Federal Use of Standards

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


SUMMARY: The Office of Management and Budget (OMB) is revising Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities." Public Law 104-113, the National Technology Transfer Act of 1995 (hereinafter known as P.L. 104-113), was passed by Congress to codify existing policies in A-119, to establish additional reporting requirements, and to authorize the National Institute of Standards and Technology (NIST) to coordinate conformity assessment activities of the agencies. P.L. 104-113 was signed into law by the President on March 13, 1996. This proposed revision of Circular A-119 implements the new law and makes certain other modifications.

DATES: Comments are requested on the proposed revisions to Circular A-119 no later than (insert date 60 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Direct written comments to: Information Policy and Technology Branch, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB Room 10236, Washington, D.C., 20503. E-mail comments may be sent to: huth_v@eop.gov.


SUPPLEMENTARY INFORMATION: Section 12(d) of the National Technology Transfer Act of 1995 (P.L. 104-113, or "the Act") codified the policies of Circular A-119. Section 12(d)(1) states that "Except as provided in paragraph (3) of this subsection, all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments."
To carry out this requirement, Section 12(d)(2) states that agencies and departments "shall consult" with those bodies and "shall ... participate" with them in developing voluntary consensus standards "when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources."

Finally, Section 12(d)(3) states that, where it would be "inconsistent with applicable law or otherwise impractical" to use standards that those bodies develop or adopt, an agency or department may use other standards; however, the head of the agency or department must send to OMB "an explanation of the reasons for using such standards." The law states that, beginning with fiscal year 1997, OMB will transmit to Congress and its Committees an annual report summarizing all explanations received in the preceding year.

This Circular provides instructions, beginning with FY 97, for agencies to report explanations of instances in which agencies used standards which were not developed by voluntary consensus standards bodies. For FY 96, OMB issued a letter on May 17, 1996, to the heads of departments and agencies notifying them of the Act and of the new reporting requirement. For the period March 13, 1996 (date of enactment of the Act) to September 30, 1996, any explanations that agencies have generated should be transmitted to NIST no later than January 31, 1997, for forwarding to OMB.


Accordingly, the revisions proposed to the Circular are not intended to change the policy with respect to agencies' use of voluntary consensus standards, but instead are intended to conform the Circular's terminology to the Act and to increase the Circular's clarity and effectiveness.

SUMMARY OF CHANGES:

This proposed revision incorporates the following changes:

(1) Section 5 clarifies the definitions for "agency" and "standard." The definition for "adoption" has been replaced by a definition for "use." The definition for "voluntary standards" has been replaced by a definition for "voluntary consensus standards." The definition for "voluntary standards bodies" has been replaced with a definition for "voluntary consensus standards bodies." New definitions for "conformity assessment," "impractical," "performance standard," and "technical standard" have been added. Finally, terminology throughout the Circular has been modified to reflect these changes.

(2) Section 6a has been revised to state that these policies apply to all policy objectives and activities, including procurement and regulatory activities, to clarify that these policies do not pre-empt or restrict
agencies' authorities and responsibilities to regulate, and to clarify that agencies retain discretion to decline to use an existing voluntary consensus standard if the agency determines that such standard is inconsistent with applicable law or otherwise impractical.

(3) Section 6b has been modified to state that agencies are to refrain from actively participating in standards development committees when involvement in such committees does not clearly relate to the mission of the agency and to avoid dominating committee proceedings. Section 7b.6 has been modified to state that agency support for standards development activities is not to be contingent upon the outcome of the standards activity.

(4) Section 6c has been modified to reflect the need for greater coordination among the federal agencies prior to their participation on technical committees. The material in Section 7c, which provides guidance on this subject, was formerly Sections 8b.2(a-e) and 8b.3. Some minor changes were made to ensure consistency in terminology. Section 9c has been added in order to make coordination of standards activities the explicit responsibility of the Standards Executive.

