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Part IV

Executive Office of the President

Office of Management and Budget

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

EXECUTIVE OFFICE OF THE PRESIDENT

Office of Management and Budget

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

AGENCY: Office of Management and Budget, EOP.

ACTION: Final Revision of Circular A-119.

SUMMARY: The Office of Management and Budget (OMB) has revised Circular A-119 on federal use and development of voluntary standards. OMB has revised this Circular in order to make the terminology of the Circular consistent with the National Technology Transfer and Advancement Act of 1995, to issue guidance to the agencies on making their reports to OMB,

to direct the Secretary of Commerce to issue policy guidance for conformity assessment, and to make changes for clarity.

DATES: Effective February 19, 1998.

ADDRESSES: Direct any comments or inquiries to the Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB Room 10236, Washington, D.C. 20503. Available at http://www.whitehouse.gov/WH/EOP/omb or at (202) 395-7332.

FOR FURTHER INFORMATION CONTACT: Virginia Huth (202) 395-3785.

SUPPLEMENTARY INFORMATION:

I. Existing OMB Circular A-119

Standards developed by voluntary consensus standards bodies are often appropriate for use in achieving federal policy objectives and in conducting federal activities, including procurement and regulation. The policies of OMB Circular A-119 are intended to: (1) Encourage federal agencies to benefit from the expertise of the private sector; (2) promote federal agency participation in such bodies to ensure creation of standards that are useable by federal agencies; and (3) reduce reliance on government-unique standards where an existing voluntary standard would suffice.

OMB Circular A-119 was last revised on October 20, 1993. This revision stated that the policy of the federal government, in its procurement and regulatory activities, is to: (1) `[r]ely on voluntary standards, both domestic and international, whenever feasible and consistent with law and regulation;" (2) ``[p]articipate in voluntary standards bodies when such participation is in the public interest and is compatible with agencies' missions, authorities, priorities, and budget resources;" and (3) ``[c]oordinate agency participation in voluntary standards bodies so that * * * the most effective use is made of agency resources * * * and [that] the views expressed by such representatives are in the public interest and * * * do not conflict with the interests and established views of the agencies." [See section 6 entitled ``Policy'].

II. Authority

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.

In February 1996, Section 12(d) of Public Law 104-113, the ``National Technology Transfer and Advancement Act of 1995,'' (or ``the Act'') was passed by the Congress in order to establish the policies of the existing OMB Circular A-119 in law. [See 142 Cong. Rec. H1264-1267 (daily ed. February 27, 1996) (statement of Rep. Morella); 142 Cong. Rec. S1078-1082 (daily ed. February 7, 1996) (statement of Sen. Rockefeller); 141 Cong. Rec. H14333-34 (daily ed. December 12, 1995) (statements of Reps. Brown and Morella)]. The purposes of Section 12(d) of the Act are: (1) To direct ``federal agencies to focus upon increasing their use of [voluntary consensus] standards whenever possible,'' thus, reducing federal procurement and operating costs; and (2) to authorize the National Institute of Standards and Technology (NIST) as the ``federal coordinator for government entities responsible for the development of technical standards and conformity assessment activities,'' thus eliminating ``unnecessary duplication of conformity assessment activities.'' [See Cong. Rec. H1262 (daily ed. February 27, 1996) (statements of Rep. Morella)].

The Act gives the agencies discretion to use other standards in lieu of voluntary consensus standards where use of the latter would be ``inconsistent with applicable law or otherwise impractical.'' However, in such cases, the head of an agency or department must send to OMB, through NIST, ``an explanation of the reasons for using such standards.'' The Act 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.

III. Notice and Request for Comments on Proposed Revision of OMB Circular A-119

On December 27, 1996, OMB published a ``Notice and Request for Comments on Proposed Revision of OMB Circular A-119'' (61 FR 68312). The purpose of the proposed revision was to provide policy guidance to the agencies, to provide instructions on the new reporting requirements, to conform the Circular's terminology to the Act, and to improve the Circular's clarity and effectiveness.

On February 10, 1997, OMB conducted a public meeting to receive comments and answer questions.

In response to the proposed revision, OMB received comments from over 50 sources, including voluntary consensus standards bodies or standards development organizations (SDOs), industry organizations, private companies, federal agencies, and individuals.

IV. Discussion of Significant Comments and Changes

Although some commentators were critical of specific aspects of the proposed revision, the majority of commentators expressed support for the overall policies of the Circular and the approaches taken. The more substantive comments are summarized below, along with OMB's response.

The Circular has also been converted into ``Plain English'' format. Specifically, the following changes were made. We placed definitions where the term is first used; replaced the term ``must'' with ``shall'' where the intent was to establish a requirement; created a question and answer format using ``you'' and ``I'; and added a Table of Contents.

We replaced proposed sections 6, 7 and 10 (``Policy,'' ``Guidance,'' and ``Conformity Assessment'') with sections 6, 7, and 8, which reorganized the material. We reorganized the definitions for ``standard,'' ``technical standard,'' and ``voluntary consensus standard.'' We reorganized proposed section 8 on ``Procedures'' into sections 9, 10, 11, 12. For clarity, we have referenced provisions by their location both in the proposed Circular and in the final Circular.

Proposed Section 1--Purpose. Final Section 1

1. Several commentators suggested that this section should be modified to make clear that the primary purpose of

the revision of the Circular is to interpret the provisions of section 12(d) of Pub. L. 104-113 so that federal agencies can properly implement the statutory requirements. We revised the wording of this section to reflect this suggestion.

Proposed Section 2--Rescissions. Final Section 1

2. We moved this section to Final Section 1.

Proposed Section 3--Background. Final Section 2

3. Several commentators suggested substituting ``use'' for ``adoption'' in this section to conform to the new set of definitions. We agree, and we modified the final Circular.

Proposed Section 4--Applicability. Final Section 5

4. Several commentators found this section unclear. One commentator suggested deleting ``international standardization agreements,'' suggesting this section could be interpreted as conflicting with proposed section 7a(1) which encouraged consideration of international

standards developed by voluntary consensus standards. We agree, and we modified the final Circular.

Proposed Section 5a--Definition of Agency. Final Section 5

5. A commentator suggested defining the term ``agency mission.'' Upon consideration, we have decided that this term is sufficiently well understood as to not require further elaboration; it refers to the particular statutes and programs implemented by the agencies, which vary from one agency to the next. Thus, we did not add a definition.

6. A commentator questioned whether federal contractors are intended to be included within the definition of ``agency.'' Federal contractors do not fall within the definition of ``agency.'' However, if a federal contractor participates in a voluntary consensus standards body on behalf of an agency (i.e., as an agency representative or liaison), then the contractor must comply with the ``participation'' policies in section 7 of this Circular (i.e., it may not dominate the proceedings of a voluntary consensus standards body.).

Proposed Section 5b--Conformity Assessment. Final Section 8

7. In response to the large number of commentators with concerns over the definition of conformity assessment, we have decided to not define the term in this Circular but to defer to NIST when it issues its guidance on the subject. The Circular's policy statement on conformity assessment is limited to the statutory language.

