

The Office of Management and Budget (OMB) is proposing to revise 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 changes that have taken place in the world of regulation, standards, and conformity assessment since the Circular was last revised in 1998.

For two decades, it has been the policy of the United States Government to support the development and use of efficient and effective standards and conformity assessment approaches that, when adopted by Federal agencies, can address important regulatory, procurement, and policy objectives, such as increasing the net benefits of Federal regulation. Promoting and using high-quality standards and standardization systems in turn supports the broader goals of enhancing economic growth, innovation, and competition and of facilitating international trade by avoiding the creation of unnecessary obstacles to trade.

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 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. In response, OMB in 1998 issued a revised version of Circular A-119, which remains the current version. In this notice, OMB is seeking public comment on proposed revisions to the Circular. These proposed revisions reflect the experience gained by U.S. agencies in implementing the Circular since 1998; domestic and international developments in regulatory, standards, and conformity assessment policy; concluding and implementing U.S. trade agreements; and comments received in response to OMB's March 2012 Request for Information on whether and how to supplement Circular A-119.

BACKGROUND AND DISCUSSION OF PUBLIC COMMENTS: In Section 12(d) of the NTTAA, Congress stated that Federal agencies "shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities," except when an agency determines that such use "is

inconsistent with applicable law or otherwise impractical.” (Section 12(d), as amended, is found as a “note” to 15 U.S.C. § 272. Congress amended Section 12(d) in 2001, in Section 1115 of P.L. 107-107, to include paragraph (4) on “expenses of government personnel.”)

In response to the enactment of the NTTAA, OMB prepared a proposed revision to Circular A-119 and issued a Federal Register notice seeking public comment on the proposal (see 61 Fed. Reg. 68312 (December 27, 1996)). Following its consideration of the comments, OMB issued a final revision of the Circular in 1998, 63 Fed. Reg. 8546 (February 19, 1998), which can be found on OMB’s website at http://www.whitehouse.gov/omb/circulars_a119/.

The policies in the Circular are intended to maximize the reliance by agencies on voluntary consensus standards and reduce to a minimum agency reliance on standards other than voluntary consensus standards, including reliance on government-unique standards. The Circular also provides guidance for agencies participating in the work of bodies that develop voluntary consensus standards and describes procedures for satisfying the NTTAA’s agency-reporting requirements. In addition, consistent with section 12(b) of the NTTAA, the Circular directs the Secretary of Commerce to issue guidance to agencies in order to coordinate conformity assessment activities. The NIST conformity assessment guidelines, which were issued in 2000, are available at http://gsi.nist.gov/global/docs/FR_FedGuidanceCA.pdf and 65 Fed. Reg. 48894.

The proposed revisions to the Circular reflect, among things, recent guidance to agencies and Executive Orders. On January 17, 2012, OMB’s Office of Information and Regulatory Affairs (OIRA), the Office of Science and Technology Policy, and the Office of the United States Trade Representative released a Memorandum that issued guidance to Federal agencies on “Principles for Federal Engagement in Standards Activities to Address National Priorities.”¹

In addition, OMB notes more generally the requirements of three recent executive orders:

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

1. Executive Order 13563 (“Improving Regulation and Regulatory Review”), which emphasizes that the U.S. regulatory system “must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation,” and which stresses the importance of public participation and careful consideration of both benefits and costs;
2. Executive Order 13609 (“Promoting International Regulatory Cooperation”), which seeks to reduce unnecessary differences in regulation between the United States and its major trading partners through international regulatory cooperation, and encourages the development of Federal strategies to promote good regulatory practices internationally, as well as U.S. regulatory approaches, as appropriate; and
3. Executive Order 13610 (“Identifying and Reducing Regulatory Burdens”), which 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.

The revisions to Circular A-119 are also important to ensure agencies are properly informed regarding their statutory obligations in standards-setting activities. 19 U.S.C. § 2532 specifically 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 non-discriminatory treatment for like domestic or imported products;
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 2012, OMB decided to explore whether to re-visit Circular A-119 to make revisions in light of changes which have taken place in the world of regulation, standards and conformity assessment since 1998. In order to gather relevant information, 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 that 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 which have emerged or moved to the forefront since the current version of the Circular was promulgated in 1998. Public comments submitted in response to OMB’s RFI can be found at <http://www.regulations.gov/#!documentDetail;D=OMB-2012-0003-0001>.

OMB received approximately 70 comments from a wide range of stakeholders, including companies and trade associations, academics, public interest groups, standards developing bodies, conformity assessment bodies, and private citizens. These comments are summarized below along with the proposed changes to the Circular.

Encouraging Agency Use of Standards and Participation in Standards Development: Many of the comments OMB received on the RFI requested the Circular continue to express a strong preference for Federal agencies to use voluntary consensus standards in lieu of developing their own standards; clarify that the agencies should favor the use of voluntary consensus standards over the use of voluntary non-consensus standards; and further encourage Federal participation in the development of voluntary consensus standards. Some comments, however, noted the importance to the U.S. economy of voluntary non-consensus standards, particularly in emerging technology areas. These comments suggested the use of these standards should also be encouraged in certain circumstances, and that agencies should participate in their development as well.

In this notice, OMB is seeking comment on proposed revisions which, if adopted, would establish a general preference for using voluntary consensus standards in Federal regulations and for other Federal agency uses. The current Circular prefers voluntary consensus standards over government-unique standards (as is required under Section 12(d) of the NTTAA). The revision continues this preference and establishes a further preference for voluntary consensus standards over other types of standards (including voluntary standards that are developed by voluntary non-consensus bodies). In seeking comment on such a revision to the Circular, OMB acknowledges that other types of voluntary standards, including those developed by voluntary non-consensus bodies, are in use in the marketplace and may be relevant in meeting agency missions and priorities. Accordingly, under the draft revisions, agencies would be able to use such standards under certain circumstances.

