PB99-154999

NISTIR 6412

1997 Annual Report on the Implementation of Office of Management and Budget (OMB) Circular A-119 and P.L. 104-113

Patrick Cooke, Editor
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U.S. DEPARTMENT OF COMMERCE
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October 1999

U.S. DEPARTMENT OF COMMERCE
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TECHNOLOGY ADMINISTRATION
Gary R. Bachula, Acting Under Secretary for Technology

NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY
Raymond G. Kammer, Director

ANNUAL REPORT ON THE
IMPLEMENTATION OF OMB CIRCULAR A-119
COVERING THE PERIOD OCTOBER 1, 1996 THROUGH SEPTEMBER 30, 1997

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PREFACE

The Office of Management and Budget (OMB) Circular A-119, "Federal Participation in the Development and use of Voluntary Standards," and Section 12 of P.L. 104-113 (the National Technology Transfer and Advancement Act) direct that the National Institute of Standards and Technology prepare an annual report providing information on Federal use of voluntary consensus standards for OMB to transmit to Congress. The present report provides Federal standards-related information for fiscal year 1997 (FY 97). This FY 97 report also contains material finalized during 1998, including the revised OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," that gives greater guidance for Federal compliance with P.L. 104-113. The FY 98 report will also report against the revised Circular. The FY 97 report also contains supplementary material from two Federal agencies, as well as a review from the Office of Government Ethics on Federal participation in standards organizations, especially on Boards of Directors. The full report is also available at http://ts.nist.gov/oss.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

February 16, 1999

The Honorable Constance Morella
Chairwoman, Subcommittee on Technology
Committee on Science
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

Enclosed is the annual report by the Office of Management and Budget on the Federal government's use of voluntary consensus standards, as required by Section 12(d) of the National Technology Transfer Act Amendments of 1996 (NTTAA, P.L. 104-113). This report fulfills the reporting requirements of NTTAA and summarizes the Federal government's use of voluntary consensus standards during fiscal year 1997, the first full fiscal year in which the NTTAA was in effect.

Voluntary consensus standards are those technical standards developed and used by private sector organizations in such areas as testing, manufacturing, and engineering. Under OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards," there has been longstanding presumption in favor of Federal agencies using voluntary consensus standards, rather than government-unique standards, to carry out their procurement and regulatory activities. In addition to conserving agency resources, Federal reliance on voluntary consensus standards also avoids imposing additional costs on the private sector. In the NTTAA, Congress strengthened the Circular's policies of promoting Federal adoption of voluntary consensus standards and participation in the development of such standards.

Following the enactment of the NTTAA, OMB worked with the National Institute of Standards and Technology (NIST) and other Federal agencies to revise Circular A-119 to reflect the Act's provisions. OMB requested public comment on proposed revisions to the Circular in December 1996. After considering the comments that we received, OMB issued final revisions to the Circular in February 1998 (Tab A). In addition to making other changes to the Circular, the revision establishes processes that enable interested members of the public to inform agencies of voluntary consensus standards that should be used in Federal procurements and regulations in lieu of government-unique standards.

In accordance with the reporting requirements in the proposed Circular (the final revision having not yet been issued), agencies submitted to NIST information about their voluntary consensus standards activities for fiscal year 1997. Based on these submissions, NIST prepared the enclosed report (Tab B), which covers the period October 1, 1996 through September 30, 1997. The Department of Agriculture provided a separate report on its activities during this period (Tab C).

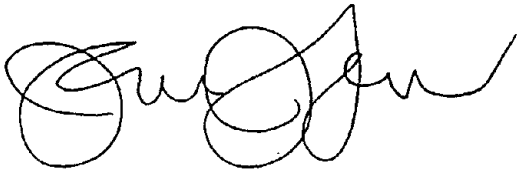
The NIST report notes that, during fiscal year 1997, Federal agencies adopted 543 voluntary consensus standards. In addition, 187 voluntary consensus standards were substituted for government-unique standards.

Finally, the report states that, in fiscal year 1997, in only seven cases did an agency use a government-unique standard rather than an available voluntary consensus standard. Five of these cases were reported by the Department of Health and Human Services and are described in Tab D. Two of these cases were reported by the Department of Transportation on page A-40 of the report. (However, the case reported by the U.S. Coast Guard involving pressure monitoring devices should not be included within this category, because there was, in fact, no existing voluntary consensus standard.)

Finally, I am pleased to report that, in August 1998, an issue was resolved that should facilitate participation by agencies in voluntary consensus standards bodies. As NIST notes in its report, agency participation may have been dampened by uncertainties regarding how the criminal conflict-of-interest statute (18 U.S.C. 208) applies to such participation. At the request of OMB, the Office of Government Ethics (OGE) and the Justice Department's Office of Legal Counsel (OLC) reviewed this issue. In the enclosed correspondence between OGE and OLC (Tab E), these agencies determined that agency participation on the boards of voluntary consensus standards is appropriate. This correspondence has been circulated amongst the agencies and should facilitate their participation in standards setting organizations.

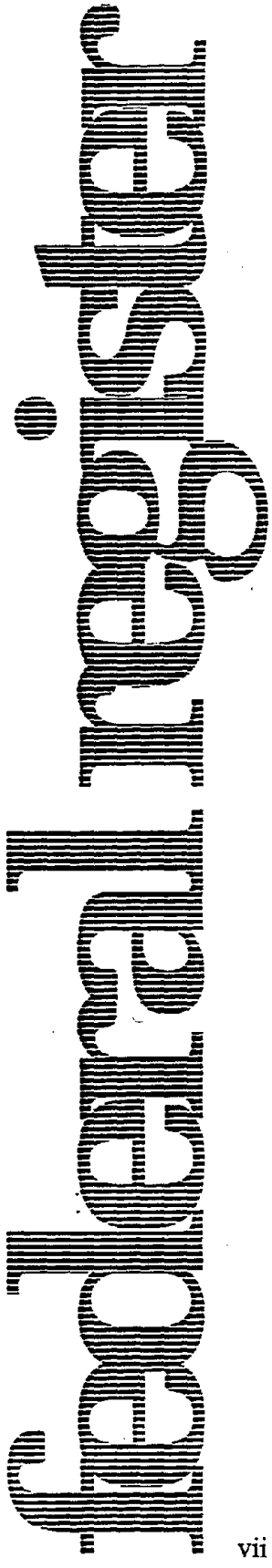
Thank you for your ongoing interest in and support for policies related to Federal use of voluntary consensus standards.

Sincerely,



Jacob J. Lew
Director

Enclosures



Thursday
February 19, 1998

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
II. Authority
III. Notice and Request for Comments on Proposed Revision of OMB Circular 119–A
IV. Discussion of Significant Comments and Changes

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

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

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 outdated 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

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

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?

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.

(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.

[FR Doc. 98–4177 Filed 2–18–98; 8:45 am]
BILLING CODE 3110–01–P

TAB B

ANNUAL REPORT TO THE OFFICE OF MANAGEMENT AND BUDGET (OMB) ON THE IMPLEMENTATION OF OMB CIRCULAR A-119

For Period Covering:
October 1, 1996 - September 30, 1997

Executive Summary

OMB Circular A-119[1], "Federal Participation in the Development and Use of Voluntary Standards," requires the National Institute of Standards and Technology (NIST) to report annually to the Office of Management and Budget on the progress that NIST has made in coordinating Federal agencies' use of voluntary standards and participation in standardization activities, and to provide summaries of the status of agency interactions with private sector voluntary standards bodies. The present annual report addresses the extent and nature of participation by Federal agencies in the development of voluntary standards, their use of voluntary standards, and an evaluation of the effectiveness of the policy promulgated in the Circular.

Because Public Law 104-113, the "National Technology Transfer and Advancement Act of 1995" (NTTAA), contains many requirements parallel to those in the Circular, directing NIST to coordinate with Federal, state, and local agencies and with the private sector in standards and conformity assessment activities, this report also summarizes those efforts. In addition, the NTTAA requires Federal agencies to use voluntary standards to the extent practicable, and to report when they have developed agency-specific standards. Federal agency activities with respect to using voluntary standards are reported here in terms of the requirements of the NTTAA, although more detailed OMB guidance for implementing the NTTAA is still being developed.

NIST has chosen to rely on and strengthen the Interagency Committee on Standards Policy (ICSP) as the primary means of fulfilling NIST's responsibilities for coordinating Federal standards-related activities. The extent and variety of ICSP activities are therefore reported in detail below. NIST plans to strengthen this effective tool for inter-agency coordination during 1998.

As chair of the ICSP, NIST in November 1997 requested each agency to provide information on the status of its implementation of both the Circular and the NTTAA. This new reporting request is in keeping with the requirements of the 1993 OMB A-119 Circular, accompanied by the new requirements resulting from the mandate of P.L. 104-113 for Federal agencies to use voluntary consensus standards, and to report the development of any new agency-specific standards.

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[1]OMB issued a newly-revised Circular A-119 on February 19, 1998 (see Tab A). Because the current report summarizes FY 97 activities, the new revision is not addressed in the body of this report.

The present report describes NIST's coordination activities, with special emphasis on implementing NTTAA and the activities of the ICSP, including an overview of standards policy coordination, related external events, compliance with NTTAA, and future courses of action. The reports submitted to NIST by other Federal departments and agencies are appended, along with the recently revised charter of the Interagency Committee on Standards Policy, a list of members of the Interagency Committee on Standards Policy, and NIST publications related to P.L. 104-113. The agency reports, with minimal or no editing and formatting, are in Appendix A for Cabinet level departments and Appendix B for independent agencies, the Executive Office of the President, and one legislative branch agency. Information was not available from all agencies due to institutional reorganizations and personnel changes. Moreover, some agencies simply had little to report or were not directly involved in standardization.

The NTTAA requires new agency information on requirements regarding the status of its implementation activities. The agency data collected here reflects the shift in required reporting (data on number of agency participants in voluntary standards bodies, voluntary standards used and number of voluntary standards substituted for government-unique standards, and information regarding agency use of "government-unique standards"). In contrast to these new requirements, reported in Table 1, the current Circular (i.e., the October 20, 1993, version) requested information of a similar but somewhat different nature. That information included: number of agency employees participating in at least one standards-developing group; number of voluntary standards adopted from participating in such groups; number of existing standards replaced as a result of the five-year review cycle; and identification of voluntary standards that promote environmentally-sound and energy-efficient principles.

The summary data provided by agencies indicate significant changes in the numbers of Federal employees participating in voluntary standards bodies, a matter of grave concern for Federal policy makers. Table 1 presents a significant decrease from the more than 5200 Federal participants reported in 1996 to less than 3300 reported in 1997. The striking decrease was particularly apparent in a number of agencies, including the Departments of Commerce, Defense (DOD), Health and Human Services, Transportation and Treasury, and such independent agencies as the Federal Communications Commission and Environmental Protection Agency, and may have been due to agency downsizing and retirements. At the same time, modest increases were noted at the Departments of Energy (DOE), Interior, and Veterans Affairs, General Services Administration and National Aeronautics and Space Administration. Moreover, agencies reported the development of very few agency-specific standards, while noting a markedly increased use of voluntary standards. In particular, DOD has now adopted 7257 voluntary standards, while DOE has adopted 809, many in the last year.

Thus, agencies have successfully initiated the shift to greater use of voluntary standards, with an accompanying decrease in the development of new agency-specific standards. At the same time, the dramatic decrease in the number of Federal participants in voluntary standards committees is a major concern since Federal input to the standards process is likely to become less effective.

Introduction

The October 20, 1993, Office of Management and Budget (OMB) revised Circular A-119, "Federal Participation in the Development and Use of Voluntary Standards," establishes a policy for all Federal executive branch agencies concerning the use of voluntary standards and participation of Federal employees in their development. It sets forth ". . .the policy of the Federal Government in its procurement and regulatory activities to rely on voluntary standards, both domestic and international, whenever feasible and consistent with the law and regulation pursuant to the law." Voluntary standards should be adopted and used by Federal agencies ". . .in the interests of greater economy and efficiency" and should be given preference over non-mandatory government standards unless use of such voluntary standards would adversely affect performance or cost, reduce competition, or have other significant disadvantages.

The Circular encourages Federal agency employees to participate when voluntary standards activities ". . .are in the public interest, and when it is compatible with the agency's missions, authorities, priorities, and budget resources." Participation should be aimed at contributing to the development of voluntary standards that will eliminate the need to develop and maintain separate government standards.

The Circular requires coordination of agency participation so that: (1) the most effective use is made of agency resources and representatives; and (2) the views expressed by those representatives are in the public interest and, at a minimum, do not conflict with the interests and established views of the agencies. Agencies must establish procedures to ensure that their representatives who participate in voluntary standards activities comply with the requirement to coordinate agency views.

The Circular provides a policy statement with strengthened administrative guidance to Federal agencies on using domestic and international voluntary standards for procurement and regulatory purposes, on further improving interaction with private sector organizations to develop such standards, and coordinating Executive Branch responsibilities for participation in the development of voluntary standards. To achieve these goals each agency has designated a standards executive to provide agency leadership on standards policy issues with agency-wide responsibilities for implementing the Circular. The Circular also requires improved agency accountability, coordination, and recognition of trade policy objectives, along with World Trade Organization standards code obligations in the treatment of standards by Federal agencies. It requires significant changes in agency administration, adoption, utilization and reporting of standards-related activities to implement the Circular, as well as increases the responsibility of the Secretary of Commerce for Executive Branch implementation.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (NTTAA), P.L. 104-113, directs NIST to provide public sector leadership in standards and conformity assessment and to work with

other Federal, state, and local agencies and the private sector to support the creation and maintenance of a sound technical infrastructure for standards and conformity assessment activities for the United States.