(5) Section 7a.5 has been added to describe one way in which agencies may identify voluntary consensus standards.

(6) Section 8 establishes procedures for reviewing existing voluntary consensus standards when issuing or revising a regulation or initiating a procurement. Such procedures provide for public notice and comment on proposed standards and require agencies to respond to public comment and to explain the final outcome.

(7) Section 10a establishes requirements for reporting on exceptions to the use of voluntary consensus standards, as required by P.L. 104-113. The reporting requirements of Section 10b, although not required by statute, have been retained. The language has been modified to provide for coordination with the reporting requirements in Section 10a.

(8) Section 10 directs the National Institute of Standards and Technology to issue guidance to the agencies in order to promote the coordination of Federal, State, and local standards activities and conformity assessment activities with the private sector, as required by Section 12(b) of P.L. 104-113.

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

Sally Katzen
Administrator
Office of Information and Regulatory Affairs
1. **Purpose.** This Circular establishes policy to be followed by agencies in working with voluntary consensus standards bodies and in using voluntary consensus standards, in accordance with Section 12(d) of the National Technology Transfer and Advancement Act (hereinafter cited as P.L. 104-113). It also implements reporting requirements for the use of voluntary consensus standards and addresses the role of the National Institute for Standards and Technology (NIST) in coordinating conformity assessment activities.

2. **Rescissions.** This Circular supersedes OMB Circular No. A-119, dated October 20, 1993, which is rescinded.

3. **Background.** Many standards that are developed by voluntary consensus standards bodies are appropriate or adaptable for the Government's purposes. The adoption of such standards, whenever practicable and appropriate, eliminates the cost to the Government of developing its own standards. At the same time, Government participation in standards-related activities provides incentives and opportunities to establish standards that serve national needs. Moreover, harmonization of standards promotes efficiency and economic competition, thus encouraging long-term growth for U.S. enterprises. Adoption of standards developed by voluntary consensus standards bodies also furthers the policy of reliance upon the private sector to supply Government needs for goods and services, as stated in OMB Circular No. A-76, "Performance of Commercial Activities."

4. **Applicability.** This Circular applies to all agency participation in voluntary consensus standards activities, domestic and international, but not to activities carried out pursuant to treaties and international standardization agreements.

5. **Definitions.** As used in this Circular:

   a. Agency means any executive department, independent commission, board, bureau, office, agency, Government-owned or controlled corporation or other establishment of the Federal Government, including any regulatory commission or board, except for independent regulatory commissions insofar as they are
subject to separate statutory requirements regarding the use of voluntary consensus standards. It does not include the legislative or judicial branches of the Federal Government.

b. Conformity assessment means any procedures used directly or indirectly to determine if relevant requirements in technical regulations or standards are fulfilled. The activities which are commonly termed "conformity assessment" include product testing, inspection and/or certification, including self-certification; accreditation of testing and calibration laboratories; and management system registration (for both quality and environment). Conformity assessment procedures include: sampling, testing and inspection, evaluation, verification and assurance of conformity, laboratory accreditation (for both testing and calibration), registration accreditation, and approval.

c. Impractical, with respect to an agency's decision not to use an existing voluntary consensus standard, includes circumstances in which such use would demonstrably fail to serve the agency's program needs; would be infeasible; would be unnecessarily duplicative, inadequate, inefficient, or inconsistent with agency mission; or would impose more burdens, or would be less useful, than the use of another standard.

d. Performance standard means a standard that states requirements in terms of required results with criteria for verifying compliance but without stating the methods for achieving required results. A performance standard defines the functional requirements for the item, the environment in which it must operate, and interface and interchangeability characteristics, while a design standard specifies 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. "Performance standard" is a subset of "standard" as defined in section 5f. of this Circular.

e. Secretary means the Secretary of Commerce or that Secretary's designee.