The proposed revisions would also encourage agencies to participate in the activities of intergovernmental organizations and voluntary non-consensus bodies (where consistent with agency missions and the objectives of the Circular), and would provide additional guidance to agencies on how Federal representatives should participate in standards development activities, including serving on the boards of standards developing bodies (consistent with the NTTAA and other applicable Federal law).

The revisions to the Circular would also provide criteria for agencies to consider when they examine whether a voluntary standard meets agency needs and should be used for purposes of their regulations. Such criteria, which were adopted in part from Recommendation 78-4 of the Administrative Conference of the United States (ACUS) (see <http://www.acus.gov/research/the-conference-current-projects/incorporation-by-reference/>), include substantive considerations (reflecting the technical merit of the document) and procedural considerations (reflecting the process by which the standard was developed and/or views were formulated). These revisions would provide additional guidance to agencies on how they should discuss their implementation of the Circular in their rulemakings and guidance documents.

In addition, the proposed revisions set out general guidance for agency consideration of intellectual property and the development of standards. OMB is interested in receiving

comments from the public regarding whether it should consider providing more specific guidance for agencies with respect to intellectual property rights (IPR)-related considerations with regard to standards. For example, for the purposes of an agency's use of a standard, what factors, if any, should an agency consider regarding the interests of intellectual property holders whose intellectual property is incorporated in the standard and the interests of parties seeking to implement that standard?

Ensuring the Timely Updating of Standards: Several commenters on the RFI noted that many standards which have been “incorporated by reference” in regulation are outdated; some commenters further asserted that a number of such references have not been updated in decades. This lack of updating may keep agencies from fully achieving their regulatory goals, such as in the protection of health and safety. Further, commenters noted some instances in which two or more agencies were requiring regulated entities to comply with different versions of the same standard, which may result in unnecessary compliance costs for regulated entities.

OMB is seeking comment on revising the Circular to require agencies to utilize the retrospective review mechanism set out in Executive Orders 13563, “Improving Regulation and Regulatory Review,” and 13610, “Identifying and Reducing Regulatory Burdens,” to ensure standards incorporated by reference are updated on a timely basis. This could help ensure requirements reflect state-of-the-art technologies and approaches for protecting health and safety, ensuring interoperability, and meeting other agency objectives. The revisions also encourage agencies to work together to reference the same version of standards in regulation and procurements, consistent with statute and agency mission and objectives.

Providing Guidance on Conformity Assessment: All commenters on the RFI who addressed this issue expressed moderate to very strong support for OMB providing guidance to agencies with respect to conformity assessment. Commenters recommended the guidance encourage agencies to rely on private sector conformity assessment; provide criteria for agencies to utilize when selecting the appropriate conformity assessment procedure; and help agencies comply with

relevant international obligations regarding conformity assessment. OMB is seeking comment on providing guidance to agencies on conformity assessment in four areas.

- 1) The proposed revisions would encourage agencies to consider international conformity assessment schemes and private sector conformity assessment activities in conjunction with, or where appropriate, in lieu of conformity assessment activities or schemes developed or carried out by the government (except where inconsistent with law or otherwise impractical).
- 2) The proposed revisions set out criteria for agencies to consider when they are selecting or designing an appropriate conformity assessment procedure and direct them to consult with NIST and OMB as part of the process.
- 3) The proposed revisions direct agencies to consult with the Office of the United States Trade Representative (USTR) on the relevant international commitments for conformity assessment, as well as to consider Executive Order 13609, “Promoting International Regulatory Cooperation.”
- 4) To implement the guidance and otherwise reduce burdens on the regulated, the proposed revisions encourage agencies to conduct conformity assessment-specific retrospective reviews, consistent with Executive Orders 13563 and 13610.

Ensuring Compliance with International Obligations: Numerous commenters on the RFI suggested OMB provide guidance to agencies on how to comply with relevant international obligations, including the WTO Agreement on Technical Barriers to Trade and other trade agreements.

In response to these suggestions, OMB is seeking comment on proposed revisions that were developed with USTR, which has statutory authority in this area pursuant to 19 U.S.C. § § 2171 & 2541. Accordingly, under these revisions, the Circular directs Federal agencies to consult with USTR on how to comply with international trade obligations relating to standards and

conformity assessment, including those codified at 19 U.S.C. § 2531. In addition, the proposed revisions direct Federal agencies to consult with the State Department, to the extent international obligations other than trade obligations may be implicated. The proposed revisions also direct agencies to take into account their obligations under Executive Order 13609 when the agencies engage in standards and conformity assessment activities. In addition, with respect to the Federal government's formulation of global strategies on standards and conformity assessment, regulation, and international trade, the proposed revisions would encourage 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.

Recognizing the importance of standards and conformity assessment practices that support global trade and enable regulatory cooperation, OMB also encourages comments on how the policies set out in this Circular can support ongoing efforts to reduce costs associated with unnecessary regulatory differences across major trading partners.

Enhancing Transparency and Stakeholder Participation: OMB is seeking comment on proposed revisions aimed at increasing transparency and stakeholder participation in standards development.

First, the revisions would encourage each agency to notify the public when it is participating in the standards development process of a particular body with the objective of addressing issues of national priority or to support significant regulatory action or international regulatory cooperation. This would provide regulated entities and interested members of the public with advance notice, as well as adequate information, to help them determine whether they should participate in the standards development process and how to do so. OMB also invites views on whether it would be useful to develop additional mechanisms through which an agency would provide advance notice to the public when it is considering whether to use a voluntary standard in regulation, procurement, or program activities – and, if such additional mechanisms would be helpful, any suggestions for how these mechanisms would operate. For example, an agency

could publish an annual Federal Register Notice identifying the agency's websites that contain information about its standards-related activities.

Second, OMB is seeking comment on whether the Interagency Committee on Standards Policy should establish a process for gathering input from the public periodically on relevant developments in standards and conformity assessment.

