context.