Proposed Section 5c--Definition of Impractical. Final Section 6a(2)

8. A commentator suggested that if an agency determines the use of a standard is impractical, the agency must develop an explanation of the reasons for impracticality and the steps necessary to overcome the use of the impractical reason. We decided that no change is necessary. The Act and the Circular already require agencies to provide an ``explanation of the reasons.'' Requiring agencies to describe the steps necessary ``to overcome the use of the impractical reason'' is unnecessarily burdensome and not required by the Act.

9. A commentator suggested that the definition of ``impractical'' is too broad and proposed deleting words such as ``infeasible'' or ``inadequate.'' We have decided that the definition is appropriate, because things that are infeasible or inadequate are commonly considered to be impractical. Thus, we made no change.

10. A commentator suggested eliminating the phrase ``unnecessarily duplicative'' because it is unlikely that a voluntary consensus standard that was considered ``impractical'' would also be ``unnecessarily duplicative.'' We agree, and the final Circular is

modified accordingly.

11. A few commentators suggested adding ``ineffectual'' to the definition. A few other commentators suggested adding the phrase ``too costly or burdensome to the agency or regulated community.'' Another commentator suggested the same phrase but substituted the term ``affected'' for ``regulated.'' We have decided that concerns for regulatory cost and burden fall under the term ``inefficient'' contained in this definition. Thus, we made no change.

12. A few commentators suggested deleting the term ``demonstrably'' as it implies a greater level of proof than that required in the Act. Upon consideration, we have decided that the term ``demonstrably'' is unnecessary, as the Act already requires an explanation, and it may be reasonably inferred that an explanation can be demonstrated. Thus, we deleted the term.

Proposed Section 5d--Definition of Performance Standard. Final Section 3c

13. A commentator suggested deleting the ``and'' in the definition. We have decided that this suggestion would distort the meaning. Therefore, no change is made.

14. A few commentators suggested substituting the term ``prescriptive'' for ``design'' because of the multiple connotations associated with the term ``design.'' In addition, several commentators suggested related clarifying language. We agree, and we modified the final Circular.

Proposed Section 5f--Definition of Standard. Final Section 3

15. Several commentators suggested overall clarification of this section, while other commentators endorsed the proposed section. One commentator suggested that ``clarification is necessary to distinguish the appropriate use of different types of standards for different purposes (i.e., acquisition, procurement, regulatory).'' This commentator proposed that, ``For example, regulatory Agencies should only rely upon national voluntary consensus standards (as defined in Section 5j) for use as technical criteria in regulations but a federal agency may want to use industry-developed standards (without a full consensus process) for certain acquisition purposes if there are no comparable consensus standards.'' We do not agree with this proposal. The same general principles apply in the procurement context as in the regulatory context.

16. A commentator suggested that the definition of ``standard'' be limited to ensure that agencies are only required to consider adopting voluntary ``technical'' standards. The final Circular clarifies this by clearly equating ``standard'' with ``technical standard.''

17. One commentator recommended adding to the definition of ``standard'' an exclusion for State and local statutes, codes, and ordinances, because agency contracts often require contractors to meet State and local building codes, which contain technical standards which may not be consensus-based. For example, the Department of Energy builds facilities that must be compliant with local building codes, which may be more strict than nationally accepted codes. It is not the intent of this policy to preclude agencies from complying with State and local statutes, codes, and ordinances. No change is necessary, because the Act already states that, ``If compliance * * * is inconsistent with applicable law * * * a Federal agency may elect to use technical standards that are not developed or adopted by voluntary consensus standards bodies.''

Proposed Section 5f--Definition of Standard. Final Section 4

18. Several commentators had concerns with this section, believing that the final sentence in the proposed

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version might imply that other-than-consensus standards may qualify as consensus processes. This is not the case. We have clarified this point through the reorganization of final sections 3 and 4 and through minor clarifying language. In addition, we note that the subject of the Circular is ``voluntary consensus standards,'' which are a subset of ``standards.'' Consistent with the 1993 version, the final Circular defines ``standard'' generally to describe all the different types of standards, whether or not they are consensus-based, or industry- or company-based. Accordingly, we have inserted the phrase ``government-unique'' in final section 4b(2) in order to provide a complete picture of the different sources of standards, while also adding a reference to ``company standards'' in final section 4b(1), previously found in the definition of ``standard.''

Proposed Section 5g--Definition of Technical Standard. Final Section 3a

19. Several commentators suggested combining this term with the definition of standard. We agree, and the terms have been merged.

20. Another commentator suggested adding the phrase ``and related management practices'' because this phrase appears in Section 12(d)(4) of the Act. We agree, and we modified the final Circular.

Proposed Section 5h--Definition of Use. Final Section 6a(1)

21. Several commentators suggested that limiting an agency's use to

the latest edition of a voluntary consensus standard was unnecessarily restrictive. We agree, and we modified the final Circular.

Proposed Section 5i--Definition of Voluntary Consensus Standards. Final Section 4

22. Several commentators objected to the phrase regarding making ``intellectual property available on a non-discriminatory, royalty-free or reasonable royalty basis to all interested parties." Several commentators also supported this language. This section does not limit the ability of copyright holders to receive reasonable and fair royalties. Accordingly, we made no change.

Proposed Section 5j--Voluntary Consensus Standards Bodies. Final Section 4a(1)

23. Several commentators proposed that the words ``but not necessarily unanimity" be inserted for clarification. We agree, and we modified the final Circular.

24. A commentator suggested deleting the examples of voluntary consensus standards bodies. We agree that the examples were unnecessary and confusing, and we modified the final Circular.

25. A few commentators suggested that the Circular acknowledge the American National Standards Institute (ANSI) as the means of identifying voluntary consensus standards bodies. Since the purpose of the Circular is to provide general principles, rather than make determinations about specific organizations or guides, these determinations will be made by agencies in their implementation of the Act. Thus, we made no change.

26. A commentator suggested that the definition be modified so ``that only those organizations that permit an acceptable level of participation and approval by U.S. interests can be considered to qualify." We have decided that no change is necessary, because the requirements of consensus--openness, balance of interests, and due process--likewise apply to international organizations.

27. The same commentator suggested adding the phrase ``the absence of sustained opposition" to the definition of ``consensus." Although we did not make this change, we added other language that improves the definition.

28. Several commentators proposed that the Circular further clarify aspects of this section, including further definitions of ``balance of interest," ``openness," and ``due process." We have decided that the definition provided is sufficient at this time, and no change is made.

29. Several commentators proposed that this definition should be ``clarified to state the Federal agencies considering the use of voluntary consensus standards, not the organizations themselves, are to

decide whether particular organizations qualify as voluntary consensus standards bodies by meeting the operational requirements set out in the definition." For purposes of complying with the policies of this Circular, agencies may determine, according to criteria enumerated in final section 4, whether a standards body qualifies. However, it is the domain of the private sector to accredit voluntary consensus standards organizations, and accordingly, we have inserted clarifying language in final section 6l.