NIST activities for implementing P.L. 104-113 are largely the responsibility of the Office of Standards Services (OSS). The Director of OSS chairs the Interagency Committee on Standards Policy (ICSP) on behalf of the NIST Director and the Secretary of Commerce, and uses the ICSP as the primary vehicle for coordinating Federal activities under the NTTAA and Circular. NIST develops few agency-unique standards for either procurement or regulation purposes, but plays a major role in standards-related technical and policy-related activities, as directed by both the Circular and NTTAA.

Coordination of Agency Activity

The ICSP was established in 1968 to encourage coordination and liaison among Federal agencies on matters related to standards. In 1992, the Secretary of Commerce reconstituted the ICSP to provide the required "interagency consultative mechanism to advise the Secretary and agency heads in implementing the policy." In October 1997, the Secretary of Commerce approved a new Charter for the ICSP, attached as Appendix C, with similar goals.

The ICSP is currently composed of representatives of the 14 Federal Cabinet departments, 11 independent Federal agencies and, three offices in the Executive Office of the President. NIST provides the Chair and the Secretariat for the ICSP.

Representatives on the ICSP are from:

Cabinet Departments

- Department of Agriculture (USDA)
- Department of Commerce (DOC)
- Department of Defense (DOD)
- Department of Education (DOEd)
- Department of Energy (DOE)
- Department of Health and Human Services (HHS)
- Department of Housing and Urban Development (HUD)
- Department of Interior (DOI)
- Department of Justice (DOJ)
- Department of Labor (DOL)
- Department of State (DOS)
- Department of Transportation (DOT)
- Department of Treasury (TREASURY)
- Department of Veterans Affairs (VA)

Independent Agencies

- Consumer Product Safety Commission (CPSC)
- Environmental Protection Agency (EPA)
- Federal Communications Commission (FCC)
- Federal Emergency Management Agency (FEMA)
- Federal Trade Commission (FTC)
- General Services Administration (GSA)
- International Trade Commission (ITC)
- National Aeronautics and Space Administration (NASA)
- National Archives and Records Administration (ARCHIVES)
- National Science Foundation (NSF)
- Nuclear Regulatory Commission (NRC)
- U.S. Postal Service (USPS)
- U.S. Agency for International Development (USAID)

Executive Office of the President

- Office of Management and Budget (OMB)
- Office of the United States Trade Representative (USTR)
- Office of Consumer Affairs (USOCA)

The ICSP membership roster is given in Appendix D.

ICSP Activities During 1997

The ICSP addressed issues to stimulate implementation activities within and among Federal agencies in a series of six meetings in FY 1997.

ICSP meetings focused on such topics as revision of the OMB Circular A-119, strategic standards management, effective participation in standards committees, updating regulatory references to out-of-date standards, and information resources available to agencies. Several agencies including NRC, HUD, and DOE described agency processes for coordinating activities both internally and externally. Several ICSP meetings also included presentations by private sector bodies such as the American Society for Testing and Materials (ASTM), the American National Standards Institute (ANSI), Council of American Building Officials (CABO), ACIL (formerly the American Council of Independent Laboratories), Underwriters Laboratories (UL), and others. As a result of the ICSP meetings, EPA and ASTM met subsequently to develop and implement procedures for updating EPA references to out-of-date ASTM standards.

During 1997, OSS served as secretariat for the five working groups of the ICSP in which specific topics such as ISO[2] 9000, ISO 14000, laboratory accreditation, standards information and directories, and regulatory issues were addressed to meet Federal needs. Specific ICSP work activities were carried out by ICSP Working Groups with participants designated by ICSP representatives. These activities are described below.

1. Working Group on Regulatory Agencies. The Working Group is composed of representatives from Federal regulatory agencies which identify areas of mutual interest, serve as a forum for information exchange, and bring agencies together on activities of common concern. During FY 1997, the Working Group provided revisions to the OMB Circular A-119 to meet particular regulatory needs and developed plans for regulatory agencies to implement the NTTAA.

2. Working Group on Quality Management Systems (ISO 9000). The Government and Industry Quality Liaison Panel (GIQLP) is co-chaired by DOD, NASA, and a representative from the Electronics Industry Association (EIA). The GIQLP is a partnership of 12 Federal agencies, three major trade associations, the American National Standards Institute (ANSI) and the American Society for Quality (ASQ). Its goals include: providing contractors with guidance on the establishment of a single quality management system in a contractor's facility that is capable of meeting each customer's requirements; promotion of the effective use of advanced practices; and promotion of effective and efficient oversight methods. The single quality management system is defined by the contractor for a specific facility and contains a basic quality management system (based on the appropriate elements of ISO 9001) augmented by facility-wide advanced quality practices, as appropriate.

   In October 1997 the GIQLP completed its second revision of the Quality Management Systems Guide (Guide), which provides an overview of the work of the GIQLP in harmonization of procurement practices in the quality area. This Guide and other supporting material have been placed on an Internet site established by the GIQLP. The URL address of that site is: http://www.giqlp.org. The supporting material explains the GIQLP concepts in greater detail and provides examples, training material, and lessons learned.

3. Working Group on ISO 14000. The Working Group met bimonthly over the past year to define agency needs related to ISO 14000, Environmental Management Systems (EMS). The Working Group evidenced a strong commitment and enthusiasm for putting together Federal agencies' issues and perspectives on ISO 14000. Participants are successfully identifying and devising means for meeting Federal issues and needs with regard to ISO 14000/EMS.

   The Working Group created an operating guide to provide information and recommendations to the ICSP regarding development and implementation of the ISO 14000 standards in the

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[2]International Organization for Standardization

Federal sector through: information sharing; identifying current uses of ISO 14000 by agencies; identifying capabilities and initiatives; and identifying and supporting ways to link agency efforts.

Throughout the year, the Working Group addressed topics such as: Air Force Interim Policy on Environmental Safety and Health EMS, DOE's Raising Awareness of EMS within the Agency, ISO 14000 and Procurement, and the work of various offices within EPA on ISO 14000 and EMS. These topical discussions provided guidance to agencies for resolving agency-specific issues.

4. Working Group on Laboratory Accreditation. The Working Group met at NIST in June 1997 with representatives from the many Government agencies that either operate accreditation programs or have a strong interest in laboratory accreditation. Each attendee presented a short briefing on the nature of his or her agency's accreditation activities, showing a diversity of programs and ideas, and leading to an excellent exchange of information.

   Five topics were highlighted for consideration at future meetings: (1) applicability of ISO Guide 25, "General requirements for the competence of calibration and testing laboratories," to Federal programs, especially in light of laboratories that operate in accordance with Good Laboratory Practice (GLP); (2) value of international recognition of accreditation programs; (3) duplication of accreditation programs within the Federal sector; (4) ISO 9000 versus ISO Guide 25 in the accreditation of laboratories; and (5) the role of Federal agencies in the National Cooperation for Laboratory Accreditation (NACLA).

   Subsequent meetings were held between the chairman and representatives of the Department of the Navy (Strategic Systems Program Office and Naval Sea Systems Command), Air Force, Department of Energy, and the Food and Drug Administration to gain a better understanding of specific programs and to discuss specific agency roles in laboratory accreditation. Planning is underway for a meeting in spring 1998 to further develop and discuss laboratory accreditation issues facing Federal agencies.

5. Working Group on Directory Database. The Working Group revised and distributed its final report to reflect comments from group members. The report included "Guidelines for the Development of Harmonized Federal Agency Directories," and forms for collecting information contained in the directories. The Working Group met once in 1997 and discussed the trend by agencies of using the Internet to collect and maintain directory information.

   In April, a questionnaire was sent out to all ICSP members to determine which agencies have developed directories, how they are published and made available, methods for collecting information, and Internet use and access. Thirteen agencies responded to the questionnaire: seven agencies currently have directories; two are planning to develop one; three agencies publish their directories; and three agencies have them available via the Internet.

The Working Group recommends that agencies that have not developed directories should be encouraged to do so. Once all agencies have directories available, the ICSP will need to determine how best to access this information.

6. Working Group on Standards Management. The Working Group is directed at sharing information and activities supporting the efficient and effective management of each agency's and department's standards activities, including electronic information sharing and coordination. Working Group members and their representatives attended DOE's Standards Management Workshop and observed DOE's Technical Standards Managers Committee meetings and Department Standards Committee meetings. Members are now planning a joint Federal technical standards conference and workshop for fiscal year 1998 to share standards management information and lessons learned.

Conclusions

Table 1 summarizes data provided by agencies as required by Circular A-119 on participation activities and adoption of voluntary standards. Major improvements were noted in the activities of the ICSP in the number of participating agencies, frequency of committee meetings, and the accomplishments of the Working Groups as reported earlier.

In summary, the data provided by agencies and presented in Table 1 indicate a significant decrease from 1996 to 1997 in the numbers of Federal employees participating in voluntary standards bodies. This decrease should be a matter of grave concern for Federal policy makers. There was a significant decrease from the more than 5200 Federal participants reported in 1996 to less than 3300 reported in 1997 for a number of reasons, most likely including agency downsizing and retirement. The striking decrease was particularly apparent in seven agencies, including the Departments of Commerce, Defense, Health and Human Services, Transportation and Treasury, and such independent agencies as the Federal Communications Commission and the Environmental Protection Agency. At the same time, modest increases were noted at the Departments of Energy, Interior, and Veterans Affairs, General Services Administration and NASA. The decline in participants means that Federal input to the standards process is likely to continue to decrease and be less effective. While most of the decrease in personnel is likely attributable to retirements, downsizing and buy-outs, some may have been due to unclear guidance about the ethics implications of participating in voluntary standards committees. The more specific guidance anticipated in the 1998 revision of the Circular may remove this uncertainty.

On the other hand, agencies reported the development of very few agency-specific standards, while noting a markedly increased use of voluntary standards. Agencies reported using 543 voluntary standards in 1997, and substituting 187 voluntary standards for government-unique standards. Only HHS and DOT reported the development of new agency-specific standards during 1997. By contrast, DOD has now adopted 7257 voluntary standards, while DOE has adopted 809, many in the last year.

Thus, agencies have successfully initiated the shift to greater use of voluntary standards, with an accompanying decrease in the development of new agency-specific standards. At the same time, the dramatic decrease in the number of Federal participants in voluntary standards committees must be a major concern for standards policy makers, since this is a key avenue for Federal agencies to provide input into the standards they will need in the future.

Recommendations

1. All Federal agencies should strengthen their efforts to implement the NTTAA and OMB Circular A-119, particularly in planning for resource and staff allocation for participation in appropriate voluntary standards activities.

2. Most Federal agencies have already made significant progress in their use of voluntary standards for agency programs and missions. This trend should be vigorously continued for both procurement and regulatory activities. Agencies should increase their participation in those activities.

3. Federal agencies should develop specific policy and programmatic elements to support the implementation of the NTTAA and OMB Circular A-119. Elements for consideration are presented in a report prepared by ICF Kaiser for the Environmental Protection Agency[3], regarding the establishment of agency standards policy and units for monitoring standards activities; resource allocation; infrastructure; reporting; and assessing program effectiveness.

4. Agencies should consider their own strategic needs when planning for agency participation in standards activities. They should use available resources, including NIST, to determine applicable Standards Developing Organizations (SDOs) (both national and international), relevant voluntary standards, and the need for new standards in emerging technologies and processes. NIST should continue to facilitate interactions between agencies and the voluntary standards process.

5. The ICSP should develop guidelines for use when agencies prepare staff for participation in standards-related activities. These guidelines should reflect: the need to prepare agency views and coordinate positions with other relevant agencies so that all Federal needs are reflected as standards are developed; appropriate activities in committees to avoid the appearance of dominance; and consideration of likely future agency and national needs during the development and revision of voluntary standards.

6. Federal agencies should improve and utilize systems for tracking the adoption or referencing of voluntary standards, as well as the level of staff participation in voluntary standards-

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[3]"Federal Agencies Participation in the Development and Use of Voluntary Standards," ICF Kaiser Consulting Group, October 1997.

developing bodies. Agencies should use electronic means for setting up directory databases of participants and exchanging information about standards related issues.