f. Standard (or "technical standard," as found in P.L. 104-113), as used in this Circular, means: (1) common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods; (2) 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, products, systems, services, or practices; or descriptions of fit and measurements of size; (3) "performance standard" as defined above; or (4) "non-government standard", which is defined as a standardization document developed by a private sector association, organization or technical society which plans, develops, establishes or coordinates standards, specifications, handbooks, or related documents. The term does not include professional standards of personal conduct, institutional codes of ethics, or standards issued by individual companies. It also does not include
standards created under other legal authority, such as those contained in the United States Pharmacopeia and the National Formulary, as referenced in 21 U.S.C. 351. A "Standard" may also be a "voluntary consensus standard," as defined below, or it may be what are commonly referred to as "industry standards" or "de facto standards," which are developed by industry associations which do not always adhere to the full consensus process.

g. Technical Standard, as used in this Circular, is synonymous with "standard." Examples of technical standards include, but are not limited to, size and strength specifications; technical performance criteria for a product, process, or material; test methods; procurement guidelines; sampling procedures; business practices; management systems; definitional standards; and installation safety codes.

h. Use means (i) use of the latest edition of a standard in whole, in part, or by reference for procurement purposes, and (ii) the inclusion of the latest edition of a standard in whole, in part, or by reference in regulation(s).

i. Voluntary consensus standards are standards developed or used by voluntary consensus standards bodies, both domestic and international, and which are made available in a manner which includes provisions requiring that owners of relevant intellectual property have agreed to make that intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties. A "Voluntary consensus standard" may also be known in common usage as a "voluntary standard," a "consensus standard," or a "consensus technical standard."

j. Voluntary consensus standards bodies are domestic or international organizations which plan, develop, establish, or coordinate voluntary standards using agreed-upon procedures. For purposes of this Circular, "voluntary, private sector, consensus standards bodies," as cited in P.L. 104-113, is an equivalent term. These bodies may include nonprofit organizations, industry associations, accredited standards developers, professional and technical societies, institutes, committees, task forces, or working groups. P.L. 104-113 and this Circular encourage the participation of government representatives in these bodies to increase the likelihood that the standards they develop will meet both public and private sector needs. A voluntary consensus standards body observes principles such as openness, balance of interest, and due process. Further, voluntary consensus standards bodies operate by consensus, which is defined as general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests. Consensus requires that all views and objections be considered and that an effort be made toward their resolution.
6. **Use and Development of Voluntary Consensus Standards.**

- Agencies shall use existing voluntary consensus standards, both domestic and international, in their regulatory and procurement activities as a means of carrying out policy objectives or activities determined by the agencies, unless use of such standards would be inconsistent with applicable law or otherwise impractical. Agencies shall use such voluntary consensus standards for test methods, procurement guidelines, management systems, sampling procedures, or protocols to determine whether established regulatory limits or targets have been met. This requirement does not preempt or restrict agencies' authorities and responsibilities to make regulatory decisions authorized by statute. Such regulatory authorities and responsibilities include determining the level of acceptable risk; setting the level of protection; and balancing risk, cost, and availability of technology in establishing regulatory standards. Agencies retain discretion to decline to use existing voluntary consensus standards if the agency determines that such standards are inconsistent with applicable law or otherwise impractical.

- Agencies shall consult with voluntary consensus standards bodies and shall participate with such bodies in their development and adoption of voluntary consensus standards when, in the determination of the agencies, participation is in the public interest and is compatible with their missions, authorities, priorities, and budget resources. Agency representatives shall refrain from actively participating in voluntary consensus standards bodies or their committees when involvement does not relate to the mission of the agency. In all cases, agency representatives shall ensure that the agency's influence does not dominate proceedings.

- Agencies shall coordinate their participation in voluntary consensus standards bodies so that: (1) the most effective use is made of agency resources and representatives; (2) the views expressed by such representatives are in the public interest and, at a minimum, do not conflict with the interests and established views of the agencies; (3) the positions among agencies serving on the same technical committees are consistent with administration policy; and (4) agency technical and policy positions are clearly defined and known in advance to all federal participants on a given committee.