Proposed Section 6a. Final Section 6c

30. A commentator proposed deleting in section 6a ``procurement guidelines'' suggesting it was confusing and inappropriate to mandate use of voluntary consensus standards for ``procurement guidelines or procedures.'' We have decided to delete the reference to ``procurement guidelines.'' The Circular says nothing about ``procurement procedures.''

31. The same commentator suggested adding in section 6a ``monitoring objectives'' as part of an agency's regulatory authorities and responsibilities. We have decided that, under the Act and the Circular, agencies already have sufficient discretion regarding the use and non-use of standards relating to such authorities and responsibilities. Thus, we have made no change.

Proposed Section 6a. Final Section 6f

32. Some commentators expressed concern that once a standard was determined to be a voluntary consensus standard, an agency might incorporate such standard into a regulation without performing the proper regulatory analysis. To address this concern, another commentator suggested adding language referencing ``The Principles of Regulation'' enumerated in Section 1(b) of Executive Order 12866. We agree, and we modified the final Circular.

Proposed Section 6b. Final Section 7

33. In the proposed revision of the Circular, sections 6b and 7b(2) were strengthened by adding language that directed agency representatives to refrain from actively participating in voluntary consensus standards bodies or their committees when participating did not relate to the mission of the agency.

Several commentators were not satisfied with these changes and remain concerned that an agency member might dominate a voluntary consensus standards body as a result of the agency member chairing and/or providing funding to such body, thus making the process not truly consensus. These commentators urged additional limitations on agency

participation in voluntary consensus standards bodies, including: Prohibiting federal agency representatives from chairing committees or voting (or if chairing a committee, then denying them the authority to select committee members); having only an advisory role; participating only if directly related to an agency's mission or statutory authority; and participating only if there is an opportunity for a third party challenge to the participation through a public hearing.

On the other hand, most commentators supported the proposed changes and agreed that federal participation in voluntary consensus

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standards bodies should not be further limited, because federal participation benefited both the government and the private sector. These commentators noted that agencies must be involved in the standards development process to provide a true consensus and to help support the creation of standards for agency use. These purposes are consistent with the intent of the Act.

In the final Circular, we have added language to clarify the authorities in the Circular. We have also strengthened the final Circular by adding language in final section 7f that directs agency employees to avoid the practice or the appearance of undue influence relating to their agency representation in voluntary consensus standards activities. We would also like to underscore the importance of close cooperation with the private sector, including standards accreditors, in ensuring that federal participation is fair and appropriate.

With respect to imposing specific limitations on agency participation in such bodies, which would result in unequal participation relative to other members, we have decided that such limitations would (1) not further the purposes of the Act and (2) could interfere with the internal operations of voluntary consensus standards organizations.

First, the Act requires agencies to consult with voluntary consensus standards bodies and to participate with such bodies in the development of technical standards ``when such participation is in the public interest and is compatible with agency and departmental missions, authorities, and budget resources." The legislative history indicates that one of the purposes of the Act is to promote federal participation. [See 141 Cong. Rec. H14334 (daily ed. December 12, 1995) (Statement of Rep. Morella.)] Moreover, neither the Act nor its legislative history indicate that federal agency representatives are to have less than full and equal representation in such bodies. Given the explicit requirement to consult and participate and no concomitant statement as to any limitation on this participation, we believe the Act was intended to promote full and equal participation in voluntary

consensus standards bodies by federal agencies.

Second, although an agency is ultimately responsible for ensuring that its members are not participating in voluntary consensus standards bodies in a manner inconsistent with the Circular and the Act, it would be inappropriate for the federal government to direct the internal operations of private sector voluntary consensus standards bodies or standards development organizations (SDOs) by proscribing the activities of any of its members. The membership of an SDO is free to choose a chair, to establish voting procedures, and to accept funding as deemed appropriate. We expect that the SDO itself or a related parent or accrediting organization would act to ensure that the organization's proceedings remain fair and balanced. An SDO has a vested interest in ensuring that its consensus procedures and policies are followed in order to maintain its credibility.

Proposed Section 6b. Final Sections 7e, 7f, and 7h

34. Other commentators were concerned that an agency representative could participate in the proceedings of a voluntary consensus standards body for which the agency has no mission-related or statutorily-based rationale to become involved. For example, a situation might exist in which a technical standard developed by the private sector could be so widely adopted as to result in the emergence of a de facto regulatory standard, albeit one endorsed by the private sector rather than by the government. For example, a construction standard for buildings could become so widely accepted in the private sector that the result is that the construction community acts as if it is regulated by such standards. The commentator suggested that if an agency were to participate in the development of such a technical standard, in an area for which it has no specific statutory authority to regulate, that agency could be perceived as attempting to regulate the private sector ``through the back door.'' A perception of such activity, whether or not based in fact, would be detrimental to the interests of the federal government, and agencies should avoid such involvement.

In response to this concern, we feel that changes initiated in the proposed revision and continued in the final Circular sufficiently strengthened the Circular in this regard. In particular, section 7 expressly limits agency support (e.g., funding, participation, etc.) to ``that which clearly furthers agency and departmental missions, authorities, priorities, and budget resources.'' Moreover, this language is consistent with the Act. Thus, if an agency has no mission-related or statutory-related purpose in participation, then its participation would be contrary to the Circular.

An agency is ultimately responsible for ensuring that its employees are not participating in such bodies in a manner inconsistent with the Act or this Circular. Agencies should monitor their participation in

voluntary consensus standards bodies to prevent situations in which the agency could dominate proceedings or have the appearance of impropriety.

Agencies should also work closely with private sector oversight organizations to ensure that no abuses occur. Comments provided by ANSI described the extensive oversight mechanisms it maintains in order to ensure that such abuses do not occur. We encourage this kind of active oversight on the part of the private sector, and we hope to promote cooperation between the agencies and the private sector to ensure that federal participation remains fair and equal.

Proposed Section 7--Policy Guidelines. Final Section 6c

35. A few commentators inquired whether the Circular applies to ``regulatory standards.'' In response, the final Circular distinguishes between a ``technical standard,'' which may be referenced in a regulation, and a ``regulatory standard,'' which establishes overall regulatory goals or outcomes. The Act and the Circular apply to the former, but not to the latter. As described in the legislative history, technical standards pertain to ``products and processes, such as the size, strength, or technical performance of a product, process or material'' and as such may be incorporated into a regulation. [See 142 Cong. Rec. S1080 (daily ed. February 7, 1996) (Statement of Sen. Rockefeller.)] Neither the Act nor the Circular require any agency to use private sector standards which would set regulatory standards or requirements.

Proposed Section 7. Final Section 6g

36. A commentator inquired whether the use of non-voluntary consensus standards meant use of any standards developed outside the voluntary consensus process, or just use of government-unique standards. The intent of the Circular over the years has been to discourage the government's reliance on government-unique standards and to encourage agencies to instead rely on voluntary consensus standards. It is has not been the intent of the Circular to create the basis for discrimination among standards developed in the private sector, whether consensus-based or, alternatively, industry-based or company-based. Accordingly, we added language to clarify this point.