Table 1. FEDERAL AGENCY INFORMATION ON PARTICIPATION/ADOPTION OF VOLUNTARY STANDARDS ACTIVITIES REQUIRED BY OMB CIRCULAR A-119 (DATA AS OF 9/30/97)

AGENCY	NO. OF VOLUNTARY CONSENSUS STANDARDS BODIES IN WHICH AGENCY PARTICIPATES	NO. OF AGENCY EMPLOYEES PARTICIPATING	CHANGE FROM FY '96	NO. OF VOLUNTARY CONSENSUS STANDARDS USED SINCE 10/96	NO. OF VOLUNTARY CONSENSUS STANDARDS SUBSTITUTED FOR GOVT.-UNIQUE STANDARDS	NO. OF GOVT.-UNIQUE STANDARDS USED IN LIEU OF VOLUNTARY CONSENSUS STANDARDS
DOC	141	386	-134		33	
OCA	4	1	0			
CPSC	46	22	+1	0	0	
DOD	86	>600	-1600	73[1]	58	
DOE	75	871	+23	10[2]	0	0
EPA	11	200	-22	31[3]	4[4]	0
FCC	10	44	-56	1	0	0
GSA	100	54	+22	4	0	0
HHS	140	242	-88	72	0	5
HUD	9	8	-6	0		
DOI	38	109	+47	205	0	0
DOJ	1	6				
DOL	10	28	+2	6		
NASA	47	154	+15	[5]	92	
ARCHIVES	20	18	+4	20	0	0
NCS	17	16	+1	5		
NSF	2	3	0	0	0	0
NRC	16	165	+2	54	0	0
STATE	1[6]	6	0			
DOT	133	292	-128	54		2
TREASURY	10	25	-15	3	0	
VA	28	26	+10	0	0	0
TOTALS	945	3276	-1922	543	187	7

1. Total number of DOD-adopted voluntary standards is 7527.

2. Total number of DOE-adopted voluntary standards is 809.

3. EPA's 31 final regulations reference at least one or more voluntary standards.

4. EPA report provides additional information.

5. NASA has "identified" 414 standards for potential adoption.

6. Department of State represents the United States in the International Telecommunication Union (ITU). ITU is an intergovernmental organization of the United Nations System whose membership is composed of so states.

APPENDICES

Appendix A:	Cabinet Department Reports	A-1
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Appendix A: Cabinet Department Reports

DEPARTMENT OF COMMERCE (DOC)

The Department of Commerce encourages and supports its staff to participate in standards committee activities relating to the mission of the Department, particularly in response to Office of Management and Budget (OMB) Circular A-119, "Federal Participation in the Development and Use of Voluntary Standards." Agency employees participate in the standards development activities of: U.S. private sector standardization bodies; local, state, and Federal governments; industry; and private and governmental (both treaty and non-treaty) international organizations. Standards of interest to the Department cover such areas as energy conservation, information and computer technology, telecommunications and environmental safety and health, and a variety of other product sectors and fields of technology.

The Standards Assistance and Management Information (SAMI) project in the Office of Standards Services, National Institute of Standards and Technology (NIST), collects and disseminates information on DOC staff participation in outside standards-writing activities. A directory, published annually, contains statistics on standards committee participation, alphabetical listings of staff participants and standards organizations and committees, and a list of acronyms and abbreviations. Department employees are encouraged to provide the SAMI office with additional information concerning participation in standards activities not already included in the directory.

The DOC information maintained by the SAMI office is divided into two parts: NIST and non-NIST agencies. During this reporting period, a total of 386 Commerce Department staff participated in the outside standards committees of 141 (97 national and 44 international) standards-developing organizations. Sixty-three staff members of non-NIST Commerce agencies participated in 42 standards organizations (28 national and 14 international) encompassing 108 committees, holding 138 memberships on those committees. Nine of those standards organizations had five or more DOC participants. NIST had 323 participants in the activities of 99 standards organizations (69 national and 30 international). This participation encompassed 769 committees and 1,162 NIST memberships on these committees. Ten of the standards organizations in which NIST staff members participated had 15 or more NIST memberships.

The following organizations/agencies accounted for 66 percent (91) of the 141 other DOC committee memberships.

Organizations with Other DOC Members:	No. of Committee Memberships
American National Standards Institute	19
Office of Management and Budget	24
Department of Defense/Federal Aviation Administration/Department of Commerce	7

Federal Committee for Metrological Service and Supporting Research	6
Department of State	15
International Organization for Standardization	8
International Telecommunication Union - Telegraph	7
International Telecommunication Union - Radio	5

The following standards organizations accounted for 86 percent (952) of the 1162 NIST committee memberships:

Organizations with NIST Members:	No. of Committee Memberships
American Society for Testing and Materials	569
American National Standards Institute	107
Institute of Electrical and Electronic Engineers	74
International Organization for Standardization	49
American Society of Mechanical Engineers	32
International Organization of Legal Metrology	24
International Electrotechnical Commission	36
American Concrete Institute	16
Telecommunications Industry Association	24
National Conference on Weights and Measures	21

Other DOC Agencies: Summary of Standards-Related Activities

National Oceanic and Atmospheric Administration (NOAA)

Standardization of data acquisition and data management practices is vital to the mission at DOC's National Oceanic and Atmospheric Administration (NOAA). NOAA seeks to establish voluntary standards with selected industrial associations, academia, and national organizations of state and local governments (e.g., the American Association of State Climatologists), as well as through participation in professional societies (e.g., American Meteorological Society). All NOAA line organizations engage in standards development for disciplines of interest to them. In general, standards that apply to many NOAA activities are established with other Federal agencies (e.g., DOD, FAA, USDA); through participation in international organizations such as the World Metrological Organization; and by means of bilateral and multilateral agreements with other nations. These standardization activities apply to all phases of environmental data acquisition, processing and distribution.

National Telecommunications and Information Administration (NTIA)

The NTIA contributes to the development and application of national and international telecommunication standards by way of participation and leadership roles in various voluntary standards committees at national and international levels (e.g., Telecommunications Industry Association, International Telecommunication Union). These standards enhance the quality and reliability of the domestic telecommunications infrastructure, promote healthy competition in telecommunications products and services, and expand international trade opportunities for U.S. telecommunications firms.

Patent and Trademark Office (PTO)

The Patent and Trademark Office participates and contributes to the resolution of identified requirements for international standards, primarily through the Permanent Committee on Industrial Property Information of the World Intellectual Property Organization (WIPO). PTO staff also participate in standardization activities of the International Patent Classification Union and the ANSI committee on Patent Standards.

Bureau of the Census

DOC's Bureau of the Census is active in the development of standards and specifications for definition of metropolitan statistical areas, digitizing of geographic information, and statistical, economic and geographic definitions.

National Institute of Standards and Technology (NIST): Summary of Standards-Related Activities

In addition to the activities described above in support of P.L. 104-113, the NIST's Office of Standards Services (OSS) operates a number of standards-related programs and services to assist business, industry, and government in using and understanding standards, technical regulations, and conformity assessment procedures affecting trade in the global marketplace.

- The National Center for Standards and Certification Information (NCSCI) is the U.S. focal point for standards information and related activities at home and abroad; it provides information on U.S., foreign, regional, and international voluntary standards bodies, mandatory government regulations, and conformity assessment procedures for non-agricultural products. NCSCI is the U.S. member of the International Organization for Standardization Information Network (ISONET), and serves as the U.S. inquiry point under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade, the North American Free Trade Agreement (NAFTA), and the Asia Pacific Economic Cooperation (APEC) Subcommittee on Standards and Conformance.

- NCSCI maintains an extensive collection of reference materials, including U.S. military and other Federal Government specifications, U.S. industry and national standards, international standards, and selected foreign national standards. Staff members respond to requests for specialized standards information; arrange for translations of foreign standards and regulations; and disseminate information to U.S. industry concerning proposed foreign regulations and general standards issues.

- Two telephone hotlines provide weekly updates on draft European standards and on proposed foreign technical regulations that might significantly affect trade.

NIST Standards Advisory Committee

The NIST Standards Advisory Committee implements the Office of Management and Budget's (OMB) Circular A-119 at NIST, coordinating voluntary standards activities and addresses concerns across the Institute and providing a mechanism for information exchange among NIST professional staff on standards activities.

The Standards Advisory Committee, with broad representation, held five meetings during 1997 to develop recommendations for NIST standards policies and procedures. Committee members provided input into the Standards Assistance and Management Information project, which collects and disseminates information on a NIST-wide basis on staff participation in standards activities. The Committee has initiated a framework for Strategic Standards Management at NIST, and is currently reviewing the Institute's standards policies, including the structure for handling standards participation fees and dues. The Chair of the Standards Advisory Committee provided two briefings on national and international standards to the NIST Visiting Committee on Advanced Technology (VCAT).

Federal Information Processing Standards (FIPS)

During 1997, NIST's Information Technology Laboratory continued to review Federal Information Processing Standards (FIPS) to ensure that all FIPS are up-to-date and still needed. FIPS are issued by the National Institute of Standards and Technology (NIST) after approval by the Secretary of Commerce pursuant to Section 5131 of the Information Technology Management Reform Act of 1996 and the Computer Security Act of 1987, Public Law 104-106. In July 1997, the Information Technology Laboratory withdrew thirty-three FIPS after conducting an open process to solicit public review and comments. These FIPS were withdrawn because they were obsolete or had not been updated to adopt current voluntary industry standards. Federal agencies and departments are directed by the National Technology Transfer and Advancement Act of 1995, Public Law 104-113, to use technical standards that are developed in voluntary consensus standards bodies. Consequently, there is no longer a need to establish FIPS that duplicate these available industry standards.

National Technology Transfer and Advancement Act

NIST standards-related activities were formalized by the passage of the National Technology Transfer and Advancement Act (P.L. 104-113), which directed NIST to take responsibility to provide public sector leadership in standards and conformity assessment and in working with other Federal agencies and the private sector to support the creation and maintenance of a sound technical infrastructure for the United States. NIST chairs the Interagency Committee for Standards Policy and has the unique position for coordination and policy input for standards and conformity assessment structures and activities in the United States, and for leading the development of a realistic, workable technical infrastructure to support the goal of an effective global market. NIST activities in support of P.L. 104-113 are described below.

NIST Coordination and Policy Activities in Support of the Law and Circular

In 1996, NIST published a broad, overarching implementation plan (NIST IR 5967) for fulfilling DOC/NIST requirements under the NTTAA. This plan is also available on the NIST website at http://ts.nist.gov/ts/htdocs/210/nttaa/nttaa.htm. This plan contains five broad strategic areas: Guidance to Federal Agencies; Strategic Standards Management for Federal Agencies; Coordination with States and Localities on Standards Activities; Coordination with Standards Developing Organizations (SDOs) and the American National Standards Institute (ANSI); and Conformity Assessment. NIST also created an operational level plan specifying tasks in the five areas, and has thus far completed the following tasks:

Guidance to Federal Agencies

1. During 1997, the Office of Standards Services (OSS) assisted the Office of Management and Budget in its analysis of the comments and response to the comments for its proposed revision of OMB Circular A-119. As part of this activity, NIST hosted seven meetings with Federal agencies for input to the revision, as well as convening an ANSI/NIST/OMB joint workshop on the Circular in February 1997.

2. OSS developed and maintains an NTTAA website (URL: http://ts.nist.gov/ts/htdocs/210/nttaa/nttaa.htm, or ts.nist.gov/oss) with frequent updates of NTTAA implementation activities. The website provides linkages for other Federal agencies (and others) to key sites on the web related to NTTAA matters.

Strategic Standards Management

1. Strategic standards management is defined as setting organizational needs, priorities, and strategies for participating in the development and use of voluntary standards. It requires identification of resources to meet organizational needs, target areas for developing or revising voluntary standards, and coordination of standards positions, policies, and votes within an organization. Guidance for internal NIST activities is developed through a NIST

Standards Advisory Committee comprised of representatives from all NIST operating units, and is developing a strategic standards management plan for Commerce. In addition, one ICSP meeting focused on Strategic Standards Management with a keynote presentation by the American National Standards Institute (ANSI). The possibility of additional activities with ANSI will be explored to assist NIST and Federal agencies with developing strategic standards management plans and procedures.

2. On September 8, 1997, NIST held a day-long conference on "Using Voluntary Standards in the Federal Government" which focused on successful use by Federal agencies of voluntary consensus standards developed by the private sector. The conference was attended by more than 200 participants, including representatives from eight major standard-developing organizations and from 21 Federal agencies that work with the private sector to develop mutually beneficial standards, resolve policy issues, and use standards for Federal procurement or regulation.

Coordination with the States and Localities

1. NIST is currently working with state and local agencies to identify and develop procedures for using and implementing voluntary standards, as well as identifying organizations and stakeholders who can contribute and benefit from a coordinated effort to join together in bringing technology-based regulations, codes, standards and testing to state and local agencies.

2. Activities include efforts with several groups to establish an oversight council to work with and advise state and local agencies in standards-related activities. Through this council states will be able to develop cooperative agreements to support specific areas of need. Such agreements may help state and local agencies to lower overall technology costs, avoid unnecessary duplication and redundancy, create shared information technology solutions, and gain market visibility for their needs in standards and conformity assessment. NIST is also scheduling and conducting workshops on standards and conformity assessment in an effort to educate state and local agencies in the advantages of using voluntary standards. NIST will form an active State-Federal Partnership to help fill the apparent void in knowledge about standards and technological advancements.

3. Beginning in the fall of 1997, NIST staff provided information on standards activities for the American Society of Mechanical Engineers' Western Regional Conference on Accessing Technology and other major groups. NIST plans several workshops and conferences in 1998, including a NIST-State Workshop on the theme of "Innovation and Technology" where a special track will address implementation of the National Technology Transfer and Advancement Act at the state and local levels.

4. In 1997, NIST assisted the Multi-State Working Group (MSWG) on ISO 14000/ Environmental Management Systems (EMS), which comprises more than ten states, NIST,

EPA, plus environmental, academic, and regulated community representatives. The group is examining ways to achieve environmental gains through more effective, less-costly compliance and through the promotion of pollution prevention methods and technologies. EPA and a number of states are interested in coordinating the implementation and data collection/analysis phases of their ISO 14001 pilot projects. The MSWG's goal is to share pilot project performance information and results and thus substantially increase the value of the projects for all interested parties.