Third, many commenters on the RFI expressed views on the question of incorporation by reference. Some commenters urged OMB to require agencies to make standards incorporated by reference available for free on the Internet, whereas others urged no change in current law and policy. OMB notes that the legal issue of what is "reasonably available" is being addressed by the Office of Federal Register, which received a petition on the subject in 2012 (see <https://www.federalregister.gov/articles/2012/02/27/2012-4399/incorporation-by-reference>). In October 2013, the Office of the Federal Register posted a partial grant of petition and notice of proposed rulemaking (see <https://www.federalregister.gov/articles/2013/10/02/2013-24217/incorporation-by-reference>). OMB is seeking comment on whether to provide agencies with criteria to consider when determining whether a voluntary standard is "reasonably available."

To address the policy question of reasonable availability, OMB is requesting comment on adopting, in the Circular, the recently issued ACUS Recommendation 2011-5, *Incorporation by Reference*, 77 Fed. Reg. 2257 (January 17, 2012) (<http://www.gpo.gov/fdsys/pkg/FR-2012-01-17/html/2012-621.htm>), with certain modifications. The Recommendation was adopted by ACUS through a consensus process in which a broad array of stakeholders participated, including standards developing bodies, academics, public interest groups, regulators, and industry. The Recommendation provides guidance to Federal agencies on what factors to consider when incorporating standards by reference into the U.S. Code of Federal Regulations. In this notice, OMB is also seeking comment on several of the factors found in the ACUS Recommendation, as well as additional ones, for agencies to consider. These include: whether the standards developer is willing to make read-only access to the standard available for free on its website during the comment period; 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 small businesses, public interest groups and the general public to participate in technical committee and technical advisory group work); and whether standards developers can provide a non-copyrighted, non-technical summary that adequately explains the content of the standard in a way that is understandable to a member of the public that lacks relevant technical expertise.

OMB does not believe the public interest would be well-served by requiring standards incorporated by reference to be made available “free of charge.” As some commenters on the RFI pointed out, the costs of standards development are substantial, and requiring that standards be made available “free of charge” will have the effect of either shifting those costs onto others or else depriving standards developing bodies of the funding through which many of them now pay for the development of these standards. Such changes could have serious adverse consequences on important governmental objectives, including the ability of U.S. regulators to protect the environment and the health, welfare, and safety of U.S. workers and consumers. OMB is seeking comments on proposed revisions to improve the level of transparency and breadth of stakeholder participation in standards development and enhance accessibility to standards, while also enabling agencies to meet their objectives and comply with U.S. law and policy, including the NTTAA and IPR law and policy, as well as international obligations.

One commenter suggested (as an alternative to “free access” to standards incorporated by reference) that standards be cited in regulation as only one method by which a regulated entity would be able to demonstrate its compliance with relevant requirements (rather than the incorporated standard being the exclusive method of compliance). Generally speaking, the public interest can be served by providing for regulatory flexibility in the achievement of regulatory objectives, and OMB encourages agencies to explore such flexibilities in the crafting of regulations (see sections 6i and 6k of the proposed Circular: “i. What factors should my agency consider when determining whether to allow the use of more than one standard?”; “k. Should my agency give preference to performance standards?”). However, in this particular context, it is not clear to what extent the suggested approach would be effective in addressing the concern that has been raised about the availability of standards that are incorporated by

reference. Even in those situations in which providing the suggested flexibility would be appropriate from a regulatory perspective, OMB believes that many entities would still choose to rely on incorporated standards as the method by which they would demonstrate their compliance with relevant requirements.

Fourth, some commenters also expressed the view that coordination on standards between agencies and the private sector should be enhanced, and in particular that the Interagency Committee on Standards Policy should engage with stakeholders on a more frequent basis.

Strengthening the Role of Agency Standards Executives: Several commenters on the RFI suggested that there was insufficient emphasis and coordination (both within and among Federal agencies) with respect to standards and conformity assessment. OMB is seeking comment on a proposed list of qualifications that all Standards Executives should meet before they are designated by their agencies as Standards Executives. Such qualifications could help ensure that Standards Executives possess the necessary knowledge and expertise to guide their agencies' implementation of the Circular. OMB is also seeking comment on revisions to the Circular that are aimed at ensuring that agencies provide their Standards Executives with sufficient authority within their respective organizations so that they can carry out their missions effectively, recognizing that agencies should be provided with flexibility in how to achieve this goal. OMB is also seeking comment on how training of agency personnel and coordination within and among Federal Agencies could be improved, including with respect to participation of Federal agencies in the standards development activities of voluntary standards bodies.

Management and Reporting on the Development and Use of Standards: OMB is also proposing to update the Circular's provisions on how the U.S. Government should manage and report on the development and use of standards, based on experience gained since 1998. OMB is requesting comments from the public on how useful this reporting has been and whether additional improvements can be made to the process. OMB also invites comment on the utility and practicability of integrating conformity assessment procedures into the current reporting mechanism.

Accordingly, OMB is seeking public comments on the proposed revisions to Circular A-119 that are set forth below in the draft of what would be a revised version of the Circular.

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

TABLE OF CONTENTS

BACKGROUND

1. What is the Purpose of this Circular?
2. What are the Goals of the Government In Using Voluntary Consensus Standards?

DEFINITIONS

3. What is a Standard?
4. What is Conformity Assessment?

POLICY

5. Who Does This Policy Apply To?
6. What is the Policy for Federal Use of Standards?
 - a. When must my agency use voluntary consensus standards?
 - b. What if a voluntary consensus standards body is likely to publish a suitable standard in time for an agency to use it?
 - c. How does this policy affect my agency's regulatory authorities and responsibilities?
 - d. How does this policy affect my agency's procurement authority?
 - e. When deciding to use a standard, what are some of the things my agency should consider?
 - f. Does this policy establish a preference between voluntary consensus standards and other types of standards?

- g. Are there standards-related international obligations that agencies must adhere to regarding the use of standards?
- h. What obligations does my agency have when considering whether to recognize a standard in use in the market of a trading partner?
- i. What factors should my agency consider when determining whether to allow the use of more than one standard?
- j. What should my agency consider with regard to intellectual property and the development of standards?
- k. Should my agency give preference to performance standards?
- l. How should my agency reference voluntary standards?
- m. What if no voluntary consensus standard exists?
- n. 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?
- o. How should my agency ensure that standards incorporated by reference are updated on a timely basis?
- p. How should my agency determine whether a voluntary standard is “reasonably available” in a regulatory or non-regulatory context?