Proposed Section 7. Final Section 6f

37. One commentator inquired how OMB planned to carry out the ``full

account" of the impact of this policy on the economy, applicable federal laws, policies, and national objectives. This language is from the current Circular and refers to the considerations agencies should make when considering using a standard. No change is necessary.

Proposed Section 7. Final Section 17

38. Several commentators noted that the proposed revision eliminated language from the current Circular which stated that its provisions ``are intended for internal management purposes only and are not intended to (1) create delay in the administrative process, (2) provide new grounds for judicial review, or (3) create legal rights enforceable against agencies or their officers." We have decided that, while some sections of the Circular incorporate statutory requirements, other sections remain internal Executive Branch management policy. Accordingly, we have retained the language, with minor revisions.

Proposed Section 7a

39. One commentator inquired as to whether the use of a voluntary consensus standard by one agency would mandate that another agency must use such standard. Implementation of the policies of the Circular are on an agency by agency basis, and in fact, on a case by case basis. Agencies may have different needs and requirements, and the use of a voluntary consensus standard by one agency does not require that another agency must use the same standard. Each agency has the authority to decide whether, for a program, use of a voluntary consensus standard would be contrary to law or otherwise impractical.

40. Another comment suggested that the Circular did not contain sufficient assurance that the standards chosen would be true consensus standards. We have expanded the guidance in the Circular to address this concern by first expanding the definition of ``consensus" in final section 4a(1)(v). Second, we have described in final section 6l how agencies may identify voluntary consensus standards. Third, we have developed reporting procedures that allow for public comment.

Proposed Section 7a(1). Final Section 6h

41. Several commentators suggested that ``international voluntary consensus standards body" be defined in proposed section 5. We have decided that this definition is not necessary, as the term ``international" is sufficiently well understood in the standards community, and the term ``voluntary consensus standards body" has already been defined. Moreover, the distinction between ``international standards" and ``domestic standards" is not relevant to the essential

policies of the Circular, and this point is clarified in this section.

42. Several commentators also noted that two trade agreements (``TBT'' and the ``Procurement Code'') of the World Trade Organization were mentioned but inquired as to why other international agreements like the World Trade Organization Agreement on Sanitary and Phytosanitary Measures or the North American Free Trade Agreement were not mentioned. We did not intend this list to be exhaustive. Therefore, we deleted this phrase to emphasize the main point of this section.

43. Several commentators questioned why the Circular included language that standards developed by international voluntary consensus standards bodies ``should be considered in procurement and regulatory applications.'' We recognize that both domestic and international voluntary consensus standards may exist, sometimes in harmony, sometimes in competition. This language, which is unchanged from the current version of the Circular, states only that such international standards should be ``considered,'' not that they are mandated or that they should be given any preference. In addition, some confusion has emerged based on a perceived conflict between the commitments of the United States with respect to international treaties and this Circular. No part of this Circular is intended to preempt international treaties. Nor is this Circular intended to create the basis for discrimination between an international and a domestic voluntary consensus standard. However, wherever possible, agencies should consider the use of international voluntary consensus standards.

Proposed Section 7a(2). Final Section 6i

44. One commentator suggested that the Circular promote the concept of performance-based requirements when regulating the conduct of work for safety or health reasons (e.g., safety standards). Where performance standards can be used in lieu of other types of standards (or technical standards), the Circular already accomplishes this by stating in final section 6i that ``preference should be given to standards based on performance criteria.''

Proposed Section 7a(3). Final Section 6j

45. One commentator suggested using stronger language to protect the rights of copyright holders when referenced in a regulation. Others thought the language too strong. We have decided that the language is just right.

Proposed Section 7a(4). Final Section 6k, 7j

46. One commentator suggested that legal obligations that supersede the Circular and cost and time burdens need to be emphasized as factors

supporting agencies' developing and using their own government-unique standards. Another commentator suggested that untimeliness or unavailability of voluntary consensus standards development should be a reasonable justification for creation of a government standard. On the first point, these specific changes are not necessary, because the Act and the Circular already state that agencies may choose their own standard ``where inconsistent with applicable law or otherwise impractical." On the second point, we did clarify the language in final sections 6k and 7j.

47. Another commentator suggested that the Circular should define in this section factors that are considered to be ``impractical." See comments on proposed section 5c. We made no change.

Proposed Section 7a(5). Final Section 6l.

48. This section is intended to give agencies guidance on where they may go to identify voluntary consensus standards. One commentator proposed language to indicate that, in addition to NIST, voluntary consensus standards may also be identified through other federal agencies. Another commentator proposed language that such standards may also be identified through standards publishing companies. We agree, and the Circular is changed.

Proposed Section 7b

49. Other commentators proposed that Federal Register notices be published whenever a federal employee is to participate in a voluntary consensus standards body. We have decided that this would be overly burdensome for the agencies and would provide comparatively little benefit for the public. Moreover, each agency is already required in section 15b(5) to publish a directory of federal participants in standards organizations. We made no change.

Proposed Section 7b(2). Final Section 7d

50. Some commentators noted that the current Circular's language, which states that agency employees who ``at government expense" participate in voluntary consensus standards bodies shall do so as specifically authorized agency representatives, has been deleted

from the proposed revision. These commentators opposed this deletion. This phrase has been reinstated. Federal employees who are representing their agency must do so at federal expense. (On the other hand, employees are free to maintain personal memberships in outside

organizations, unless the employee's agency has a requirement for prior approval.) We expect that, as a general rule, federal participation in committees will not be a problem, while participation at higher levels, such as officers or as directors on boards, will require additional scrutiny. Employees should consult with their agency ethics officer to identify what restrictions may apply.

Proposed Section 7b(2). Final Section 7

51. Several commentators suggested changing the language in this section from ``permitting agency participation when relating to agency mission,'' to ``permitting agency participation when compatible with agency and departmental missions, authorities, priorities, and budget resources,'' as stated in the Act. We have decided to accept this suggestion, and the Circular is changed.

Proposed Section 7b(4). Final Sections 7d, 7g

52. One commentator suggested that the Circular should prohibit agency employees from serving as chairs or board members of voluntary consensus standards bodies. We have not amended the Circular to prohibit agency employees from serving as chairs or board members of voluntary consensus standards bodies. However, we have modified final section 7g to clarify that agency employees, whether or not in a position of leadership in a voluntary consensus standards body, must avoid the practice or appearance of undue influence relating to the agency's representation and activities in the voluntary consensus standards bodies. In addition, we added language in final section 7d to remind agencies to involve their agency ethics officers, as appropriate, prior to authorizing support for or participation in a voluntary consensus standards body.

Proposed Section 7b(5). Final Section 7h

53. One commentator suggested changing the word ``should'' to ``shall'' regarding keeping the number of individual agency participants to a minimum. We decided that this change is unnecessary and made no change.