NIST funds the MSWG Secretariat and is also in the process of publishing the group's Environmental Management Systems Voluntary Project Evaluation Guidance.

Coordination with the SDOs and ANSI

1. As mentioned above, NIST sponsored a conference on success stories of Federal agencies in using voluntary standards. The conference presented material in three areas: use of voluntary standards in regulation and working with key SDOs, in procurement, and in meeting future national needs. Another conference on Federal use of voluntary standards is scheduled for August 1998, this time in conjunction with DOE, EPA and DOD.

2. NIST staff attended and participated in Board and Council meetings of ANSI, including the Government Member Council, Company Member Council and Organizational Member Council meetings, American Society of Mechanical Engineers (ASME), American Society on Testing and Materials (ASTM), U.S. National Committee of the International Electrotechnical Commission (IEC), the Institute of Electrical and Electronics Engineers (IEEE), and other standards developing organizations. These meetings focused on over-arching standards-related policy issues.

3. NIST also supported ANSI in creating the NSSN (National Standards Service Network), a web-based information site covering more than 250,000 standards from over 600 standards-developing bodies. The system allows users to make simple word search queries about standards. NIST is currently procuring a site-wide license for NSSN, to enhance its existing information resources in the National Center for Standards and Certification Information (NCSCI).

Coordination of Conformity Assessment Activities

1. NIST hosted an open forum in January 1997 and subsequent monthly meetings throughout the year on the formation of the National Cooperation for Laboratory Accreditation (NACLA). A report on the forum (NIST IR 6008) describes needs, goals, and possible solutions for coordinating laboratory accreditation activities in the United States. NACLA's goal is to formalize a public/private organization to coordinate U.S. laboratory accreditation activities, to recognize the technical competence of accrediting bodies for use by government and private sector activities, and, as directed by the Law, to reduce redundant, duplicative

conformity assessment activities. An interim board has been developing operational procedures, and plans to inaugurate a more formal structure in the Spring of 1998 in response to the needs identified in the January 1997 forum.

2. During 1997 NIST conducted other conformity assessment activities, including establishment of the Accrediting Body Evaluation Program (ABEP) to recognize the competence of laboratory accreditation bodies under the Fastener Quality Act (P.L. 101-592, amended by P.L. 104-113). It also began the implementation of the National Voluntary Conformity Assessment System Evaluation (NVCASE) to notify U.S. conformity assessment bodies as competent to meet foreign government requirements, particularly under the U.S.-EU MRA.

3. Additional conformity assessment activities were carried out by ICSP working groups focusing on quality management (ISO 9000), environmental management systems (ISO 14000), and laboratory accreditation. Specific activities are described above for each group.

4. NIST continues to operate the National Voluntary Laboratory Accreditation Program (NVLAP) in response to Federal laws and regulations and to specific private sector demands. NVLAP currently has programs in support of the Asbestos Hazard Emergency Response Act (P.L. 99-519) and the Environmental Protection Agency for asbestos testing, the Nuclear Regulatory Commission for radiation dosimetry, the Department of Commerce for energy efficient motors and lighting, Fastener Quality Act for fasteners, the Department of Housing and Urban Development for construction materials, the Federal Communications Commission for electromagnetic compatibility (EMC), and the National Conference of Standards Laboratories for calibration. NVLAP performs approximately 900 annual accreditations.

DEPARTMENT OF DEFENSE (DoD)

1. DoD Employee Participation. The DoD currently has over 600 employees participating in the standards development activities of 86 voluntary standards bodies.

2. DoD Adopted Voluntary Standards. Since our input for the FY 1996 report, we have adopted an additional 73 voluntary standards, bringing the total number of DoD-adopted voluntary standards to 7,527.

3. Government Standards Replaced by Voluntary Standards. The following 58 Government specifications and standards were replaced by voluntary standards since our input for the FY 1996 report:

GOVERNMENT SPECIFICATION/STANDARD	REPLACEMENT VOLUNTARY STANDARD
MIL-M-14	ASTM D5948-96
MIL-F-5509	SAE AS4841, SAE AS4842, SAE AS4843, SAE AS4875
MIL-T-6737	SAE AMS5575, SAE AMS 5576
MIL-S-7108	SAE AMS6425
MIL-S-8503	SAE AMS6448
MIL-S-8690	SAE AMS6274
MIL-D-10662	ASTM D5960
MIL-T-10727	ASTM B545, ASTM B339
MIL-F-13927	ASTM G21
MIL-S-18728	SAE AMS6350, SAE AMS6351, SAE AMS 6345, SAE AMS4130
MIL-S-18729	SAE AMS6350, SAE AMS6351, SAE AMS5345, SAE AMS4130
MIL-S-25043	SAE AMS5528, SAE AMS5529
MIL-S-38249	SAE AMS3374
MIL-S-51078	ANSI/AWWA B502-94
MS9020	SAE AS3578
MS9021	SAE AS3578
MS9024	NAS 1715
MS9825	NAS 1715
MS27961	ANSI/BHMA A1556.1, ANSI/BHMA A2133

GOVERNMENT SPECIFICATION/STANDARD	REPLACEMENT VOLUNTARY STANDARD
MS27962	ANSI/BHMA A156.17
MS27970	ANSI/BHMA A156.20
MS27963	ANSI/BHMA A156.17
MS27971	ANSI/BHMA A156.20
MS33584	SAE AS4330
MS51538	ASTM F1667
MS51539	ASTM F1667
MS51541	ASTM F1667
MS51543	ASTM F1667
MS51544	ASTM F1667
MS51545	ASTM F1667
MS51546	ASTM F1667
MS51547	ASTM F1667
MS51548	ASTM F1667
MS51549	ASTM F1667
MS63044	NAS 1711
MS90710	ASTM F1667
MS90711	ASTM F1667
MS90712	ASTM F1667
MS90713	ASTM F1667
MS90714	ASTM F1667
MS90715	ASTM F1667
MS90717	ASTM F1667
MS90718	ASTM F1667
MIL-STD-453	ASTM E1742
MIL-STD-1189	AIM BC1
MIL-STD-6866	ASTM E1417-95
A-A-460	ANSI/BHMA A156.14
A-A-1995	ANSI Z87.1
A-A-1996	ANSI Z87.1
J-W-1997	NEMA NW-1000
R-P-355	ASTM D-5727

GOVERNMENT SPECIFICATION/STANDARD	REPLACEMENT VOLUNTARY STANDARD
FF-N-105	ASTM F1667
GG-G-531	ANSI Z87.1
HH-I-558	ASTM C612, ASTM C553, ASTM C592, ASTM C547
QQ-C-523	ASTM B30-95
QQ-P-35	ASTM A967
Rr-S-366	ASTM E-11, ASTM E-323
ZZ-H-461	RMA IP-7

4. Section 7 of the proposed revision to OMB Circular A-119 provides guidelines for using voluntary consensus standards bodies. As written, this section reinforces current DoD policies regarding use of voluntary standards, reliance on performance documents, and encouragement of participation in voluntary standards bodies. The intent of this section is clear, we do not believe further changes are necessary at this time.

NATIONAL COMMUNICATIONS SYSTEM (NCS)

1. The Office of the Manager, National Communications System (OMNCS) provides the chair of the Federal Telecommunication Standards Committee (FTSC). This committee prepares standards on matters affecting national security and emergency preparedness (NS/EP) and in other areas of communications approved by the committee on the basis of requests from members.

2. During FY 1997, five Federal Telecommunications Recommendations (FTR), based on consensus standards committee approved documents, were approved by the FTSC for publication.

a. FTR 1024A-1997. Project 25 Radio Equipment [land mobile radio systems]. Combination of Telecommunications Industry Association (TIA) documents in the 102 series.

b. FTR 1062-1997. Group 3 Facsimile Apparatus for Document Transmission. Based on ANSI/TIA/EIA-465-A-1995.

c. FTT 1063-1997. Procedures for Document Facsimile Transmission. Based on ANSI/TIA/EIA-466-A-1996.

d. FTR 1070-1997. Detail Specification for 62.5 um Core Diameter/125-um Cladding diameter Class 1a Multimode, Graded Index Optical Waveguide Fibers. Based on ANSI/EIA/TIA-492AAAA-1989.

e. FTR 1090-1997. Commercial Building Telecommunications Cabling Standard. Based on ANSI/TIA/EIA-568-A-1995.

3. Dr. Dennis Bodson, Chief, Technology and Standards Division, and Chair, FTSC, is the OMNCS focal point for communication standards matters. His telephone number is 703.607.6200, and his e-mail address is bodsond@ncs.gov.

4. The FTSC and members of the Office of the Manager, NCS (OMNCS) work extensively with voluntary standards organizations to ensure that Government requirements are considered as the standards are developed. The OMNCS has 17 employees who participate in industry voluntary standards activities. Paragraph 6 lists the committees in which they participate.

5. Voluntary standards related committees in which the staff of the Office of the Manager, National Communications System, participate.

Commercial and International Organizations Accredited by ANSI-T1, Telecommunications, ISDN, BISDN, Signaling Systems, Personal Communications services (PCS) Asynchronous

Transfer Mode (ATM), Synchronous Optical Networks (SONET), Network Management (The secretariat of T1 is the Alliance for Telecommunications Industry Solutions (ATIS).
  - Participate in 6 subcommittees
- National Committee for Information Technology
- Standards (NCITS, formerly X3), Data Communications, Information Processing Systems, Data Interchange, OSI Protocols (The secretariat of NCITS is the Informational Technology Industry Council (ITI)
  - Participate in 8 subcommittees
- TR-8, TR-29, TR-30, TR-45, TR-46, Land Mobile Radio (LMR), Data communications, Cellular, PCS, Facsimile (The secretariat of the TR committees is the Telecommunications Industry Association)
  - Participate in 7 subcommittees
- JTC1 TAG Information Technology (U.S. Preparatory Meeting for JTC1 input)

Commercial and International Organizations Not Accredited by ANSI-ATM Forum
- Multimedia Forum
- Telecommunications Industry Forum (TCIF) and Electronic Communications Implementation Committee (ECIC) (The secretariat of TCIF and ECIC is ATIS.)

Federal Interagency Committees
- Federal Telecommunication Standards Committee (Chair & Executive Secretary)
- Federal Wireless Policy Committee (Vice-Chair)
- Federal Wireless User's Forum (Chair)
- IITF (Information Infrastructure Task Force) (Standards Panel Member)
- FLEWUG (Federal Law Enforcement Wireless User's Group) (Member)

Federal, State, and Local Committees

- APCO (Association of Public Safety Communications Officials)
  - Project 25 (LMR) (Member Steering Committee)
  - Project 31 (Wireless/E911)

International Organizations

- NATO (North Atlantic Treaty Organization)
  - Protocol Interoperability Working Group
  - Civilian Communications Planning Committee
- International Telecommunication Union - Telecommunications Sector (United Nations Treaty Organization)
  - Participate in 7 Study Groups
- International Telecommunication Union - Radio Sector (United Nations Treaty Organization)
  - Participate in 2 Study Groups

- International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC)
  - Joint Technical Committee 1

Office of the Manager, National Communications System, Status of Agency Interaction With Voluntary Standards Bodies

HEALTH AND HUMAN SERVICES, DEPARTMENT OF (HHS)
Food and Drug Administration (FDA)

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Summary of the nature and extent of FDA participation in the development and utilization of voluntary consensus standards.

1) The number of voluntary consensus standards bodies in which there is agency participation = **140**;

   the number of agency employees participating = **242**;

2) the number of voluntary consensus standards the agency has used since October 1, 1996 (or those based on the procedures set forth in Section 8 of the proposed revision to OMB Circular A-119 (December 27, 1996) = **72**;

* 3) identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards (or as outlined under paragraph 7c(6) of the proposed revision to the Circular) = **0**;

4) an evaluation of the effectiveness of the guidelines in Section 7 of the proposed revision to the Circular and recommendations for any changes;

   The guidelines in Section 7 of the proposed revision to OMB Circular A-119 will assist in establishing a framework within which to evaluate an agency's standards management program. FDA has met most of the objectives contained in the guidelines, and is continuing to develop procedures to more effectively participate in and track its standards development activities, as well as to increase its utilization of voluntary consensus standards.

* 5) the number of times the agency used government-unique standards in lieu of voluntary consensus standards = **5**.

* = FDA utilizes voluntary consensus standards except in cases when none are available or appropriate in meeting regulatory levels of protection, such as for food/color additives, pesticides, and certain veterinary medicine products.

Explanatory Notes

The central purpose of Food and Drug Administration (FDA) involvement in the development and use of standards is to assist the agency in fulfilling its domestic public health and regulatory missions. The agency participates widely in the development of standards, both domestic and international, and adopts or uses standards when this action will enhance its ability to protect consumers and the effectiveness or efficiency of its regulatory efforts. Further, using standards, especially international ones, is a means to facilitate the harmonization of FDA regulatory requirements with those of foreign governments, and thus to further domestic and global public health. Therefore, FDA encourages participation in the development of standards as a useful adjunct to regulatory controls.