7. **Guidelines.** In implementing the policy established by this Circular, agencies should recognize the positive contribution of standards development and related activities. When properly conducted, standards development can increase productivity and efficiency in Government and industry, expand opportunities for international trade, conserve resources, improve health and safety, and protect the environment. It also must be recognized, however, that these activities, if improperly conducted, can suppress free and fair competition; impede innovation and technical progress; exclude safer and less expensive products; or otherwise adversely affect trade, commerce, health, or safety. Full account in
carrying out this policy shall be taken of the impact on the economy, applicable Federal laws, policies, and national objectives, including, for example, laws and regulations relating to antitrust, national security, small business, product safety, environment, metricalization, technological development, and conflicts of interest. The following guidelines are provided to assist and govern the agencies' use of, and participation in the development and adoption of, voluntary consensus standards.

- a. Use of Voluntary Consensus Standards.
  
  (1) In the interests of promoting trade and implementing the provisions of the Agreement on Technical Barriers to Trade and the Agreement on Government Procurement (commonly referred to as the Technical Barriers to Trade (TBT) Agreement and the "Procurement Code," respectively) of the World Trade Organization, international standards (standards developed and/or adopted by international voluntary consensus standards bodies) should be considered in procurement and regulatory applications.

  (2) In using voluntary consensus standards, preference should be given to standards based on performance criteria when such criteria may reasonably be used in lieu of design, material, or construction criteria.

  (3) Voluntary consensus standards used by agencies should be referenced, along with their dates of issuance and sources of availability, in appropriate publications, regulatory orders, and related in-house documents. Such use should take into account the rights of copyright holders and other similar obligations.

  (4) Agencies should not be inhibited from developing and using government standards in the event that voluntary consensus standards bodies cannot or do not develop a needed, acceptable standard in a timely fashion. Nor should this Circular be construed as committing any agency to the use of a voluntary consensus standard which, after due consideration, is determined by the agency to be inconsistent with applicable law or otherwise impractical.

  (5) Voluntary consensus standards may be identified through databases of standards maintained by the National Institute of Standards and Technology (NIST) or by voluntary consensus standards bodies.

- b. Participation in Voluntary Consensus Standards Bodies.

  (1) Participation by knowledgeable agency employees in the standards activities of voluntary consensus standards bodies, both domestic and international, should be actively encouraged and promoted by agency officials when consistent with P.L. 104-113 and this Circular.
(2) Agency employees who participate in standards activities of voluntary consensus standards bodies shall do so as specifically authorized agency representatives. Agency representatives shall refrain from actively participating in standards development committees when involvement in such committees does not relate to the mission of the agency. Agency participation in voluntary consensus standards bodies does not necessarily connote agency agreement with, or endorsement of, decisions reached by such organizations.

(3) Agency representatives shall participate in such bodies' development of voluntary consensus standards that:

(i) will eliminate the necessity for development or maintenance of separate Government standards; and

(ii) will further such national goals and objectives as increased use of the metric system of measurement; environmentally sound and energy efficient materials, products, systems, services, or practices; and public health and safety.

(4) Agency representatives serving as members of voluntary consensus standards bodies should participate actively and on an equal basis with other members. In doing so, agency representatives should not seek to dominate such groups. Active participation includes full involvement in discussions and technical debates, registering of opinions and, if selected, serving as chairpersons or in other official capacities. Agency representatives may vote, in accordance with the procedures of the voluntary consensus standards body, at each stage of standards development unless prohibited from doing so by law or their agencies.

(5) The number of individual agency participants in a given voluntary standards activity should be kept to the minimum required for effective presentation of the various program, technical, or other concerns of Federal agencies.