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

- a. Must agency participants be authorized?
- b. Does agency participation indicate endorsement of any decisions reached by voluntary standards bodies?
- c. Do agency representatives participate equally with other members?

8. What is the Policy on Conformity Assessment?

- a. Should my agency consider relying on private sector conformity assessment activities in conjunction with or, where appropriate, in lieu of governmental conformity assessment?
- b. What considerations should my agency make when it is considering the type of conformity assessment procedure(s) to use?
- c. What obligations does my agency have when considering whether to recognize a conformity assessment procedure in use in the market of a trading partner?

- d. How does this policy affect my agency's regulatory authorities and responsibilities?
- e. When should my agency utilize the retrospective review mechanism with respect to conformity assessment?

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

MANAGEMENT AND REPORTING OF STANDARDS USE

10. How Does my Agency Manage and Report on the Development and Use of Standards?

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

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

- a. How does my agency report the use of standards in procurements on a categorical basis?
- b. How does my agency report the use of standards in procurements on a transaction basis?

AGENCY RESPONSIBILITIES

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

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

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

SUPPLEMENTARY INFORMATION

16. When will this Circular be Reviewed?

17. What is the Legal Effect of this Circular?

18. Do you have further Questions?

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. 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 law or otherwise impractical. The policies in this Circular are also 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. agency from engaging in standards-related activities that create unnecessary obstacles to the foreign commerce of the United States.

This Circular also provides guidance for agencies participating in the work of voluntary consensus standards bodies and describes procedures for satisfying the reporting requirements in the NTTAA. The policies in this Circular are intended to minimize the reliance by agencies on government-unique standards. This 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.

This Circular also discusses application of 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:

- (i) Production of timely, effective standards and efficient conformity assessment approaches that are essential to addressing an identified government need;
- (ii) Achieving cost-efficient, timely, and effective solutions to legitimate regulatory, procurement, and policy objectives;
- (iii) Promoting standards and standardization systems that promote and sustain innovation and foster competition;
- (iv) Enhancing U.S. growth and competitiveness and ensuring non-discrimination, consistent with international obligations; and

- (v) Facilitating international trade and avoiding the creation of unnecessary obstacles to trade.

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 these five 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 reduce, eliminate, or prevent the creation of unnecessary differences in regulation between the United States and its trading partners, consistent with Executive Order 13609, “Promoting International Regulatory Cooperation;” and
- d) Agencies reduce the cumulative effects, including the cumulative burdens, of regulation, consistent with Executive Order 13610.

2. What are the Goals of the Government in Using Voluntary Consensus Standards?

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

- a. Eliminating the cost to the Government of developing its own standards and decreasing the cost of goods procured and the burden of complying with agency regulation;
- b. 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
- c. Furthering the policy of reliance upon private sector expertise to supply the Government with high quality, cost-efficient goods and services.

DEFINITIONS

3. 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 Section 3f.
- d. "Voluntary standard" is a standard as defined above that is in the form of a standardization document developed by an association, organization, body, or technical society that plans, develops, establishes, or coordinates standards, specifications, handbooks, guidance, guidelines, or related documents and whose content meets the definition of "standard" set out in section 3a. An agency can make compliance with a voluntary standard mandatory as a matter of law when it incorporates the standard (or relevant part(s) thereof) into a regulation and requires compliance with it, or by making compliance with a voluntary standard mandatory in a procurement or technical document.
- e. "Voluntary consensus standard" is a type of voluntary standard that is developed or adopted by a voluntary consensus standards body.
- f. "Voluntary consensus standards bodies" are associations, organizations, bodies, or technical societies that plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. A voluntary consensus standards development process includes the following attributes or elements:
- i. Openness: The procedures or processes used are open on a non-discriminatory basis to interested parties, and such parties are provided meaningful opportunities to participate at all stages of standards development. The procedures or processes

- for participating in standards development and for developing the standard are transparent;
- ii. Balance of representation: The standards development process should have a balance of representation. The representation appropriate to the development of consensus in any given standards activity is a function of the nature of the standard being developed and the sector.
 - iii. Due process: Due process shall include adequate notice of meetings, sufficient time to review drafts and prepare views and objections, full access to the views and objections of other participants, and a fair and impartial process for resolving conflicting views;
 - iv. Appeals process; and
 - v. Consensus, which may be 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 6g for a discussion of international standards.

4. 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. It also includes accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability.

POLICY

5. Who Does This Policy Apply To? This Circular applies to all agencies and agency representatives who use standards or conformity assessment procedures and/or participate in the development of voluntary standards. "Agency" means any executive department, commission, board, bureau, office, Government-owned or controlled corporation, or other

establishment of the Federal government. It does not include the legislative or judicial branches of the Federal government.

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

a. When must my agency use voluntary consensus standards? In accordance with section 12(d) of the NTTAA (found as a “note” to 15 U.S.C. § 272), all Federal agencies must use existing voluntary consensus standards in lieu of agencies’ developing and using their own or other standards in their procurement, regulatory, or other agency activities, except when use of an existing voluntary consensus standard would be inconsistent with law or otherwise impractical.

In addition to consideration of voluntary consensus standards, it is also important to recognize the contributions of standardization activities that take place outside of the voluntary consensus process, particularly in emerging technology areas. Therefore, in instances where there are no suitable voluntary consensus standards, agencies should consider, to the extent consistent with law – as an alternative to using a government-unique standard – other voluntary standards that deliver the most generally favorable technical and economic outcomes (such as improved interoperability) and that are widely utilized in the marketplace.