FDA has been involved in standards activities for more than twenty years, and in January 1977 the agency promulgated a final regulation now found at 21 CFR 10.95 covering the participation by FDA employees in standards-setting activities outside the agency. This regulation encourages FDA participation in standards setting activities that are in the public interest, and specifies the circumstances under which FDA employees can participate in various types of standards bodies.

The agency built upon that rule with a draft policy statement published in the Federal Register on November 28, 1994, and a subsequent final policy published on October 11, 1995. Entitled *International Harmonization; Policy on Standards,* it provides the agency's overall policy on use and participation in standards development for all product areas regulated by the agency.

In an initiative aimed at furthering harmonization, on January 28, 1995, FDA published in the Federal Register a proposed rule to facilitate the sharing of draft regulations and other predecisional documents with state and foreign officials. The final rule, entitled *Public Information; Communications with State and Foreign Government Officials* was published on December 8, 1995.

FDA participation in standards activities varies within each of the agency's centers, because of differing applicability of voluntary consensus standards in each substantive area. Voluntary consensus standards are most relevant in the medical device area, and consequently the majority of the agency's activities are centered there.

Center for Devices and Radiological Health (CDRH)

On October 7, 1996, FDA published in the Federal Register its final rule revising the current good manufacturing practice (CGMP) requirements for medical devices. The new quality systems regulation is compatible with specifications for quality systems contained in an

international quality standard developed through the International Organization for Standardization (ISO), namely ISO 9001 "Quality Systems Part 1. Specifications for Design/Development, Production, Installation, and Servicing." This action was taken to add preproduction design controls and to achieve consistency with quality system requirements for medical devices worldwide.

On August 1, 1996, FDA began a voluntary pilot program using private sector third parties to review marketing applications for certain low and moderate risk medical devices, utilizing standards developed by ISO and the International Electrotechnical Commission (IEC). This program is being evaluated as part of the agency's efforts to carry out its mission more efficiently while maintaining an appropriate level of public protection and will be extended as a result of the recent *FDA Modernization Act of 1997.*

On May 9, 1997, FDA issued a final rule establishing a mandatory performance standard for electrode lead wires and patient cables, based in part on an IEC standard. The agency took this action because it determined that a performance standard was needed to prevent electrical connections between patients and electrical power sources, to substantially reduce the risk of electrocution from unprotected electrode lead wires and patient cables. This is an example of a mandatory regulation based on a voluntary consensus standard.

In October 1997, a draft guidance document was made available for public comment on the agency's Internet home page, which instructs FDA medical device reviewers to utilize the criteria contained in the IEC 601 series of standards in the device approval programs. Independent (third party) certification to the standards will be sufficient to demonstrate the safety of electrical medical devices for the aspects of safety addressed by the standards.

CDRH has maintained a database to track the standards activities of its employees for several years. Recently, the Center purchased searchable (ROM) databases of voluntary consensus standards from a private company (IHS) as well as several standards development organizations, to facilitate reference to such standards by agency reviewers.

Center for Drug Evaluation and Research (CDER) / Center for Biologics Evaluation and Research (CBER)

Numerous employees in FDA's Center for Drug Evaluation and Research (CDER) and other FDA Centers are involved in the standards development activities of the U.S. Pharmacopeia (USP), a private, voluntary, not-for-profit national standard setting body of more than 1500 health care professionals, recognized authorities in medicine, pharmacy, and allied sciences. USP publishes and revises the United States Pharmacopeia and the National Formulary (NF), the legally recognized compendia of drug standards in the United States.

Both CDER and the CBER are major FDA participants in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human

Use (ICH). This ongoing project, begun in 1989, has been undertaken by Government agencies responsible for regulation of drugs and by industry trade organizations for the European Union (EU), Japan, and the United States. ICH brings together regulatory authorities and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of new product registration. The work products, created in working groups of experts from the regulatory agencies and industry, consist of a series of consensus guidelines documents to harmonize pharmaceutical testing guidelines. FDA officials also participate in a consensus standard setting activity sponsored by the Council for International Organizations of Medical Sciences and implemented in ICH, that is aimed at standardizing the safety-related terminology used in adverse experience reporting.

FDA also actively participates with the World Health Organization (WHO) in setting international criteria for regulating drugs and biologics.

Although FDA's work with USP is specifically excluded from reporting under OMB Circular A-119 and ICH and WHO do not meet the definition of voluntary consensus standard bodies under the Circular, substantial agency resources are devoted to the development of these various standards, and this work is an important part of FDA's overall standards activities.

Center for Food Safety and Applied Nutrition (CFSAN) / Center for Veterinary Medicine (CVM)

Standards activities of multilateral organizations, such as the WHO and the Organization for Economic Cooperation and Development (OECD) are often important to FDA and frequently involve multiple product types. The principal international standards activities in the areas of food and veterinary medicine fall under the activities of the Codex Alimentarius Commission under the Food and Agricultural Organization (FAO) and the WHO, and the Office of International Epizooties (for veterinary medicine). Experts from FDA's CFSAN, CVM, Office of Policy and Office of Regulatory Affairs are heavily involved in Codex activities.

FDA's CVM has recently begun a harmonization initiative similar to the ICH, that will develop harmonized requirements for the registration of veterinary drugs. It is known as VICH, for Veterinary ICH.

International/Treaty Standards-Related Activities

FDA takes part in numerous international standards activities which fall under treaty organizations, (and thus are not reportable under the provisions of OMB Circular A-119). These standards activities are nonetheless important to the agency in fulfilling its public health regulatory mission. Some of these are referred to above, i.e. WHO, FAO, and OECD.

The agency also participates in international trade discussions of the World Trade Organization (WTO) specifically, the Agreement on Technical Barriers to Trade, and the Agreement on Sanitary and Phytosanitary Measures, and the same counterpart committees of the North

American Free Trade Agreement (NAFTA), to ensure that FDA's requirements are preserved and its regulatory practices can remain focused on fulfilling the agency's mission to protect the public health while being supportive of emerging, broader U.S. Government obligations and policies. FDA has participated in several initiatives that are part of the Asia Pacific Economic Cooperation (APEC) forum. FDA topics have included food safety, food labeling, bulk drugs, and standards for latex gloves and condoms. FDA also participates in activities leading toward a Free Trade Area of the Americas (FTAA) through representation on working groups on standards, and sanitary and Phytosanitary measures.

FDA Standards Policy and Program Management

The FDA's Standards Policy Committee (SPC) is chaired by the agency standards executive, and composed of top management representatives from all centers and offices within the agency. The SPC meets quarterly to review and discuss both domestic and international standards issues, and recommend agency-wide standards policy to the Commissioner. The committee oversees the coordination of FDA standards activities and official participation of employees in standards development endeavors both within and outside FDA; tracks, compiles and reports required information; and ensures appropriate standards review when applicable.

The agency experts on quality systems and environmental management serve as liaison members to the FDA's SPC, to strengthen agency expertise and participation in issues and activities related to these areas. The agency also has a contact group of experts on private laboratory issues that holds meetings as needed to assure coordination of testing and conformity assessment issues.

It is the intent of FDA's standards policy to (1) enable the agency to participate in international standards activities that will assist it in implementing statutory provisions for safeguarding the public health; (2) increase its efforts to harmonize its regulatory requirements with those of foreign governments, including setting new standards that better serve the public health; and, (3) respond to laws and policies that encourage agencies to use voluntary standards that provide the desired degree of protection.

As part of the President's and Vice President's National Performance Review, FDA is currently carrying out a comprehensive review of its existing regulations. As part of this review, the agency is considering the appropriateness of existing regulations and policies, as specified in the proposed revision to OMB Circular A-119. During 1997, the American Society for Testing and Materials (ASTM) identified various FDA food additive and medical device regulations which contained references to out-of-date ASTM standards. FDA is currently drafting a proposed rule to amend those regulations, to update the references to various standards to reflect current standards designations.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT (HUD)

In response to the reporting requirements of OMB Circular A-119, Paragraph 9 dated October 20, 1993, HUD reports the following information:

A. (1) There are a total of eight HUD employees participating in standards development groups. Six employees from the Manufactured Housing & Standards Division and two employees from the Office of Lead Hazard Control are participating on nine voluntary consensus standards bodies and a NIST standards activity. Organizations with which they participate are:

a. American Architectural Materials Association
b. American Hardboard Association
c. American National Standards Institute
d. American Society for Civil Engineers
e. American Society for Testing & Materials
f. Council of American Building Officials
g. International Approval Services
h. NSF International
i. Underwriters Laboratories

(2) No new voluntary consensus standards have been adopted which resulted from agency participation in a standards development group since October 1, 1996.

(3) HUD's Office of Consumer and Regulatory Affairs is currently conducting a comprehensive review of its existing standards and expects to update many references during calendar 1998.

B. No voluntary consensus standards have been adopted during this period for the purpose of promoting environmentally sound and energy efficient materials, products, systems, services, or practices. HUD is updating its reference to the CABO Model Energy Code for housing insured under the FHA mortgage insurance programs to incorporate the 1995 revisions.

C. HUD supports the policy of OMB Circular A-119 and references more ASTM voluntary consensus standards than any other Federal Agency.

If you have any questions concerning the above, please contact Ms. Marion Connell at (202) 708-6409.

DEPARTMENT OF ENERGY (DOE)

The DOE implements the Federal guidance and requirements in OMB Circular A-119 and the statutory requirements in Public Law (P.L.) 104-113 (15 USC 272) on the use of voluntary standards through specific Departmental policy and supporting management systems.

DOE P 251.1, "Directives System," establishes a Directives System for managing DOE requirements and guidance documents and incorporates technical standards (i.e., those standards that are specifically addressed in P.L. 104-113) as the foundation of the Department's directives system hierarchy. This policy clearly states DOE's preference to "adopt National Consensus Standards and other commercial and industry standards. . ." in the conduct of Departmental activities. The policy also contains provisions restricting the use of mandated technical standards in DOE rulemaking and orders stipulating DOE-specific requirements.

DOE P 410.1A, "Promulgating Nuclear Safety Requirements," also requires notice and comment rulemaking to promulgate new nuclear safety requirements. The new nuclear safety requirements promulgated by the Department are "performance-based" rules which permit the adoption of commercial and industry standards as acceptable methods to implement the rules when appropriate for the work to be conducted and the hazards to be encountered.

These Departmental policies on the use of voluntary standards are subsequently implemented through a management system established through DOE Order 1300.2A, "Department of Energy Technical Standards Program." This Order requires DOE elements to use international and national voluntary standards in preference to Federal and DOE standards, consistent with P.L. 104-113 and OMB A-119. It also establishes an integrated Department-wide Technical Standards Program and supporting infrastructure designed to implement Federal and DOE technical standards requirements and manage related activities within DOE. As advocated in OMB Circular A-119 and P.L. 104-113, the Order encourages and supports staff participation in the planning, development, and coordination activities of voluntary standards committees.

As of November 1997, DOE Order 1300.2A is being updated to incorporate references to P.L. 104-113 and the pending revision to OMB Circular A-119. In the interim, the Assistant Secretary for Environment, Safety and Health issued an information memorandum to the Department's cognizant secretarial officers (i.e., senior DOE line managers in Washington, D.C.) describing the new Public Law, its impact upon DOE, and the planned implementation of the law through the Technical Standards Program.

Another element serving to manage implementation of OMB Circular A-119 is DOE's Department Standards Program. This was established to institute "standards" (in this application, "standards" include policy, laws, rules, guides, and technical standards) as the basis for work throughout the Department. A Department Standards Committee (DSC) was established in 1994 and served to establish DOE standards policy and remove barriers to implementing a Department-wide standards-based culture. The DSC assists DOE line organizations in the

implementation of this Department Standards Program. The "Criteria for the Department's Standards Program," DOE/EH/-0416, August 1994, describes elements of the standards-based operating culture envisioned by DOE leadership. Information on the Department Standards Program and the DSC can be accessed at the following Internet address (Universal Resource Locator [URL]):

http://www.dsc.doe.gov

The DSC has sponsored development and implementation of a DOE-wide process that enables DOE contractors to select voluntary consensus standards as the basis for their work in-lieu-of mandated DOE-developed standards. This "Work Smart" standards approach (also referred to as the "necessary and sufficient" process) enables DOE laboratory and management and operating contractors, with DOE approval, to identify and apply the set of standards (including technical standards) that best fits their activities. This approach focuses on outcomes and performance, rather than "how" things are to be done within DOE, and is supported by a major contract reform effort designed to more closely link performance expectations with contractual obligations based on standards.

Key Departmental policy and requirements documents defining this approach include DOE P 450.3, "Authorizing Use of the Necessary and Sufficient Process for Standards-Based Environment, Safety and Health Management," and DOE M 450.3-1, "The Department of Energy Closure Process for Necessary and Sufficient Sets of Standards." Field pilot projects of the approach have been completed, and significant efficiencies and cost savings have been demonstrated. Based on the success of the pilot projects, the "Work Smart" standards approach was expanded to cover a broad range of Department programs and facilities. In FY 1997, key Technical Standards Program personnel participated in several DSC working groups that focused on tailoring/integration of "Work-Smart" standards activities and DSC support for the Department's "Integrated Safety Management" initiative.

The DOE Standards Executive, Richard L. Black, Director, Office of Nuclear Safety Policy and Standards, continues to be responsible for developing and implementing the DOE Technical Standards Program throughout the Department. He also advises and provides staff support to the Department Standards Committee. Through Mr. Black's participation on the Interagency Committee on Standards Policy, DOE continues to provide information to other Federal agencies on the Department's approach to establishing a standards-based culture.