Proposed Section 7b(6)

54. A few commentators suggested requiring that the amount of federal support should be made public or at least made known to the supported committee of the voluntary consensus standards body or SDO. We have decided that this is unnecessary because we expect that the amount of federal support will already be known to a committee

receiving the funds.

Proposed Section 7b(7). Final Section 7g

55. A commentator suggested either deleting ``and administrative policies'' or inserting ``internal'' before ``administrative policies'' to clarify that the prohibition is intended to apply to the internal management of a voluntary consensus standard body. This phrase is parenthetical to the words ``internal management;'' thus, the suggested revision is unnecessary.

Proposed Section 7b(8). Final Section 7i

56. One commentator questioned the relationship of the Circular to the Federal Advisory Committee Act (FACA). Federal participation in standards activities would not ordinarily be subject to FACA, because FACA applies to circumstances in which private individuals would be advising the government. The private sector members of standards organizations are not advising the government, but are developing standards. Nevertheless, issues may arise in which agencies should be aware of FACA.

Proposed Section 7b. Final Sections 7e, 7f

57. Several commentators, fearing agency dominance, criticized the proposed revision of the Circular for promoting increased agency participation. We have decided that the revisions to the Circular are balanced, in that they encourage agency participation while also discouraging agency dominance. Moreover, legislative history states, ``In fact, it is my hope that this section will help convince the Federal Government to participate more fully in these organizations' standards developing activities.'' [See 141 Cong. Rec. H14334 (daily ed. December 12, 1995) (Statement of Rep. Morella.)]

Proposed 7c (4). Final Section 15b

58. A commentator suggested changing ``standards developing groups'' to ``voluntary consensus standards bodies'' for consistency. We agree, and we modified the final Circular.

Proposed 7c(6). Final Section 15b(7)

59. The current and proposed versions of the Circular required agencies to review their existing standards every five years and to replace through applicable procedures such standards that can be replaced with voluntary consensus standards. Several commentators

suggested adding language that either requires agencies to review standards referenced in regulations on an annual basis or an ongoing basis. Other commentators proposed extending the review period to ten years (in order to mirror the review cycle of the Regulatory Flexibility Act) or to eliminate the review entirely because it was burdensome.

We decided to change this requirement to one in which agencies are responsible for ``establishing a process for ongoing review of the agency's use of standards for purposes of updating such use.'' We decided that this approach will encourage agencies to review the large numbers of regulations which may reference obsolete and out-dated standards in a timely manner. Agencies are encouraged to undertake a review of their uses of obsolete or government-unique standards as soon as practicable.

60. A commentator proposed language to require agencies to respond to requests from voluntary consensus standards bodies to replace existing federal standards, specifications, or regulations with voluntary consensus standards. This change is not necessary, because the Circular already requires agencies to establish a process for reviewing standards. (See comment 59.) We made no change.

Proposed Section 8. Final Section 11

61. Several commentators suggested eliminating the requirement in the proposed Circular for an analysis of the use and non-use of voluntary consensus standards in both the Notice of Proposed Rulemaking (NPRM) and the final rule in order to simplify and clarify Federal Register notices. As an alternative, these commentators proposed including such analysis in a separate document that accompanies the NPRM and the subsequent final rule.

We have decided that, rather than simplifying the rulemaking process, this change would make it more difficult for the public to comment on the rule and would complicate the process by adding another source of information in a separate location. However, we did make some minor changes to this section to clarify that agencies are not expected to provide an extensive report with each NPRM, Interim Final Rulemaking, or Final Rule. The section was also modified to improve the ability of agencies to identify voluntary consensus standards that could be used in their regulations, to ensure public

notice, and to minimize burden. First, the notice required in the NPRM may merely contain/include (1) a few sentences to identify the proposed standard, if any; and, if applicable, (2) a simple explanation of why the agency proposes to use a government-unique standard in lieu of a

voluntary consensus standard. This step places the public on notice and gives them an opportunity to comment formally. Second, we expect that the majority of rulemakings will not reference standards at all. In these cases, the agency is not required to make a statement or to file a report. In those instances where an agency proposes a government-unique standard, the public, through the public comment process, will have an opportunity to identify a voluntary consensus standard (when the agency was not aware of it) or to argue that the agency should have used the voluntary consensus standard (when the agency had identified one, but rejected it).

62. Several commentators suggested adding a new section entitled ``Sufficiency of Agency Search.'' The purpose of this new section would be to limit an agency's obligation to search for existing voluntary consensus standards under the requirements of this section. We have decided that this section is unnecessary in light of the requirements elsewhere in the Circular for identifying voluntary consensus standards. Accordingly, we made no change.

63. One commentator suggested that agencies be required to fully investigate and review the intent and capabilities of a standard before making a decision to use a particular voluntary consensus standard. We have decided that the effort an agency would have to undertake to conduct its own scientific review of a voluntary, consensus standard is unnecessary, as SDOs adhere to lengthy and complex procedures which already closely scrutinize the uses and capabilities of a standard. However, in adopting a standard for use, whether in procurement or in regulation, agencies are already required to undertake the review under the Act and the Circular, as well as the review and analysis, described in other sources, such as the Federal Acquisition Regulation or the Executive Order 12866 on Regulatory Planning and Review. Accordingly, we made no change.

64. A few commentators suggested that the Circular should ensure prompt notification to interested parties when voluntary consensus standards activities are about to begin and should encourage greater public participation in such activities. Another commentator noted a lack of clear procedures on how voluntary consensus standards bodies handle public comments and whether those comments are available to interested persons or organizations. OMB has determined that these responsibilities fall within the jurisdiction of voluntary consensus standards bodies and are outside the scope of the Act and the Circular. Accordingly, we made no change.

Proposed Section 8. Final Sections 6g and 12c

65. A few commentators requested clarification on the use of ``commercial-off-the-shelf'' (``COTS'') products as they relate to voluntary consensus standards. In response, we have clarified final

section 6g to state that this policy does not establish preferences between products developed in the private sector. Final section 12c clarified that there is no reporting requirement for such products.

Proposed Section 9--Responsibilities. Final Sections 13, 14, 15

66. Several commentators proposed that OMB have more defined oversight responsibility in determining whether an agency's participation in a voluntary consensus standards body is consistent with the Circular. We did not make this change. Agency Standards Executives, with the advice of the Chair of the ICSP, are responsible for ensuring that agencies are in compliance with the requirements of this Circular.

With respect to the issue of ``agency dominance'' of SDOs, we expect that SDOs will likewise ensure that members abide by their rules of conduct and participation, working closely with Standards Executives where necessary and appropriate. We inserted minor clarifying language in new sections 13, 14, and 15.

Proposed 9b(2). Final Section 14c

67. A commentator suggested broadening the category of agencies that must designate a standards executive, from designating those agencies with a ``significant interest'' in the use of standards, to those agencies having either ``regulatory or procurement'' responsibilities. We decided that this proposed change was vague and would only confuse the scope of the Circular. Accordingly, we made no change.