When the use of existing voluntary consensus standards would be inconsistent with applicable law or otherwise impractical, agencies have the discretion under section 12(d) of the NTTAA to use a government-unique standard or other voluntary standard. In those circumstances where an agency elects to use or develop a government-unique standard or other voluntary non-consensus 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 through the National Institute of Standards and Technology (NIST). For more information on reporting, see sections 10-12 of the 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 program needs; be infeasible; be inadequate, ineffectual, inefficient, or inconsistent with 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.

b. 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.

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

This policy does not preempt, restrict, or discharge 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; setting the level of protection; and balancing risk, cost, and availability of technology in establishing regulatory requirements. However, to determine whether established regulatory limits or targets have been achieved, agencies should use voluntary consensus standards for test methods, sampling procedures, or protocols, if applicable. In some situations, it may be necessary for an agency to modify or supplement voluntary standards that are being incorporated by reference in order to accomplish the agency's regulatory objectives.

d. 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 prohibits agencies from

pursuing an identified capability through reliance on a government-unique standard when a suitable voluntary consensus standard exists. (See section 6a of the Circular).

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

(i) An agency should consider the use of voluntary standards on a case-by-case basis. 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, warrant less scrutiny by an agency than standards that embody factors that are less objective.

(ii) When considering using a voluntary standard, an agency should, to the extent permitted by law, take full 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.

This evaluation should include consideration of the economic effect of the intellectual property rights (IPR) policies of the voluntary consensus standards bodies on standards implementers, such as the extent to which entities practicing the standards may obtain licenses to patented technology incorporated into the standard on a non-discriminatory and reasonable royalty or royalty-free basis. This evaluation should also include consideration of whether such IPR policies bind subsequent transfers of patented technology incorporated into the standard.

An agency should also recognize the improper use of standards can suppress free and fair competition; impede innovation and technical progress; exclude safer or less expensive products; or otherwise adversely affect trade, commerce, health, or safety. 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 described in section 1 of the Circular.

(iii) In evaluating whether to use a standard, an agency should also consider the following factors:

(1) The apparent suitability of the standard for agency use, taking into consideration factors including:

- (a) The number of fatalities and/or the severity of injuries, accidents, or illnesses known to have resulted from products, materials, processes, practices, or services that have conformed with the standard;
- (b) The level of health or safety protection the standard provides;
- (c) The cost of other available standards that may also meet the agency’s needs and whose use would be consistent with law;
- (d) The cost to the government and the regulated public of the agency developing its own standard;
- (e) The problems addressed by the standard and changes in the state of knowledge and technology since the standard was prepared or last revised;
- (f) 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;
- (g) The extent to which the standard establishes performance rather than design criteria, where feasible;

(h) Whether small and medium sized entities (SMEs) will be able to comply with the standard; and,

(i) The enforceability of the standard;

(2) The nature of the agency's statutory mandate and the consistency of the provisions of the standard with that mandate;

(3) The extent to which the body when preparing the standard reflected the attributes of voluntary consensus standards bodies set out in section 3f of the Circular. The policies of standards developing bodies should be easily accessible. Further, the rules for determining, e.g., participation, balance of representation, opportunity for review and comment, and consensus, should be clear and unambiguous;

(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 in technical committee and technical advisory group work; and

(5) Whether the standard is “reasonably available.” See section 6p of the Circular for additional information.

f. Does this policy establish a preference between voluntary consensus standards and other types of standards?

(i) Yes. Consistent with section 12(d)(1) of the NTTAA, this policy establishes a preference for the use of standards that are developed or adopted by voluntary consensus standards bodies. The use of voluntary consensus standards is preferred because voluntary consensus standards are developed using processes which provide for openness, a balance of representation, due process, appeals, and consensus decision-making.

(ii) Agencies should use voluntary consensus standards, except when use of an existing voluntary consensus standard would be inconsistent with law or otherwise impracticable.

(iii) Where a voluntary consensus standard does not exist or use of an existing voluntary consensus standard would be inconsistent with law or otherwise impracticable, this policy allows agencies to use standards that are not developed or adopted by voluntary consensus standards bodies.

g. Are there standards-related international trade obligations that agencies must adhere to regarding the use of standards? Yes. For certain types of standards and regulations and where certain conditions apply, the United States is obligated to use relevant international standards under international trade agreements to which the United States is a party.

In particular, the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (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 defines 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.

The TBT Agreement does not provide a list of international standards or international standards bodies. However, in 2000, the WTO Committee on Technical Barriers to Trade adopted a decision setting out principles that international 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). In addition, certain U.S. free trade agreements² 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 voluntary 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 Committee Decision is contained in document G/TBT/1/Rev.11, Part 1, Section 3 (pp. 12-13) and Annex 2 (pp. 46-48). The six principles set out in the document are: (i) transparency, (ii) openness, (iii) impartiality and consensus, (iv) effectiveness and relevance, (v) coherence, and (vi) the development dimension. See Annex A to this Circular.

The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which applies to sanitary and phytosanitary measures, also addresses the use of relevant international standards. The WTO SPS Agreement, Article 3.1, 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.” SPS Agreement, Article 3.1, 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

² See e.g., Korea – United States Free Trade Agreement, Article 9.3.

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, unlike the WTO TBT Agreement, identifies three bodies among others that develop international standards, guidelines and recommendations for purposes of implementing the WTO SPS Agreement. Uniquely, with respect to regulatory actions and other measures that may be covered by the SPS Agreement, the SPS Agreement sets out three recognized sets of 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; and for plant health, those developed in the framework of the International Plant Protection Convention.

Agencies should consult with USTR on questions regarding international trade obligations relating to regulations, standards, and conformity assessment procedures 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. § 2541(b), USTR “has responsibility 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 State Department on questions regarding the application of international agreements other than trade agreements.

h. What obligations does my agency have when considering whether to recognize a standard in use in a foreign market? In determining whether to recognize a standard in use in the market of a trading partner, an agency should consider relevant international

agreements in consultation with USTR in the case of trade agreements, and with the State Department in the case of other international agreements. It should also examine how such recognition 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 in use in a foreign market pursuant to section 3(d) of Executive Order 13609.