DOE Order 1300.2A emphasizes the use of technical standards within the Department. The Department's Technical Standards Program Office (TSPO) operates to implement program policy, supports the conversion of Department standards to voluntary standards, identifies voluntary standards that can suit Department needs, develops and maintains data bases to support the program and meet reporting requirements, and coordinates day-to-day Department technical standards activities. The TSPO has developed procedures, methods, and training approaches to implement the DOE Technical Standards Program and communicate the policy to use voluntary

standards throughout DOE and, when appropriate, participate in voluntary standards committee activities. The program procedures establish a five-year standards review cycle to check for continued applicability; the procedures also provide guidance on the conversion of Department standards to voluntary standards.

Information on the Technical Standards Program and the TSPO can be accessed at the following Internet address (URL):

http://apollo.osti.gov/html/techstds/techstds.html

Technical Standards Managers (approximately 80 individuals representing the various Department headquarters, field, laboratory and contractor organizations) have been designated to coordinate the consistent implementation of the program. Established in 1992, the Technical Standards Managers' Committee (comprised of these Technical Standards Managers) operates under the DOE Technical Standards Program, supports the DOE sites in technical standards activities, facilitates communications on program implementation issues, and participates in establishing program goals and procedures. Publications documenting the voluntary standards adopted by DOE and the personnel participating in the activities of voluntary standards groups are developed by the TSPO; the information in those publications is electronically posted for Internet access.

A new initiative undertaken in FY 1997 involves the recognition of "topical" standards committees within the Department. These committees are composed of subject matter experts in the DOE community and can be used as a focal point for standards activities in specific technical areas. The topical committees provide a forum for all interested DOE parties to join and participate in reviewing technical standards produced by counterpart voluntary standards organizations, address standards application issues within their area of technical expertise, and work to develop Department and Federal positions on standards issues. As of October 1997, 12 DOE topical committees have been recognized by the Technical Standards Program. (These committees are identified on the program Internet address listed at the top of this page).

In summary, DOE continues to take a "pro-active" approach to standards and standards management even as its mission continues to evolve in response to the conclusion of the Cold War and shrinking Congressional appropriations. A number of programs and facilities have shifted their focus from production, research, and/or development to environmental remediation and restoration, where DOE will literally be breaking new ground and setting standards for others to follow. In addition, Department staffing levels are declining to meet Congressional budget constraints. Still, in the face of a changing mission and a reduced workforce, DOE continues to actively use and support the development of voluntary standards to meet its needs. In FY 1997, the number of voluntary standards adopted for use increased to 809 (799 in 1996). In addition, the number of individuals participating in voluntary standards activities has increased to 871 (848 in 1996); however, the number of documented participation in standards developing groups declined to 1540 (1618 in 1996).

Also, DOE (through the TSPO) is continuing its initiative (in response to contacts from voluntary standards organizations on how the Department is meeting P.L. 104-113) to better define "candidate" DOE technical standards for conversion to voluntary standards. We are continuing to work with representatives of the American National Standards Institute's Nuclear Standards Board (ANSI-NSB) on the conversion of selected DOE technical standards to voluntary standards. (Four candidate standards have been identified to date).

In addition, DOE sponsored meetings in October 1996 and July 1997 with representatives of several voluntary standards organizations (ASTM, ASME, ANS, NFPA, ASCE, et al.) as part of a more structured program interface with the voluntary standards community to promote developing new standards that may be needed through those organizations rather than within DOE.

Other highlights of DOE's interaction with voluntary standards bodies include the following:

- In FY 1993, DOE began conducting an annual national workshop promoting the Technical Standards Program and the use of voluntary standards. These workshops featured presentations by standards executives from various voluntary standards bodies and major U.S. companies. Each workshop was attended by approximately 150 standards developers and users. The FY 1997 Technical Standards Program workshop was held on July 8-10, 1997; another workshop is planned for FY 1998.

- In addition to the ANSI-NSB, DOE representatives participate on ANSI's Board of Directors and Executive Standards Council. DOE also participates in a number of international standards groups such as ISO/TC 85, Nuclear Energy, ISO/TC 176, Quality Assurance, and ISO/TC 207, Environmental Management.

Reporting requirements for OMB Circular A-119 (paragraph 10 of proposed revision):

1) The number of voluntary consensus standards bodies in which there is agency participation, as well as the number of agency employees participating.
   - Number of standards bodies: 75
   - Number of agency personnel participating: 871
   - Total number of agency participation: 1540

2) The number of voluntary consensus standards the agency has used since October 1, 1996 (or, as appropriate, those based on the procedures set forth in Section 8 of the proposed revision to the Circular). 809 (adopted for use)

3) Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards (or as outlined under paragraph 7.c(6) of the proposed revision of the Circular. 0

4) An evaluation of the effectiveness of the guidelines in Section 7 of the proposed revision to the Circular and recommendations for any changes.

   Response - The guidance in Section 7 of the proposed revision to OMB Circular A-119 appears to be sufficient in terms of outlining the basic functions and responsibilities of Federal agency standards management and standards participation activities. It allows sufficient latitude for each Federal agency to develop its own approach tailored to specific agency needs, and places the emphasis on outcomes rather than processes.

5) As required by P.L. 104-113, when the agency used government-unique standards in-lieu-of voluntary consensus standards.

   Response - There were no recorded cases in FY 1997 where the Department selected to use an internal standard in-lieu-of an equivalent, existing voluntary standard.

DEPARTMENT OF THE INTERIOR (DOI)

Based on a survey of offices and bureaus, the Department of the Interior's response to your questions is, as follows:

1) a. The number of voluntary consensus standards bodies in which there is agency participation: 38

1) b. The number of agency employees participating: 109

2) The number of voluntary consensus standards the agency has used since October 1, 1996: 205

3) Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards: None

4) An evaluation of the effectiveness of the guidelines in Section 7 of the proposed revision to the Circular and recommendations for any changes: The Department of the Interior has no additional comments on the proposed revision of the Circular beyond those which have already been provided at meetings of the Interagency Committee on Standards Policy.

5) When the agency used government-unique standards in lieu of voluntary consensus standards: None

If you have any questions concerning this response, please call me at (202) 208-4915, email me at Donald_Bieniewicz@ios.doi.gov or fax me at (202) 208-5602.

DEPARTMENT OF JUSTICE (DOJ)

The Department of Justice's Standards Executive, Mary Ellen Condon, Director, Information Management and Security Staff, Justice Management Division, coordinates agency participation in information technology voluntary standards development, and will coordinate future agency reporting requirements covering all technologies. To the extent that standards are identified as falling under the responsibility of the Department of Justice for five-year review pursuant to paragraph 8b.(3) of OMB Circular A-119, the Standards Executive will establish the appropriate procedures.

The voluntary standards issues and decisions of greatest concern to the Department of Justice have been those that relate to antitrust matters. That is why the Antitrust Division has been for many years the Department's primary participant in the Interagency Committee on Standards Policy. The Department continues to hold this interest, and will continue to contribute its views on the antitrust considerations in voluntary standards creation and adoption.

Identification of voluntary standards adopted for the purpose of promoting environmentally sound and energy efficient materials, products, systems, services or practices:

> All standards involved in complying with Public Law 102.486, Executive Orders 12759 and 12845, and Federal IRM Regulation Interim Rule 1 and Bulletin C-35 concerning Energy-Star-qualifying computer equipment.
>
> APCO 25, which promotes radio frequency spectrum efficiency. (More efficient use of radio frequencies is believed to be both environmentally sound and energy efficient.)

DEPARTMENT OF LABOR (DOL)

OSHA Activities in Voluntary Standards

OSHA has 28 employees participating in 102 voluntary consensus standards development committees. These committees are sponsored by ten major standards development organizations:

American National Standards Institute (ANSI);
American Society of Testing Materials (ASTM);
National Fire Protection Association (NFPA);
American Society of Mechanical Engineers (ASME);
American Conference of Governmental Industrial Hygienists (ACGIH).
Institute of Electrical, Electronics Engineers (IEEE)
Wood Machinery Manufacturers Association (WMMA)
National Safety Council (NSC)
Underwriters Laboratories (UL)
National Sanitation Foundation (NSF)

Since October 1, 1996, OSHA has issued one final rule referencing six voluntary consensus standards while participating in these standards development groups.

On July 25, 1997, OSHA published a final rule covering Longshoring and Marine Terminals. The Agency referenced the following national consensus standards:

1. ANSI A14.1-1990 Safety Requirements for Portable Wood Ladders

2. ANSI A14.2-1990 Safety Requirements for Portable Metal Ladders

3. ANSI A14.5-1992 Safety Requirements for Portable Reinforced Plastic Ladders

4. ANSI Z-87.1-1989 Practice for Occupational and Educational Eye and Face Protection

5. ANSI Z-89.1-1986 Personnel Protection-Protective Headwear for Industrial Workers-Requirements

6. ANSI Z-41-1991 American National Standard for Personal Protection-Protective Footwear

OSHA has not adopted any voluntary standards for the purpose of promoting environmentally sound and energy efficient materials, products, systems, services, or practices.

In addition to implementing OMB Circular A-119, OSHA must consider the use of national consensus standards in its standards development programs, since this consideration is required under section 6(b)(8) of the Occupational Safety and Health Act of 1970 (P.L. 91-596). This

section reads as follows: Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard.

MSHA ACTIVITIES

For the past several years, MSHA has been engaged in an ambitious review of its regulations for occupational safety and health in mining. Although this review does not adhere to a 5-year cycle, it is comprehensive in nature.

MSHA frequently uses national consensus standards as the basis for its rulemaking. In some areas such as health, the Agency relies heavily on such standards. Although MSHA limits incorporation by reference of voluntary standards as much as possible, the Agency has often included them in non-mandatory appendices to its rules.

MSHA believes that encouraging the use of voluntary standards prompts the health and safety of miners. We attempt to do this by supporting membership in groups promoting various aspects of occupational health and safety.

The Department of Labor's Standards Executive is Patricia Lattimore, Assistant Secretary for Administration and Management. Her telephone number is (202) 219-9086, and her address is 200 Constitution Avenue, N.W., Room S2203, Washington, D.C. 20210.

DEPARTMENT OF STATE (DOS)

The Department of State has a major interest in standards from a policy perspective, but less direct involvement in the actual development of technical standards, with the important exception as outlined in the following paragraphs discussion the Department's policy role as obligated by international treaty. The Bureau of Economic and Business Affairs (EB) represents the Department of State on the Interagency Committee on Standards Policy (ICSP) and the Government Member Council and the Information Infrastructure Standardization Panel (IISP) and its steering committee of the American National Standards Institute.

Acting as the United States Administration under the treaty obligations found in the Convention of the International Telecommunication Union (ITU), Nairobi, 1982, the Department of State, through its Communications and Information Policy Deputate of the Bureau of Economic and Business Affairs, provides the forum where the United States telecommunications industry, both public and private sectors, develops positions and contributions for presentation at meetings of the three permanent organs of the ITU, responsible for international telecommunications recommendations (voluntary standards). The Department authorizes and/or hosts open public meetings under the Federal Advisory Act, wherein U.S. telecommunications standard-setting positions are established. The Department coordinates, leads, and/or accredits United States delegations to meetings of the International Telecommunication Union's Telecommunications Standardization Sector (ITU-T)*, the Radio Communications Sector (ITU-R)*, the Development Sector (ITU-D), and the Inter-American Telecommunication Commission (CITEL), an organ of the OAS.

More than eighty-five (85) U.S. corporations are paying and participating members of the ITU-T and the ITU-R, more than 30 are associate members of CITEL's permanent consultative committee, under the sponsorship of the State Department. Those entities, along with all interested governmental agencies, including but not limited to the Department of Defense, National Institute of Standards and Technology (NIST), National Telecommunications and Information Administration (NTIA), National Aeronautics and Space Administration (NASA), Federal Communications Commission (FCC), participate and play major roles in the voluntary standard-setting process. Within that process, a great deal of interaction takes place with other organizations involved in telecommunications standard-setting, such as, but not limited to the International Organization for Standardization (ISO), the American National Standards Institute (ANSI), Committee T1 (the ANSI accredited committee for U.S. domestic telecommunications standards). CITEL's committees extend this interaction to a number of Latin American and Caribbean regional organizations as well.

*Formally CCITT and CCIR.

Study Groups and Working parties of these sectors convene international standardization meetings on a frequent basis to develop international voluntary telecommunications standards.

In addition to accrediting and supporting delegations to the ITU and its Standardization Sectors, as well as CITEL, the State Department's Bureau of International Organization Affairs, although it has no direct interaction with voluntary standards bodies, serves as policy overseer and contributors to overall standardization policy within the Economic Commission for Europe (ECE) by ensuring participation by relevant specialized agencies and private sector groups in the deliberations of the ECE's Working Party on Standardization, especially where they have a direct bearing on U.S. commercial interests.

For example, each year the Bureau of International Organization Affairs accredits and funds representatives from the Department of Agriculture, the Department of Commerce, the Department of Transportation, and the National Institute of Standards and Technology and also accredits their industrial representatives to key ECE meetings on standardization policies. These gatherings seek to harmonize standards and/or make recommendations on standardization policies in such areas as trade, transport, agricultural products, motor vehicles, timber and coal to improve industrial efficiency and quality as well as to facilitate international trade in these areas. While the standards developed in the ECE are not officially adopted for use in the United States, they serve as guides for adjusting product design and are widely taken into account in manufacturing plans.