Proposed Section 10. Final Sections 9 and 10

68. One commentator expressed concern that the reporting requirements would require agencies to report reliance on commercial-off-the-shelf (COTS) products as a decision not to rely on voluntary consensus standards. The Act and the Circular do not limit agencies' abilities to purchase COTS or other products or services containing private sector standards. The Circular specifically excludes reporting of COTS procurements in final section 12, and final sections 9a and 12 require agencies to report only when an agency uses a government-unique standard in lieu of an existing voluntary consensus standard. Accordingly, we made no change.

Proposed 10b --Agency Reports on Standards Policy Activities. Final Section 9b

69. One commentator suggested that agencies also report the

identity of standards development bodies whose standards the agency relies on and the identities of all the standards developed or used by such bodies. We have decided that it would be unnecessary, duplicative, and burdensome to require agencies to identify this level of detail in the annual report. The identity of individual standards developed by a standards body may be obtained either through the standards body or through a standards publishing company. In addition, agencies are already required to provide in their annual report, under section 9b(1), the number of voluntary consensus standards bodies in which an agency participates. Moreover, each agency is required under section 15b(5) to identify the standards bodies in which it is involved. Accordingly, we made no change.

Proposed 10b(3). Final Section 9b

70. A commentator suggested that agencies should be required to identify federal regulations and procurement specifications in which the standards were ``withdrawn'' and replaced with voluntary consensus standards. We have decided that this requirement is unnecessary, because information is already provided in the annual report described in final section 9b(3). Accordingly, we made no change.

Proposed Section 11--Conformity Assessment. Final Section 8

71. A commentator expressed concern that the coordination by the National Institute of Standards and Technology (NIST) of standards activities between the public and private sector will undermine the coordination that ANSI has performed for many years for the private sector.

In addition, the commentator expressed concern that NIST's involvement in such coordination will undermine the United States' ability to

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compete internationally as two organizations are coordinating standards developing activities instead of one. The Act states that NIST is to ``coordinate Federal, State, and local technical standards activities and conformity assessment activities with private sector technical standards activities and conformity assessment activities.'' This language makes clear that NIST will have responsibility for coordinating only the public sector and for working with the private sector. In addition, ANSI's role is affirmed in the Memorandum Of Understanding (MOU) issued on July 24, 1995, between NIST and ANSI. The MOU states ``[t]his MOU is intended to facilitate and strengthen the influence of ANSI and the entire U.S. standards community at the

international level * * * and ensure that ANSI's representation of U.S. interests is respected by the other players on the international scene." Thus, we made no change.

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

Sally Katzen,
Administrator, Office of Information and Regulatory Affairs.

EXECUTIVE OFFICE OF THE PRESIDENT

Office of Management and Budget

Washington, D.C. 20503

February 10, 1998.

Circular No. A-119

Revised

Memorandum for Heads of Executive Departments and Agencies

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

Revised OMB Circular A-119 establishes policies on Federal use and development of voluntary consensus standards and on conformity assessment activities. Pub. L. 104-113, the ``National Technology Transfer and Advancement Act of 1995," codified existing policies in A-119, established reporting requirements, and authorized the National Institute of Standards and Technology to coordinate conformity assessment activities of the agencies. OMB is issuing this revision of the Circular in order to make the terminology of the Circular consistent with the National Technology Transfer and Advancement Act of 1995, to issue guidance to the agencies on making their reports to OMB, to direct the Secretary of Commerce to issue policy guidance for conformity assessment, and to make changes for clarity.

Franklin D. Raines,
Director.

Attachment

EXECUTIVE OFFICE OF THE PRESIDENT

Office of Management and Budget

Washington, D.C. 20503

February 10, 1998.

Circular No. A-119

Revised

To the Heads of Executive Departments and Establishments

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

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Background

1. What Is The Purpose Of This Circular?

This Circular establishes policies to improve the internal management of the Executive Branch. Consistent with Section 12(d) of Pub. L. 104-113, the ``National Technology Transfer and Advancement Act of 1995'' (hereinafter ``the Act''), this Circular directs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical. It also provides guidance for agencies participating in voluntary consensus standards bodies and describes procedures for satisfying

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the reporting requirements in the Act. The policies in this Circular are intended to reduce to a minimum the reliance by agencies on government-unique standards. These policies do not create the bases for discrimination in agency procurement or regulatory activities among standards developed in the private sector, whether or not they are developed by voluntary consensus standards bodies. Consistent with Section 12(b) of the Act, this Circular directs the Secretary of Commerce to issue guidance to the agencies in order to coordinate conformity assessment activities. This Circular replaces OMB Circular No. A-119, dated October 20, 1993.

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. Eliminate the cost to the Government of developing its own

standards and decrease the cost of goods procured and the burden of complying with agency regulation.

b. Provide incentives and opportunities to establish standards that serve national needs.

c. Encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards.

d. Further the policy of reliance upon the private sector to supply Government needs for goods and services.

Definitions of Standards

3. What Is A Standard?

a. The term standard, or technical standard as cited in the Act, includes all of the following:

(1) Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices.

(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, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions of fit and measurements of size or strength.

b. The term standard does not include the following:

(1) Professional standards of personal conduct.

(2) Institutional codes of ethics.

c. Performance standard is a standard as defined above 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 may define the functional requirements for the item, operational requirements, and/or interface and interchangeability characteristics. A performance standard may be viewed in juxtaposition to a prescriptive standard which 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.

d. Non-government standard is a standard as defined above that is in the form of 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.

4. What Are Voluntary, Consensus Standards?

a. For purposes of this policy, voluntary consensus standards are standards developed or adopted by voluntary consensus standards bodies, both domestic and international. These standards include 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. For purposes of this Circular, ``technical standards that are developed or adopted by voluntary consensus standard bodies'' is an equivalent term.

(1) Voluntary consensus standards bodies are domestic or international organizations which plan, develop, establish, or coordinate voluntary consensus standards using agreed-upon procedures. For purposes of this Circular, ``voluntary, private sector, consensus standards bodies,'' as cited in Act, is an equivalent term. The Act and the Circular encourage the participation of federal 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 is defined by the following attributes:

(i) Openness.

(ii) Balance of interest.

(iii) Due process.

(vi) An appeals process.

(v) Consensus, which is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

b. Other types of standards, which are distinct from voluntary consensus standards, are the following:

(1) ``Non-consensus standards,'' ``Industry standards,'' ``Company standards,'' or ``de facto standards,'' which are developed in the private sector but not in the full consensus process.

(2) ``Government-unique standards,'' which are developed by the government for its own uses.

(3) Standards mandated by law, such as those contained in the United States Pharmacopeia and the National Formulary, as referenced in 21 U.S.C. 351.