In addition, the United States is obligated to adhere to certain international obligations with respect to accepting standards used in 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 fulfil the objectives of their own regulations.” The WTO SPS Agreement also contains obligations regarding equivalence determinations with respect to foreign country measures. Article 4 of the SPS Agreement provides:

1. 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.
2. 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.

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.

i. What factors should my agency consider when determining whether to allow the use of more than one standard? Consistent with section 6h of the Circular (where applicable), 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 the type of standard to be referenced. For example, in the areas of health, safety, and environmental protection, it may be preferable for an agency to allow the use of only one standard. In other areas, it may be more appropriate for the agency to allow the use of multiple standards in order 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. An example of this type of area is the information and communications technology (ICT) sector in which standards often are developed and revised in shorter timeframes, with multiple standards being produced in the same technology area. Allowing the use of more than one standard may also allow producers and service providers to simultaneously meet U.S. requirements and requirements in different markets, reducing burdens for manufacturers and service providers while effectively addressing agency objectives. When using multiple standards, agencies should give clear and specific guidance so that a hybrid standard is not inadvertently created.

In considering whether to allow the use of more than one standard in a regulation, your agency should also take into consideration: whether the standards would be effective in meeting agency objectives, the attributes of the standards (see section 6(e)), and potential costs and inequities that may be created.

In the interest of transparency, where an agency allows the use of more than one standard to meet a program, procurement, or regulatory requirement – whether through referencing multiple standards in the requirement, making an equivalency determination, using its enforcement discretion, or employing some other mechanism that is consistent with law -- it

should publish regulations or guidance establishing the policies and principles governing such mechanism.

j. What should my agency consider with regard to intellectual property and the development of standards? Many standards developing bodies have policies which require participating IPR holders to commit to license any patented technology incorporated into a standard on reasonable and non-discriminatory terms. Such policies often take into account the interests of both the IPR holders and those seeking to implement the standard. Such policies should be easily accessible and the rules governing the disclosure and licensing of IPR should be clear and unambiguous.

k. Should my agency give preference to performance standards? Yes. Pursuant to 19 U.S.C. § 2532(3) and section 1(b)(8) of Executive Order 12866, in using voluntary standards, your agency should give preference to performance standards when such standards are effective and may reasonably be used. 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, this will be standards that rely more heavily on performance based criteria.

l. How should my agency reference voluntary standards? Where your agency seeks to incorporate a voluntary 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. For use in regulations, you must follow the requirements set out in 1 CFR part 51, including the date of issuance with the reference. For all other uses, your agency must determine the most appropriate form of

reference. If a voluntary standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and meet any other similar obligations, such as those relating to patented technology that must be used to comply with the standard.

m. What if no voluntary consensus standard exists? In cases where no suitable voluntary consensus standards exist, an agency may use suitable voluntary 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 voluntary standards development organizations for development of a standard, or develop a standard utilizing the process principles outlined in section 3f. As explained above (see section 6a), 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.

n. 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, for instance, when 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-facing 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.

Where 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 voluntary standards development that may be relevant for subsequent agency action through, for example, a Request for Information (RFI) or an Advanced Notice of Proposed Rulemaking (ANPRM). Agencies could also use more informal means, such as contacting relevant bodies directly.

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

o. How should my agency ensure that standards incorporated by reference 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 update standards that have been incorporated by reference on a regular basis. Each agency should undertake a standards-specific review of such incorporated standards every 3-5 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.

In accordance with the retrospective review provisions of Executive Orders 13563 and 13610, an agency should also consult with stakeholders prior to issuance of a Notice of Proposed Rulemaking (NPRM), for example through an ANPRM or an RFI. Additionally, regulated entities may petition agencies to update incorporated standards. Such consultations will help the agency to 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 rule.

- (i) In the case of standards for which updating or substituting a new standard or standards would be non-controversial, the agency should publish a standards-specific direct final rule. 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.

- (ii) In the case of standards for which updating or substituting a new standard or standards might be controversial, the agency should publish a standards-specific NPRM. 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.

- (iii) 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” rulemaking (rather than through a standards-specific NPRM), where such re-opening meets the objectives and criteria set out in Executive Orders 13563 and 13610.

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.

In the interests of transparency, due process, and enforceability, agencies should not reference a standard in a non-binding guidance document as a means of making compliance with the standard mandatory.³ An agency may, however, reference existing standards in a non-binding

³ For additional guidance, see OMB Final Bulletin, “Agency Good Guidance Practices” (January 25, 2007), available at http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/012507_good_guidance.pdf.

guidance document where the use of those standards is already (separately and independently) required by statute or regulations.

If an agency decides not to adopt the most recent version of a standard, the agency should explain its reasons in the final rule. Agencies are encouraged to verify with NIST the accuracy of standards included in the Standards Incorporated by Reference (SIBR) Database at www.standards.gov.

p. How should my agency determine whether a voluntary 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.

- 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, since access may be necessary during rulemaking to make public participation in the rulemaking process effective;
- ii. The need for access to achieve agency policy or to subject the effectiveness of agency programs to public scrutiny;
- iii. The cost to regulated and other interested parties to obtain 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; and
- iv. Whether the standards developer can provide a freely available, non-technical summary that generally explains the content of the standard in a way that is understandable to a member of the public who lacks relevant technical expertise.

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 6g 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).

When considering incorporation by reference of highly technical materials, agencies should include in the preamble of an NPRM an explanation of the materials, including a non-technical summary that generally explains the content of the standard in a way that is understandable to a member of the public who lacks relevant technical expertise and how the agency’s incorporation by reference of the standard would further the agency’s regulatory objective.

If an agency incorporates by reference material that is 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 voluntary 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, 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.

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

Consistent with section 12(d)(2) of the NTTAA, agencies must consult with voluntary standards bodies, including bodies that develop international standards, 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 of representation.

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

- 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.”
- 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.”
- 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, to provide information and communicate the views of the agency relative to the standards being developed and the procedures followed.