(6) Agency support provided to a voluntary consensus standards activity shall be limited to that which is clearly in furtherance of an agency's mission and responsibility. Agency support shall not be contingent upon the outcome of the standards activity. Normally, the total amount of Federal support should be no greater than that of all other participants in that activity, except when it is in the direct and predominant interest of the Government to develop or revise a standard and its development or revision appears unlikely in the absence of such support. The form of agency support, subject to legal and budgetary authority, and availability of funds, may include:

(i) direct financial support; e.g., grants, sustaining memberships, and contracts;

(ii) administrative support; e.g., travel costs, hosting of meetings, and secretarial functions;
(iii) technical support; e.g., cooperative testing for standards evaluation and participation of agency personnel in the activities of voluntary consensus standards bodies;

(iv) joint planning with voluntary consensus standards bodies to facilitate a coordinated effort in identifying and developing needed standards; and

(v) participation of agency personnel.

(7) Participation by agency representatives in the policy-making processes of voluntary consensus standards bodies, in accordance with the procedures of those bodies, is encouraged--particularly in matters such as establishing priorities, developing procedures for preparing, reviewing, and approving standards, and developing or adopting new standards. In order to maintain the independence of such organizations, however, agency representatives should refrain from involvement in the internal management of such organizations (e.g., selection of salaried officers and employees, establishment of staff salaries and administrative policies).

(8) This Circular does not provide guidance concerning the internal operating procedures that may be applicable to voluntary consensus standards bodies because of their relationships to agencies under this Circular. Agencies should, however, carefully consider what laws or rules may apply in a particular instance because of these relationships. For example, these relationships may involve the Federal Advisory Committee Act, as amended (5 U.S.C. App. I), or a provision of an authorizing statute for a particular agency.

• c. Coordination of participation in voluntary consensus standards bodies and standards activities.

Agency Standards Executives, designated under section 9c., shall coordinate agency participation in voluntary consensus standards bodies. This coordination shall include, but need not be limited to:

  (1) establishing procedures to ensure that agency representatives participating in voluntary consensus 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; and will, to the extent possible, ensure that the agency's participation in voluntary consensus standards bodies is consistent with agency missions.

  (2) ensuring, when two or more agencies participate in a given voluntary consensus standards body, 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;

  (3) cooperating with the Secretary in carrying out his/her responsibilities under this Circular;
(4) consulting with the Secretary, as necessary, in the development and issuance of internal agency procedures and guidance implementing this Circular, including the development and harmonized implementation of an agency-wide directory identifying agency employees participating in standards developing groups;

(5) submitting, as described in section 10, in response to the request of the Secretary, a report on exceptions to the use of existing voluntary consensus standards and a report on the status of agency standards policy activities; and

(6) reviewing their existing standards within five years of issuance of this Circular, and at least once every five years thereafter, and replacing through applicable procedures those for which an adequate and appropriate voluntary consensus standard can be substituted.

8. Procedures.

- a. When issuing or revising a regulation, agencies shall review for use existing voluntary consensus standards. Such review shall include:

  - (1) A request for comment within the preamble of a Notice of Proposed Rulemaking (NPRM). Such request shall provide:

    - (i) when an existing voluntary consensus standard is being proposed for use, a statement which identifies such standard, as well as the identity of any alternative voluntary consensus standards which may have been identified and/or considered, and an explanation of why the proposed standard should be used;

    - (ii) when the agency has determined to not propose for use an existing voluntary consensus standard, a statement which identifies such standard, provides a preliminary explanation for why such standard would not be used, and invites the public to comment and to explain why such standard or an alternative voluntary consensus standard should be used; or

    - (iii) when no existing voluntary consensus standard has been identified, a statement which invites the public to identify such voluntary consensus standards and to explain why such standard should be used; and
(2) A discussion in the preamble of a Final Rulemaking that restates the discussion in the proposed rule, acknowledges and summarizes any comments received and responds to them, and explains the agency's final decision. The final rule shall provide:

(i) when an existing voluntary consensus standard is being used, a statement that identifies such standard and any alternative voluntary consensus standards which have been identified;

(ii) when an existing voluntary consensus standard is not being used, a statement that identifies such standard and explains why such use would be inconsistent with applicable law or otherwise impractical; or

(iii) when no existing voluntary consensus standard has been identified, a statement to that effect.