Policy

5. Who Does This Policy Apply To?

This Circular applies to all agencies and agency employees who use standards and participate in voluntary consensus standards activities, domestic and international, except for activities carried out pursuant to treaties. ``Agency'' means any executive department, independent commission, board, bureau, office, agency, Government-owned or controlled corporation or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding the use of voluntary

consensus standards. It does not include the legislative or judicial branches of the Federal Government.

6. What Is The Policy For Federal Use Of Standards?

All federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical. In these circumstances, your agency must submit a report describing the reason(s) for its use of government-unique standards in lieu of voluntary consensus standards to the Office of Management and Budget (OMB) through the National Institute of Standards and Technology (NIST).

a. When must my agency use voluntary consensus standards?

Your agency must use voluntary consensus standards, both domestic and international, in its regulatory and procurement activities in lieu of government-unique standards, unless use of such standards would be

inconsistent with applicable law or otherwise impractical. In all cases, your agency has the discretion to decline to use existing voluntary consensus standards if your agency determines that such standards are inconsistent with applicable law or otherwise impractical.

(1) ``Use'' means incorporation of a standard in whole, in part, or by reference for procurement purposes, and the inclusion of a standard in whole, in part, or by reference in regulation(s).

(2) ``Impractical'' includes circumstances in which such use would fail to serve the agency's program needs; would be infeasible; would be inadequate, ineffectual, inefficient, or inconsistent with agency mission; or would impose more burdens, or would be less useful, than the use of another standard.

b. What must my agency do when such use is determined by my agency to be inconsistent with applicable law or otherwise impractical?

The head of your agency must transmit to the Office of Management and Budget (OMB), through the National Institute of Standards and Technology (NIST), an explanation of the reason(s) for using government-unique standards in lieu of voluntary consensus standards. For more information on reporting, see section 9.

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

This policy does not preempt or restrict agencies' authorities and responsibilities to make regulatory decisions authorized by statute. Such regulatory authorities and responsibilities include determining the level of acceptable risk; setting the level of protection; and balancing risk, cost, and availability of technology in establishing regulatory standards. However, to determine whether established

regulatory limits or targets have been met, agencies should use voluntary consensus standards for test methods, sampling procedures, or protocols.

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 limits an agency's authority to pursue an identified capability through reliance on a government-unique standard when a voluntary consensus standard exists (see Section 6a).

e. What are the goals of agency use of voluntary consensus standards?

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.

f. What considerations should my agency make when it is considering using a standard?

When considering using a standard, your agency should 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, and conflicts of interest. Your agency should also recognize that use of standards, if improperly conducted, 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 your agency is proposing to incorporate a standard into a proposed or final rulemaking, your agency must comply with the ``Principles of Regulation'' (enumerated in Section 1(b)) and with the other analytical requirements of Executive Order 12866, ``Regulatory Planning and Review.''

g. Does this policy establish a preference between consensus and non-consensus standards that are developed in the private sector?

This policy does not establish a preference among standards developed in the private sector. Specifically, agencies that promulgate regulations referencing non-consensus standards developed in the private sector are not required to report on these actions, and agencies that procure products or services based on non-consensus standards are not required to report on such procurements. For example, this policy allows agencies to select a non-consensus standard developed in the private sector as a means of establishing testing methods in a regulation and to choose among commercial-off-the-shelf products, regardless of whether the underlying standards are developed by voluntary consensus standards bodies or not.

h. Does this policy establish a preference between domestic and international voluntary consensus standards?

This policy does not establish a preference between domestic and international voluntary consensus standards. However, in the interests of promoting trade and implementing the provisions of international treaty agreements, your agency should consider international standards in procurement and regulatory applications.

i. Should my agency give preference to performance standards?

In using voluntary consensus standards, your agency should give preference to performance standards when such standards may reasonably be used in lieu of prescriptive standards.

j. How should my agency reference voluntary consensus standards?

Your agency should reference voluntary consensus standards, along with sources of availability, in appropriate publications, regulatory orders, and related internal documents. In regulations, the reference must include the date of issuance. For all other uses, your agency must determine the most appropriate form of reference, which may exclude the date of issuance as long as users are elsewhere directed to the latest issue. If a voluntary standard is used and published in an agency document, your agency must observe and protect the rights of the copyright holder and any other similar obligations.

k. What if no voluntary consensus standard exists?

In cases where no voluntary consensus standards exist, an agency may use government-unique standards (in addition to other standards, see Section 6g) and is not required to file a report on its use of government-unique standards. As explained above (see Section 6a), an agency may use government-unique standards in lieu of voluntary consensus standards if the use of such standards would be inconsistent with applicable law or otherwise impractical; in such cases, the agency must file a report under Section 9a regarding its use of government-unique standards.

l. How may my agency identify voluntary consensus standards?

Your agency may identify voluntary consensus standards through databases of standards maintained by the National Institute of Standards and Technology (NIST), or by other organizations including voluntary consensus standards bodies, other federal agencies, or standards publishing companies.

7. What Is The Policy For Federal Participation In Voluntary Consensus Standards Bodies?

Agencies must consult with voluntary consensus standards bodies, both domestic and international, and must participate with such bodies in the development of voluntary consensus standards when consultation and participation is in the public interest

and is compatible with their missions, authorities, priorities, and budget resources.

a. What are the purposes of agency participation?

Agency representatives should participate in voluntary consensus standards activities in order to accomplish the following purposes:

(1) Eliminate the necessity for development or maintenance of separate Government-unique standards.

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

b. What are the general principles that apply to agency support?

Agency support provided to a voluntary consensus standards activity must be limited to that which clearly furthers agency and departmental missions, authorities, priorities, and is consistent with budget resources. Agency support must not be contingent upon the outcome of the standards activity. Normally, the total amount of federal support should be no greater than that of 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 timely development or revision appears unlikely in the absence of such support.

c. What forms of support may my agency provide?

The form of agency support, may include the following:

(1) Direct financial support; e.g., grants, memberships, and contracts.

(2) Administrative support; e.g., travel costs, hosting of meetings, and secretarial functions.

(3) Technical support; e.g., cooperative testing for standards evaluation and participation of agency personnel in the activities of voluntary consensus standards bodies.

(4) Joint planning with voluntary consensus standards bodies to promote the identification and development of needed standards.

(5) Participation of agency personnel.

d. Must agency participants be authorized?

Agency employees who, at Government expense, participate in standards activities of voluntary consensus standards bodies on behalf of the agency must do so as specifically authorized agency representatives. Agency support for, and participation by agency personnel in, voluntary consensus 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 employees (whether or not on behalf of the agency) in the activities of voluntary consensus standards bodies is subject to the laws and regulations that apply to participation by federal employees in the activities of outside organizations. While we anticipate that participation in a committee

that is developing a standard would generally not raise significant issues, participation as an officer, director, or trustee of an organization would raise more significant issues. An agency should involve its agency ethics officer, as appropriate, before authorizing support for or participation in a voluntary consensus standards body.

e. Does agency participation indicate endorsement of any decisions reached by voluntary consensus standards bodies?