- a. Must agency participants be authorized?** Agency representatives who, at Government expense, participate in standards activities of voluntary standards bodies on behalf of the agency must do so as specifically authorized agency representatives. Agency support for, and participation by, agency representatives in voluntary

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 voluntary 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.” 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://www.justice.gov/olc/standardsorg.htm).

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 and leadership participation 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 activities in standards bodies and activities.

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

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

8. What is the Policy on Conformity Assessment?

Section 12(b) of the NTTAA requires the National Institute of Standards and Technology (NIST) to coordinate Federal, State, and local standards activities and conformity assessment activities with private sector standards activities and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. At OMB's direction, 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 and participate in conformity assessment activities that:

- (1) Are effective and appropriate in carrying out agency missions;
- (2) Minimize the regulatory and/or conformity assessment burden on the regulated entities;
- (3) Are in accordance with international obligations;
- (4) Conserve and leverage agency resources; and
- (5) Increase acceptance of U.S. products domestically and in foreign markets.

Agencies should be aware that conformity assessment activities and systems can be used in many different ways to support their missions. Conformity assessment activities 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 also 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 developing government-unique conformity assessment procedures

would be beneficial, where such use is feasible and appropriate and not otherwise prohibited by law. Agencies will continue to have the flexibility of choosing conformity assessment programs, whether private, public, or some combination thereof, that best help to achieve these objectives.

a. Should my agency consider relying on private sector conformity assessment activities in conjunction with or, where appropriate, in lieu of governmental conformity assessment?

Yes. Consistent with this policy guidance, all Federal agencies are encouraged to consider relying on international conformity assessment schemes or private sector conformity assessment activities in conjunction with or, where appropriate, in lieu of governmental conformity assessment, except where such activities are inconsistent with law, unfit for regulatory or other agency purpose, or otherwise impractical. 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.

b. What considerations should my agency make when it is considering the type of conformity assessment procedure(s) to use?

When an agency is evaluating whether to put in place a conformity assessment procedure, it should, consistent with statute, resource constraints, and the instruments set out in section 1 of this Circular, consider certain factors when assessing effective 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 and the anticipated costs of demonstrating

compliance (including time and resources) to the producers, suppliers, consumers, and the agency. Relying on a conformity assessment procedure in use in the marketplace, or allowing the continued use of such a procedure – provided that it is equally effective or more effective than a new procedure considered by the agency – is encouraged to reduce the burden on the affected public;

- (iii) Who will be conducting the procedure (e.g., the producer, the government, or a third party), when it will be conducted (e.g., pre-market, post-market, periodic); and what is the appropriate level of competence needed to assess conformity;
- (iv) Consistency with statutory and international obligations. There are statutory and international obligations that govern standards-related activities, including 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 that 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 under certain circumstances 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 standards, taking into account the risks non-conformity would create. The United States has also undertaken additional commitments on conformity assessment in other U.S. free trade agreements, such as obligations not to discriminate against conformity assessment bodies located in the territories of certain countries with which the United States has a free trade agreement. Agencies are urged to consult with USTR on questions regarding international obligations on conformity assessment procedures.

- (v) Consideration of the available scientific and technical information;
- (vi) Relevant industry practice and experience, and the industry’s history of compliance;
- (vii) The need to ensure consistency, reduce duplication and complexity, and coordinate with the conformity assessment approaches of other agencies, where feasible, appropriate, and consistent with law. 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 8e);”
- (viii) The appropriateness of recognizing the results of private sector conformity assessment schemes being utilized in State, local, and/or foreign government

regulation, consistent with section 8a. Agencies are also encouraged to rely on international, regional, and national systems of conformity assessment rather than creating their own conformity assessment systems, consistent with any applicable domestic law or international obligations;

(ix) The need to ensure that information requirements for conformity assessment are limited to what is necessary to assess conformity and determine fees. Agencies must also take protective measures so that any confidential or proprietary information that suppliers submit to an agency is not communicated, whether intentionally or inadvertently, to any person or organization not having legal right to such information; and

(x) The degree of transparency to stakeholders and the public of the conformity assessment procedure.

c. What obligations does my agency have when considering whether to recognize a conformity assessment procedure in use in the market of a trading partner?

Article 6.1 of the WTO TBT Agreement requires that results of conformity assessment procedures in other countries be accepted, provided they can offer an equivalent assurance of conformity with regulations and standards to those required by the relevant agencies. U.S. free trade agreements may also have obligations with respect to recognition of trading partners' conformity assessment procedures. Accordingly, in considering whether to recognize a conformity assessment procedure in use in the market of a trading partner, an agency should consult with USTR, which has statutory responsibility under 19 U.S.C. § 2541 "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 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?

(i) 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 procedures 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.

To reduce such burden, one factor to consider is whether the use, in whole or in part, of private sector conformity assessment schemes – including international systems of conformity assessment – that are already in use in the marketplace will help to ensure the continued effectiveness of agency conformity assessment schemes.

(ii) To reduce duplication, complexity, and the cumulative effects of regulation, where

(1) two or more agencies require conformity assessment for the same product/service attribute, and

(2) there is adequate information that –

(a) one agency’s requirement is as effective as other agencies’ requirements in fulfilling a common objective, and

(b) 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,

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. Consistent with law and the need for agencies to maintain appropriate levels of protection for health and safety, agencies should engage the regulated public and other stakeholders in public consultation as part of the retrospective review process described above before issuing such rulemakings.

9. 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. § 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 that Federal agencies also participate in the development of other voluntary standards, including through their activities in bodies that develop voluntary non-consensus standards, as well as in regulatory collaboration initiatives. 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 Second 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 strategies on standards and conformity assessment, regulation, and international trade.