(b) When initiating a procurement, agencies shall consider using existing voluntary consensus standards.

  (1) Where the solicitation is for products that incorporate government-unique standards, the solicitation shall include a statement which identifies the standards to be used and provides offerors an opportunity to suggest alternatives in the nature of existing voluntary consensus standards that meet the government's requirements. Where such suggestions are made and do not result in a replacement of government-unique standards by existing voluntary consensus standards, the agency shall explain why such use is inconsistent with law or otherwise impractical.

  (2) Where the solicitation is for commercial, off-the-shelf products, or for products that rely on existing voluntary consensus standards, or for products that do not rely on government-unique standards, the requirement in subsection (1) above shall not apply.

9. Responsibilities.

- a. The Secretary shall:

  (1) coordinate and foster executive branch implementation of this Circular and may provide administrative guidance to assist agencies in implementing this Circular;

  (2) continue the Interagency Committee on Standards Policy (ICSP), chaired by the National Institute of Standards and Technology (NIST), in order to consider their views and to advise the Secretary and agency heads in the Circular;
(3) as described in section 10, report to the Office of Management and Budget (OMB), with the assistance of NIST, concerning implementation of the policy provisions of this Circular; and

(4) establish procedures for agencies to use when developing directories described in paragraph 7c(4) and establish procedures to make these directories available to the public.

- b. Heads of Agencies shall:
  - (1) Implement section 6 of this Circular in accordance with the guidelines in section 7 and the procedures in section 8;

- (2) In the case of an agency with significant interest in the use of standards, designate a senior level official as the Standards Executive who shall be responsible for agency-wide implementation of this Circular and who shall represent the agency on the ICSP.

- c. The Standards Executive’s responsibilities shall include, but not be limited to, those described in section 7c.

10. Reporting Requirements.

- a. Agency Reports on exceptions to use of existing voluntary consensus standards. As required by P.L. 104-113, beginning for fiscal year 1997 and every fiscal year thereafter, agencies shall report to OMB, through NIST, no later than December 31 of the following fiscal year, any decisions by the agency during that fiscal year to use a government-unique standard in lieu of an existing voluntary consensus standard, along with an explanation of the reason(s) why use of such standard would be inconsistent with applicable law or otherwise impractical, as described in sections 8a.(2)(ii) and 8b.(1) of this Circular.

- b. Agency Reports on Standards Policy Activities. To assist OMB in its reporting to Congress, beginning for fiscal year 1996 and every fiscal year thereafter, agencies shall submit information to OMB, through NIST, on the status of agency interaction with voluntary consensus standards bodies, no later than December 31 of the following fiscal year. Such reporting shall include the nature and extent of agency participation in the development and use of voluntary consensus standards, including:
  - (1) the number of voluntary consensus standards bodies in which there is agency participation;
(2) the number of voluntary consensus standards the agency has used since the last report which have come about as a result of the requirements set forth in sections 8a. and 8b. of this Circular;

(3) identification of voluntary consensus standards that have been substituted for other standards as a result of an agency review under paragraph 7c(6) of this Circular;

(4) an evaluation of the effectiveness of the guidelines in section 7 and recommendations for any changes; and

c. No later than January 31 of the following fiscal year, NIST shall transmit to OMB such explanations as are received under section 10a. and a summary report of the information received under section 10b.

11. Conformity Assessment. Section 12(b) of P.L. 104-113 requires 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. To ensure effective coordination, NIST shall issue guidance to the agencies.

12. Policy Review. This Circular shall be reviewed for effectiveness by the OMB three years from the date of issuance.

13. Inquiries. For information concerning this Circular, contact the Office of Management and Budget, Office of Information and Regulatory Affairs: Telephone 202/395-3785.