DEPARTMENT OF TRANSPORTATION (DOT)

In response to the request by the Office of Management and Budget for information regarding the Department of Transportation's implementation of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Standards," we respectfully submit this report. The included data represent the 1997 Fiscal Year activities for the department and its agencies.

DOT Participation in Voluntary Standards Organizations

DOT recognizes the importance and the advantages of using voluntary consensus technical standards. The reduction of duplication and waste as well as the maintenance of our competitive edge are goals that DOT strives to achieve. Through its participation in the activities of standards-developing organizations, DOT continues to be on the cutting-edge of transportation-related technological innovations. Additionally, in the international realm, DOT looks to shape the creation of new standards which are adopted by other nations. The Department recognizes, as well, that, when appropriate, incorporation by reference of voluntary consensus technical standards saves the regulatory agencies both time and money.

Seven DOT agencies have reported varying degrees of participation in standards-setting organizations and related activities.

- The total number of DOT employees participating in at least one standards-developing group is two hundred and ninety-two (292).
- The total number of voluntary standards groups in which DOT employees participate is one hundred and thirty-three (133).
- Since October 1, 1996, DOT has adopted fifty-four (54) voluntary standards as a result of agency participation in a standards-developing group.

Bureau of Transportation Statistics (BTS)

Five (5) employees of BTS participate in at least one standards-developing group. These employees participate in four (4) standards-developing groups.

BTS has not adopted any voluntary standards since October 1, 1996.

Federal Aviation Administration (FAA)

This year, FAA did not provide a response, although, based on last year's response, FAA does participate in voluntary standards organizations.

Federal Highway Administration (FHWA)

Sixty (60) employees of FHWA participate in at least one standards-developing group. These employees participate in twenty (20) standards-developing groups.

Since October 1, 1996, FHWA has not adopted any voluntary standards.

Federal Railroad Administration (FRA)

Approximately thirty (30) employees of FRA participate in at least one standards-developing group. These employees participate in nine (9) standards-developing groups.

Federal Transit Administration (FTA)

Ten (10) employees of FTA participate in at least one standards-developing group. These employees participate in eight (8) standards-developing groups.

Since October 1, 1996, FTA has adopted no voluntary standard as a result of agency participation in a standards-developing group.

Maritime Administration (MARAD)

Seven (7) employees of MARAD participate in at least one standards-developing group. These employees participate in five (5) standards-developing groups.

Although MARAD does not write, issue, or enforce shipbuilding regulations or consensus technical standards, it is, nevertheless, wholly engaged in the area of regulation and consensus standards. MARAD's principal role in the regulatory area is that of a facilitator and collaborator with the U.S. Coast Guard in seeking to eliminate

unnecessary regulations which may inhibit U.S. shipbuilding competitiveness in the international marketplace. In the field of consensus technical standards, MARAD, through the National Maritime Research and Education Center (NMREC), is an active player in promoting, sponsoring, developing, and supporting the adoption of consensus technical shipbuilding standards both on the national and international level. For example MARAD has worked with the American Pilots Association (APA) through a Cooperative Agreement and helped co-sponsor a workshop on "Masters Pilot Information Exchange." The workshop brought the industry together to talk about current practices. After the workshop a "Best Practices Summary" was developed as a "standard" to be followed by member piloting organizations of the APA. While not a "standards" group, this organization represents most of the piloting associations in the United States and in effect sets standards for the industry.

National Highway Traffic Safety Administration (NHTSA)

Thirty-four (34) employees of NHTSA participate in at least one standards-developing group. The breakdown is as follows: Twenty-seven (27) employees in the Research and Development Office, two (2) employees in the Office of Defects Investigation, one (1) employee in the Office of International Harmonization, three (3) employees in the Light Duty Vehicle Division, and one (1) employee of the Special Vehicles and Systems Division. These employees participate in five (5) standards-developing groups.

Since October 1, 1996, NHTSA has adopted one (1) voluntary standards as a result of agency participation in a standards developing group. This was Compressed Natural Gas Fuel Containers. NHTSA proposed to amend its requirements for compressed natural gas fuel containers to be consistent with the recent revisions of the ANSI standard.

Office of the Secretary (OST)

No employees of OST participate in standards-developing groups.

Research and Special Programs Administration (RSPA)

Forty-five (45) employees of RSPA participate in at least one standards-developing group. The breakdown is as follows: Twenty-eight (28) employees of the Office of Pipeline Safety, and twelve (12) employees of the Office of Hazardous Materials Safety. These employees participate in thirty-two (40) standards-developing groups.

Since October 1, 1996, RSPA has adopted eleven (11) voluntary standards as a result of agency participation in a standards-developing group.

United States Coast Guard (USCG)

One hundred and one (101) employees of USCG participate in at least one standards-developing group. These employees participate in forty-two (42) standards-developing groups.

Since October 1, 1996, USCG has adopted forty-two (42) voluntary standards as a result of agency participation in a standards-developing group.

The Saint Lawrence Seaway Development Corporation (SLSDC) does not participate in standards-developing bodies. SLSDC does not work with the standards of the type that are examined by the Circular. The operations of the SLSDC are affected by the standards covered by other agencies' regulations such as the USCG.

DOT Agencies participate in the following standards-developing organizations:

The Aluminum Association
American Association for Budget and Program Analysis
American Association of State Highway and Transportation Officials
American Boat and Yacht Council
American Bureau of Shipping
American Concrete Institute
American Defense Preparedness Association
American Gas Association (AGA)
American Institute of Aeronautics and Astronautics (AIAA)
American National Standards Institute (ANSI)
American Petroleum Institute (API)
American Public Transit Association
American Public Works Association-Utility Locating Coordination Committee
American Pyrotechnics Association (APA)
American Railway Bridge and Building Association
American Railway Engineering Association
American Society of Civil Engineers (ASCE)
American Society of Mechanical Engineers (ASME)
American Society of Naval Architects and Marine Engineers
American Society of Naval Engineers
American Society for Nondestructive Testing
American Society for Testing and Materials (ASTM)
American Towing Tank Conference
American Water Works Association
American Welding Society
Association of American Railroads (AAR)
Association of Diving Contractors

Chlorine Institute
Coast Guard Interagency Committee on Waterways Management
Compressed Gas Association (CGA)
Electronics Industry Association
Factory Mutual Research Corporation
Far East Radio Navigation Service
Federal Work Group on Marine Diesel Exhaust Emissions
The Fertilizer Institute (TFI)
Gas Research Institute-Incident Reporting and Trending System
Illuminating Engineering Society of North America
International Association of Drilling Contractors
International Association of Lighthouse Authorities
International Atomic Energy Agency (IAEA)
International Civil Aviation Organization (ICAO)
International Commission of Illumination
International Conference of Building Officials
International Electrotechnical Commission
International Loran Association
International Maritime Association (IMA)
International Omega Technical Commission
International Organization of Standards
International Radio Maritime Committee
International Ship Structure Conference
International Sorbent Committee
International Ship Structure Congress
International Standards Organization (ISO)
Institute of Electrical and Electronics Engineers (IEEE)
Institute of Makers of Explosives (IME)
Institute of Navigation Council
Institute of Traffic Engineers
Instrumentation Society of America
Joint Aeronautical Commander's Group
Manufacturers Standardization Society of the Valve and Fittings Industry, Inc. (MSS)
Marine Spill Response Corporation
Marine Technology Society
National Association of Corrosion Engineers
National Association of Regulatory Utility Commissioner
National Board of Boiler and Pressure Vessel Inspectors
National Cargo Bureau, Inc.
National Committee on International Trade Documentation
National Committee on Uniform Traffic Control Devices (NCUTCD)
National Committee on Uniform Traffic Laws and Ordinances (NCTLO)
National Council on Radiation Protection and Measurements

National Electrical Manufacturers Association
National Fire Protection Association (NFPA)
National Marine Electronics Association
National Marine Manufacturers Association
National Motor Freight Traffic Association
National Sanitation Foundation
National Standards for School Transportation
National Transportation Communications for Intelligent Protocol Joints Standards Group Committee
North American Industrial Classification System (NAICS)
One-call Systems International
Open Group
Open Software Foundation (OSF)
Organization for Economic Cooperation and Development (OECD)
Petroleum Education Council
Pipeline Committee of the Transportation Research Board
Pipeline Research Committee International
Prestressed Concrete Institute
Radio Technical Commission for Aeronautics (RTCA)
Rehabilitation Engineering Society of North America (RESNA)
Society of Automotive Engineers (SAE)
Society of Naval Architects and Marine Engineers (SNAME)
Truck Trailer Manufacturers Association (TTMA)
Underwriters Laboratories, Radio Technical Commission for Maritime Services
U.S. Working Advisory Group 8 for Public Transportation and Emergency Services

Standards Replaced as a Result of the Five-Year Review

The consistent examination of regulations is a policy shared by all of the DOT agencies. RSPA, for example, has replaced 22 standards with voluntary standards as a result of its five-year review cycle. Each of its offices is continually examining its regulations, and nearly every standard adopted has been updated to reflect the most recent edition based on staff participation in standards committee activities. For example the Office of Pipeline Safety is reviewing rulemakings to adopt standards that will substitute for the existing government-unique regulations for aboveground oil storage tanks, corrosion protection procedures and facilities, and computational pipeline monitoring systems. These rulemaking will be completed during the next four to six months. The Office of Hazardous Safety Materials Safety has under review rulemakings that will substitute for the existing government-unique regulations for manufacture, testing, and retesting of cylinders to be used in compressed gas service.

Additionally, the USCG has substituted 3 voluntary standards for government-unique standards in following regulations: (1) National Fire Protection Association (NFPA) 13-1996, Standard for the Installation of Sprinkler Systems, in subpart 34.30, section 76.25-1, subpart 95.30, section

108.430, and subpart 193.30 of Harmonization with International Safety Standards Final Rule (CGD 95-028) (62 FR 5118 - September 30, 1997; (2) National Fire Protection Association (NFPA) 13-1996, Standard for the Installation of Sprinkler Systems, in sections 116.439 and 116.440 of Small Passenger Vessel Inspection and Certification Final Rule (CGD 85-080) (62 FR 51326 - September 30, 1997); and (3) Underwriters laboratories UL 1191, Standards for Components for Personal Flotation Devices, May 16, 1996, in section 164.013-3 of Harmonization with International Safety Standards Final Rule (CGD 95-028) (62 FR 51188 - September 30, 1997).

Finally, while FRA has not yet had the opportunity to replace existing standards, it intends to investigate such possibilities and implement such changes as existing rules are reviewed and revised.

Future Implementation of Circular A-119

Although the revised Circular has not yet been released, the Department of Transportation has already begun its preparations for meeting the expected, new requirements. Individually, the DOT agencies are taking actions appropriate to their legislative mandates. The USCG, for example, has established Headquarters Notice 5420 which keeps track of all committee membership listings, including employee participation with voluntary consensus standards groups. Furthermore, to ensure a timely review of all consensus standards adopted by the USCG, all standards are examined on an ongoing basis.

DOT discussed what changes would have to be made in order to efficiently implement the directives of the revised Circular. Some ideas that are being considered are: a department-wide database of voluntary consensus standards organizations in which DOT employees participate; a statement addressing the Circular which would be added to the text of all final rules; and other suggestions that would facilitate and coordinate the participation in and implementation of Circular A-119.

This year, NHTSA had one instance in which it used a government-unique standard in lieu of a voluntary standard in fiscal 1997 which was Air Bag Warning Label. This label uses yellow as the background color, instead of orange, in accordance with an ANSI standard, and uses a graphic developed by Chrysler Corporation to depict the hazards of being too close to an air bag, instead of the graphic recommended by the ISO. These decisions were based on focus group testing sponsored by the agency which strongly indicated that these unique requirements would be far more effective with respect to safety than the industry standards. The decisions not to use the industry standards were explained in detail in the final rule on this subject.

Additionally, the USCG reported that it used a government-unique standard in lieu of a voluntary consensus standard with respect to the tank level or pressure monitoring devices temporary rule. The rule established minimum performance standards for tank level or pressure monitoring

devices for single-hull tank vessels that carry oil in bulk on cargo. The reason for adopting such a government-unique standard is because, at the present time, there are no existing voluntary standards for tank level or pressure monitoring devices.

DEPARTMENT OF TREASURY (TREASURY)

1) **The number of voluntary consensus standards bodies in which there is agency participation, and the number of agency employees participating;**

The Department participated in ten voluntary consensus standards bodies that accounted for approximately twenty-five employees participating.

2) **The number of voluntary consensus standards the agency has used since October 1, 1996 (or, as appropriate, those based on the procedures set forth in Section 8 of the proposed revision to the Circular);**

The Department has used three voluntary consensus standards since October 1, 1996. Customs continues to support two government-unique standards which are CATAIR and CAMTR. CATAIR is used by the Customs brokerage industry and CAMIR is used by some parties in the transportation sector.

3) **Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards (or as outlined under paragraph 7c(6) of the proposed revision to the Circular);**

No government-unique standards have been substituted by voluntary consensus standards as a result of agency review of existing standards. The maintenance of the government-unique standards within Customs applications, the CATAIR and CAMIR formats, are at the request of the participating industry groups that use those standards.