10. How Does My Agency Manage and Report on the Development and Use of Standards?

- a. Your agency must establish a process to identify, manage, and review your agency's participation in the development and use of standards. At minimum, your agency must have the ability to (1) report to OMB, through NIST, on the agency's use of government-unique standards in lieu of voluntary consensus standards, along with an explanation of the reasons for such non-usage, as required by section 12(d) of the NTTAA and as described in section 6a of this Circular; and (2) report on your agency's participation in the development and use of voluntary consensus standards, as described in sections 11 and 12 of this Circular. 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.
- b. 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. If no voluntary consensus standard exists, your agency does not need to report its use of

government-unique standards or other standards (see section 6f). 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 6a, 12a(iii), and 12b(ii) of this Circular. Your agency must report in accordance with the instructions issued by NIST.

- c. Your agency must report to NIST information on the nature and extent of agency participation in the development and use of voluntary consensus standards from the previous fiscal year. Your agency must report in accordance with the instructions issued by NIST. Such reporting must include the following:

- (i) The number of voluntary consensus standards bodies in which there is agency participation, as well as the number of agency employees participating;

- (ii) The number of voluntary consensus standards the agency has used since the last report, based on the procedures set forth in sections 11 and 12 of this Circular;

- (iii) Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review under sections 11 and 12 of this Circular; and

- (iv) An evaluation of the effectiveness of this policy and recommendations for any changes.

Your agency is also encouraged to report to NIST the answers to items (i) through (iii) with respect to other voluntary standards also in use. NIST must maintain the reports received on www.standards.gov 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.

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

- a. For significant regulatory actions, agencies are encouraged to include in their rulemaking notices a discussion in the regulatory preamble of how they implemented this Circular. Such a discussion could include the following elements:
 - (i) Which bodies or organizations the agency consulted with to determine whether there are relevant voluntary standards in use in the marketplace (or completion of relevant voluntary standards is imminent) or if voluntary 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 voluntary 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."
- b. Your agency should use transaction based reporting in its annual report to NIST if your agency issues regulations that use or reference standards.

12. What are the Procedures for Reporting My Agency's Use of Standards in Procurements? Your agency must either report on 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 report on a categorical basis 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 which 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 voluntary standards;

(ii) Systematically review your agency's use of government-unique standards for conversion to voluntary consensus standards and, where appropriate, other voluntary 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 6a and 10b; and

(iv) Enable potential offerors to suggest voluntary consensus standards and, where appropriate, other voluntary 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 mostly through 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 which references government-unique standards, the solicitation must identify such standards and provide potential offerers an opportunity to suggest alternative voluntary consensus standards (or, where appropriate, other voluntary 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 report to OMB as described in sections 6a and 10b why using such voluntary consensus standards is inconsistent with applicable law or otherwise impractical.

c. For those solicitations that are for commercial-off-the-shelf products (COTS), or for products or services that rely on voluntary consensus standards or other voluntary standards, or for products that otherwise do not rely on government-unique standards, the requirements in this section do not apply.

AGENCY RESPONSIBILITIES

13. 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 Interagency Committee on Standards Policy, chaired by the National Institute of Standards and Technology, 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 8.

14. 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 Interagency Committee on Standards Policy; 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 10b.

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

An Agency Standards Executive:

- 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 voluntary 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 voluntary standards bodies and in conformity assessment activities:
 - (i) Effective use of agency resources and participation;
 - (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 8 of this Circular, consistent with 15 C.F.R. § 287.
- c. Coordinates the agency's participation in voluntary standards bodies by:

(i) Establishing procedures to ensure that agency representatives who participate in voluntary standards bodies will, to the extent possible, ascertain the views of the agency on matters of paramount interest and will, at a minimum, express views that are not inconsistent or in conflict with established agency views;

(ii) Ensuring that the agency's participation in voluntary standards bodies is consistent with agency missions, authorities, priorities, and budget resources;

(iii) Coordinating with voluntary standards bodies, and notifying such bodies when the agency has incorporated their standards by reference;

(iv) Ensuring, when two or more agencies participate in a given voluntary 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;

(v) Cooperating with the Secretary or his or her designee in carrying out his or her responsibilities under this Circular;

(vi) Consulting with the Secretary or his or her designee, as necessary, in the development and issuance of internal agency procedures and guidance implementing this Circular;

(vii) Preparing, as described in sections 10 through 12 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;

(viii) Establishing a process for ongoing review of the agency's use of standards for purposes of updating or substituting, pursuant to section 6o;

(ix) 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, voluntary standards bodies, so that agency support and participation will comply with applicable laws and regulations;

(x) 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;

(xi) Providing ongoing assistance and policy guidance to agency employees and managers on significant issues in standardization and conformity assessment; and

(xii) Coordinating with the Trade Policy Staff Committee (TPSC) TBT Subcommittee or other relevant TPSC subcommittees on the trade implications of standardization; and

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 on a transactional basis; and

(iii) Meeting on a regular basis with NIST, the Interagency Committee on Standards Policy, other Agency Standards Executives, USTR (and, if

applicable, your agency's representatives to the relevant subcommittee of the Trade Policy Staff Committee), and the desk officer for your agency in OMB's Office of Information and Regulatory Affairs.

SUPPLEMENTARY INFORMATION

16. When Will This Circular Be Reviewed? This Circular will be reviewed for effectiveness by OMB five years from the date of issuance. The Interagency Committee on Standards Policy will establish a process for gathering input from the public periodically on relevant developments in standards and conformity assessment, including holding discussions with regulated entities, standards developers, conformity assessment and accreditation bodies, and interested members of the public.

17. What Is the Legal Effect of This Circular? 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. This Circular is not intended to create delay in the administrative process, 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. This policy is intended as guidance to agencies and should not be used by courts to interpret statutes in the absence of agency action.

18. Do You Have Further Questions? For information concerning this Circular, contact the Office of Management and Budget, Office of Information and Regulatory Affairs: Telephone 202-395-3785.

ANNEX A

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

Decision⁴

1. 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.
2. 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.

1) Transparency

3. 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.
4. 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;

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

- (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 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.
5. 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.

2) **Openness**

6. 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.
7. 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.

3) Impartiality and Consensus

8. 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.
9. 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.

4) Effectiveness and Relevance

10. 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.

11. 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.

5) Coherence

12. 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.

6) Development Dimension

13. 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.