Agency participation in voluntary consensus standards bodies does not necessarily connote agency agreement with, or endorsement of, decisions reached by such organizations.

f. Do agency representatives participate equally with other members?

Agency representatives serving as members of voluntary consensus standards bodies should participate actively and on an equal basis with other members, consistent with the procedures of those 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 in other official capacities. Agency representatives may vote, in accordance with the procedures of the voluntary consensus standards body, at each stage of the standards development process unless prohibited from doing so by law or their agencies.

g. Are there any limitations on participation by agency representatives?

In order to maintain the independence of voluntary consensus standards bodies, agency representatives must 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). Agency representatives must not dominate such bodies, and in any case are bound by voluntary consensus standards bodies' rules and procedures, including those regarding domination of proceedings by any individual. Regardless, such agency employees must avoid the practice or the appearance of undue influence relating to their agency representation and activities in voluntary consensus standards bodies.

h. Are there any limits on the number of federal participants in voluntary consensus standards bodies?

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

i. Is there anything else agency representatives should know?

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.

j. What if a voluntary consensus standards body is likely to develop an acceptable, needed standard in a timely fashion?

If a voluntary consensus standards body is in the process of developing or adopting a voluntary consensus standard that would likely be lawful and practical for an agency to use, and would likely be developed or adopted on a timely basis, an agency should not be developing its own government-unique standard and instead should be participating in the activities of the voluntary consensus standards body.

8. What Is The Policy On Conformity Assessment?

Section 12(b) of the Act 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, the Secretary of Commerce must issue guidance to the agencies.

Management and Reporting of Standards Use

9. What Is My Agency Required to Report?

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a. As required by the Act, 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. (In addition, an agency is not required to report on its use of other standards. See Section 6g.) Your agency must include an explanation of the reason(s) why use of such voluntary consensus standard would be inconsistent with applicable law or otherwise impractical, as described in Sections 11b(2), 12a(3), and 12b(2) of this Circular. Your agency must report in accordance with format instructions issued by NIST.

b. Your agency must report to NIST, no later than December 31 of each year, 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 format instructions issued by NIST. Such reporting must include the following:

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

(2) 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.

(3) Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review under section 15b(7) of this Circular.

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

c. No later than the following January 31, NIST must transmit to OMB a summary report of the information received.

10. How Does My Agency Manage And Report Its Development and Use Of Standards?

Your agency must establish a process to identify, manage, and review your agency's 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 described in section 9a, and (2) report on your agency's participation in the development and use of voluntary consensus standards, as described in section 9b. 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 all uses of standards in one or both ways.

11. What Are The Procedures For Reporting My Agency's Use Of Standards In Regulations?

Your agency should use transaction based reporting if your agency issues regulations that use or reference standards. If your agency is issuing or revising a regulation that contains a standard, your agency must follow these procedures:

a. Publish a request for comment within the preamble of a Notice of Proposed Rulemaking (NPRM) or Interim Final Rule (IFR). Such request must provide the appropriate information, as follows:

(1) When your agency is proposing to use a voluntary consensus standard, provide a statement which identifies such standard.

(2) When your agency is proposing to use a government-unique standard in lieu of a voluntary consensus standard, provide a statement which identifies such standards and provides a preliminary explanation for the proposed use of a government-unique standard in lieu of a voluntary consensus standard.

(3) When your agency is proposing to use a government-unique standard, and no voluntary consensus standard has been identified, a

statement to that effect and an invitation to identify any such standard and to explain why such standard should be used.

b. Publish a discussion in the preamble of a Final Rulemaking that restates the statement in the NPRM or IFR, acknowledges and summarizes any comments received and responds to them, and explains the agency's final decision. This discussion must provide the appropriate information, as follows:

(1) When a voluntary consensus standard is being used, provide a statement that identifies such standard and any alternative voluntary consensus standards which have been identified.

(2) When a government-unique standard is being used in lieu of a voluntary consensus standard, provide a statement that identifies the standards and explains why using the voluntary consensus standard would be inconsistent with applicable law or otherwise impractical. Such explanation must be transmitted in accordance with the requirements of Section 9a.

(3) When a government-unique standard is being used, and no voluntary consensus standard has been identified, provide a statement to that effect.

12. What Are The Procedures For Reporting My Agency's Use Of Standards In Procurements?

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

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

Your agency must report on a category 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:

(1) Maintain a centralized standards management system that identifies how your agency uses both government-unique and voluntary consensus standards.

(2) Systematically review your agency's use of government-unique standards for conversion to voluntary consensus standards.

(3) Maintain records on the groups or categories in 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 Section 9a.

(4) Enable potential offerors to suggest voluntary consensus 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:

(1) In each solicitation which references government-unique standards, the solicitation must:

(i) Identify such standards.

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(ii) Provide potential offerors an opportunity to suggest alternative voluntary consensus standards that meet the agency's requirements.

(2) 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 Section 9a 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 non-consensus standards developed in the private sector, 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 (ICSP), 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.

d. Establishes procedures for agencies to use when developing directories described in Section 15b(5) and establish procedures to

make these directories available to the public.

e. 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 procedures described.

b. Ensure agency compliance with the policies of the Circular.

c. In the case of an agency with significant interest in the use of standards, designate a senior level official as the Standards Executive who will be responsible for the agency's implementation of this Circular and who will represent the agency on the ICSP.

d. Transmit the annual report prepared by the Agency Standards Executive as described in Sections 9 and 15b(6).

15. What Are The Responsibilities Of Agency Standards Executives?

An Agency Standards Executive:

a. Promotes the following goals:

(1) Effective use of agency resources and participation.

(2) The development of agency positions that are in the public interest and that do not conflict with each other.

(3) The development of agency positions that are consistent with administration policy.

(4) The development of agency technical and policy positions that are clearly defined and known in advance to all federal participants on a given committee.

b. Coordinates his or her agency's participation in voluntary consensus standards bodies by:

(1) Establishing procedures to ensure that agency representatives who participate 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.

(2) To the extent possible, ensuring that the agency's participation in voluntary consensus standards bodies is consistent with agency missions, authorities, priorities, and budget resources.

(3) Ensuring, when two or more agencies participate in a given voluntary consensus 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.

(4) Cooperating with the Secretary in carrying out his or her responsibilities under this Circular.

(5) Consulting with the Secretary, as necessary, in the development and issuance of internal agency procedures and guidance implementing this Circular, including the development and implementation of an agency-wide directory identifying agency employees participating in

voluntary consensus standards bodies and the identification of voluntary consensus standards bodies.

(6) Preparing, as described in Section 9, 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.

(7) Establishing a process for ongoing review of the agency's use of standards for purposes of updating such use.

(8) 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 consensus standards bodies, so that agency support and participation will comply with applicable laws and regulations.

Supplementary Information

16. When Will This Circular Be Reviewed?

This Circular will be reviewed for effectiveness by the OMB three years from the date of issuance.

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 Public Law 104-113 and to establish policies that will improve the internal management of the Executive Branch. 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.

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.

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