4) **An evaluation of the effectiveness of the guidelines in Section 7 of the proposed revision to the Circular and recommendations for any changes;**

We believe that the guidelines in Section 7 and the proposed revision to the Circular are effective. Use of voluntary standards facilitates our ability to respond to rapidly changing technology and to meet the needs of the government and the public in a timely manner.

1) The nature and extent of the Department's participation in the development and uses of voluntary consensus standards are as follows:

- **Accredited Standards Committee X12 (ASC X12) on Electronic Data Interchange (EDI)**, accredited by the American National Standards Institute (ANSI): ANSI ASC X12 sets U.S. standards for Electronic Data Interchange, develops U.S. EDI applications and coordinates standards activities with the Pan American Electronic

Data Interchange For Administration, Commerce, and Transport (EDIFACT) Board. The Pan American EDIFACT Board is responsible for setting international standards for EDI.

Three Treasury bureaus' representatives are active voting members of ASC X12. These bureaus are the Internal Revenue Service (IRS), the U.S. Customs Service, and the Financial Management Service (FMS). The Departments' participation enables the representatives to advocate for the completion of standards pertinent to the Department's business needs, and to understand the evolution of these open standards.

Customs chairs Task Group 9 under the Transportation Subcommittee (I) of the ANSI ASC X12 Committee. This group develops and maintains all transaction sets and record segments in the Customs transaction sets.

The FMS representative holds the elected position as Co-Chairs for Task Group 2 (Payments and Invoices) within the ASC X 12 Finance Subcommittee (F). The Finance Subcommittee maintains all financial transaction sets for ANSI ASC X12 that includes payment and collection standards used by FMS.

Two IRS representatives are voting members of ASC X12: one representative is the primary voting member, the other acts as the alternate. Additionally, IRS and Customs play an active role in the **Pan American EDIFACT Board**. A representative from the Departmental Offices/Chief Information Officer's staff member (DO/CIO) serves as the Government Delegate to the Pan American EDIFACT Board.

- The **National Automated Clearing House Association (NACHA)** is the regulatory body for the Automated Clearing House (ACH) Network. NACHA maintains and develops ACH payment standards and oversees policy of ACH Network and various regional ACH associations. FMS follow NACHA rules and uses the ACH Network in disbursement and collection activities for the Federal Government. FMS also participate in various NACHA work groups to review and revise ACH operating procedures.

- Customs continues to participates in the NCBFAA ABI Automation Committee standards development body. This joint Customs/industry committee establishes standards and certification criteria for exchange of data between Customs and automated importers and brokers. Customs has eight official members on this Committee.

- **The Open Group User's Council (formerly X/Open)**: The Open Group is an independent open systems standard setting organization with members worldwide.

The Open Group publishes open systems standards and brands products that are compliant with its standards.

The IRS currently has one representative to the Open Group User's Council, to keep abreast of industry's use of open systems standards.

- **Electronic Messaging Association**: The Electronic Messaging Association is a voluntary association of vendors and users of electronic messaging products and services which influence's industry standards both nationally and internationally. A Treasury's representative serves on the EMA Board of Directors, and is the only representative of a Federal agency to do so. In April of 1997, EMA recognized Treasury as its Messaging User of the Year at its annual conference. This recognition was based on its agency wide and interagency efforts to establish interoperable electronic messaging services based on industry standards.

  A representative from the DO/CIO is a board member. In addition, representatives from the IRS and the Bureau of Alcohol, Tobacco and Firearms (ATF) also participate in this voluntary standard group.

- The U.S. Secret Service (USSS) and DO/CIO participates in a joint government and industry effort developing narrow-band digital land mobile radio standards. This effort is known as Project-25. Project 25 standards are forwarded to the Telecommunications Industry Association (TIA) TR8 Engineering Committee for ballot and later published as TIA/EIA-102 Technical Service Bulletins or Technical Standards. The Department has adopted these voluntary consensus standards for its next generation of land mobile radio systems.

  The DO/CIO representative, representing the Federal Law Enforcement Wireless Users Group (FLEWUG), is a full voting member of the **Project 25 Steering Committee**. Currently, Project-25 has four USSS employees and one DO/CIO employee representing the Department.

- **IEEE's Year 2000 Terminology Study Group of the Portable Applications Standards Committee** addresses the key industry concern over the existence of multiple terms and lexicons that carry varied meanings. IEEE has formed this group to establish a standard to help individuals and organizations in developing Year 2000 solutions. Having a baseline set of terms and definitions that can serve as a foundation for such efforts is vital. With this effort, the IEEE has established test method's and recommended practice group, to provide the framework for detailed planning and execution, of all steps and tasks involved in testing for Year 2000 compliance.

The DO/CIO staff has one active participant on both committees.

The Department's Chief Information Official with agency-wide responsibility for standards activity is:

Mr. James J. Flyzik
Deputy Assistant Secretary
(Information Systems) and
Chief Information Officer
1500 Pennsylvania Avenue, NW
Room 2464
Washington, D.C. 20220

Tel.: (202) 622-1200 Fax: (202) 622-2224

DEPARTMENT OF VETERANS AFFAIRS (VA)

The following information was requested from the Department of Commerce for inclusion in the 1997 Annual Report to the Office of Management and Budget (OMB).

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

We have 26 employees participating in 28 voluntary consensus standards bodies.

2. The number of voluntary consensus standards the agency has used since October 1, 1996 (or, as appropriate, those based on the procedures set forth in section 8 of the proposed revision to the circular).

None

3. Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards (or as outlined under paragraph 7c(6) of the proposed revision to the circular).

None

4. An evaluation of the effectiveness of the guidelines in section 7 of the proposed revision to the circular and commendations for any changes and recommendations for any changes.

The proposed revision to the circular will have no side effects to our present Department goal. We accept and conform to standards developed by the Joint Commission on the Accreditation of Hospitals Organizations (JCAHO) for the VA health care system in order to obtain JCAHO certification of VA health care facilities. Standards as outlined in the accreditation program for hospitals, psychiatric facilities, mental health centers, long-term and hospice programs, ambulatory health care facilities, community nursing homes under accreditation standards (National Fire Protection Association, Life Safety Code requirements, and other building, plumbing, electrical, mechanical, and equipment standards/requirements) continue to be utilized in the regulatory, contractual, and grant determinations executed by the Veterans Health Administration. Standards are benchmarked with both private and public sectors to assure industry compliance, cost-effectiveness and quality control. These national standards have been adopted by industry and are familiar to those in the building profession.

5. As required by Public Law 104-113, when the agency used government-unique standards in lieu of voluntary consensus standards.

None

Appendix B: Independent Agency Reports

U.S. CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

The Consumer Product Safety Act (CPSA), as amended, requires the Commission to defer to issued voluntary standards, rather than promulgate mandatory standards, when the voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with the voluntary standards. In addition, the Commission is required, after any notice or advance notice of proposed rulemaking, to provide technical and administrative assistance to persons or groups who propose to develop or modify an appropriate voluntary standard. Additionally, the Commission is encouraged to provide technical and administrative assistance to groups developing product safety standards and test methods, taking into account Commission resources and priorities.

Since its inception in 1973, the Commission has promoted the development of voluntary product safety standards. Policy statements in support of voluntary standards were published by the CPSC in 1975 and 1978. These policy statements were updated in 1988 (16 U.S.C. 1031), and a staff directive on implementation of portions of these policy statements was promulgated in October 1989.

Since the principles set forth in the revised OMB Circular A-119 Rev. were published, they have been consistently supported by the Commission. The CPSC Voluntary Standards Coordinator also serves as CPSC's Standards Executive for the purpose of implementing OMB Circular A-119 and provides general oversight for staff involvement in existing standards projects including the development of strategies for increasing the level of involvement by the staff in voluntary standards activities. The Voluntary Standards Coordinator provides the Commission with reports on voluntary standards activities as well as provides similar information for the Commission's Annual Report.

The Commission's efforts to enhance voluntary standards development is complemented by the overall Federal policy set forth in the Circular.

The Commission had 22 employees directly participating in 46 voluntary standards development projects during FY 1997. Since October 1, 1996, the Commission has not incorporated in regulations portions of voluntary standards which resulted from agency participation in a standards development group. During FY 1997, there were no voluntary consensus standards that were substituted for government-unique standards as a result of an agency review of existing standards. CPSC involvement in voluntary standards activities was consistent with the "Policy for Federal Participation in Voluntary Consensus Standards Bodies" as set forth in Section 7 of the proposed revision to Circular A-119 Revised. There are no recommendations for changes at this time.

As part of the implementation of the provisions of the Circular the following CPSC representative was appointed the agency Standards Executive:

Mr. Colin B. Church
Voluntary Standards and International
Activities Coordinator
U.S. Consumer Product Safety Commission
Room 702
Washington, D.C. 20207
Tel. 301-504-0554 ext. 2229
Fax. 301-504-0407
E-mail: cchurch@cpsc.gov

The executive establishes agency views on standards issues and decisions through Commission response to staff briefing packages and recommendations. These views are reflected in the Commission's Operating Plan and Budget. Coordinating participation within the Commission and with others in voluntary standards activities is a responsibility of the Voluntary Standards Coordinator. Likewise the Voluntary Standards Coordinator is responsible for meeting reporting requirements applicable to voluntary standards involvement of Commission staff.

U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)

The U.S. Environmental Protection Agency is pleased to submit the following report on the status of the Agency's implementation of the National Technology Transfer and Advancement Act, Sec. 12. (P.L. 104-113) and the current proposed OMB Circular A-119: "Federal Participation in the Development and Use of Voluntary Standards and Conformity Assessment Activities". This submittal provides required information for the Agency's annual report on Standards Policy Activities as outlined in the latest proposed revision to Circular A-119.

In addition, the report will also indicate improvements EPA has undertaken to facilitate the Agency's commitment to effective participation in the development and use of voluntary consensus standards. Examples of some current and future activities illustrate this commitment. The two most significant advancements made in the past year are:

1. Establishment of a procedural mechanism, and a corresponding written guideline, by which rule writers now routinely check adherence to the NTTAA and,

2. Establishment of an electronic data base search mechanism and early alert service by which anyone in the Agency can retrieve current information on existing and proposed voluntary standards.

EPA is in the process of developing an improved internal tracking system for monitoring Agency participation in standards activities and is also providing standards-related training to employees. EPA continues to be an active member of the Interagency Committee on Standards Policy (ICSP) chaired by the National Institute on Standards and Technology (NIST).

ANNUAL REQUIRED INFORMATION

1. ***The number of voluntary consensus standards bodies and conformity assessment bodies in which there is Agency participation and the number of employees participating.***

Approximately 200 EPA employees participate in the following standards bodies:

- The American National Standards Institute (ANSI)
- ANSI / Registrar Accreditation Board Council for ISO 14001
- Registrar Accreditation Board Council for ISO 9000
- NACLA, Laboratory Accreditation
- ASTM, (formerly known as the American Society of Testing and Materials)
- The National Sanitation Foundation, (NSF International)
- The American Society of Quality Control (ASQC)
- The Society of Automotive Engineers (SAE)
- Underwriters Laboratory (UL)
- The International Organization for Standardization (ISO)
- The International Electrotechnical Commission (IEC)

2. The number of voluntary consensus standards the agency has used since October 1, 1996.

While EPA is putting its tracking system in place at the end of FY 1997 and the beginning of FY 1998, the Agency is, nevertheless, able to report that numerous voluntary consensus standards are used in its regulations. We searched EPA's final regulations published in FY 1997 and found the following:

- 16 final rules use, or make reference to, ASTM standards; each rule cites between 1 and 15 ASTM standards each;
- 4 final rules referred to SAE materials (specifications, recommended practices, and papers); each rule cites between 1 and 3 SAE documents;
- 5 final rules cited Standard Methods, each referencing between 1 and 6 standards; these examples normally also cited standards of American Public Health Association, the American Water Works Association, and the Water Environmental Federation;
- 3 final rules cited ISO, with each referencing either 1 or 2 standards;
- 2 final rules used ASME standards; each rule cited between 1 and 6 standards; and
- 1 final rule cited a standard of ASQC.

3. *Identification of voluntary consensus standards that have been substituted for government -unique standards as a result of an agency review of existing standards.*

Reviews are conducted through each media-specific office. While some Offices are in the process of getting trained on voluntary standards and undertaking reviews, the Office of Air and Radiation, Emission Measurement Center (EMC) and the Office of Research and Development, Quality Assurance Division have completed several important reviews and updates in 1996 which resulted in the following:

- EMC, working with ASTM, completed a review of all regulations and updated all ASTM references to current versions. Much of this work required public notification. Citing outdated ASTM standards was, in effect, supporting government-unique standards. This duplication has been eliminated.
- EMC's final revised PS-1 rule incorporated by reference a new Quality Control Document generated by the ASTM D-22 Committee which undertook its work specifically to address the Agency's quality control needs in the area of defining methods for measuring opacity of particulates in stacks.
- EMC and the National Electrical Manufacturers Association successfully partnered with ASTM to produce acceptable, alternative methods for measurements of surface coatings, since EPA's Method 24 did not work well for some applications. The alternative ASTM methods have been published through the EMC procedures documents.

- In ORD's Quality Assurance office, EPA Order 5360.1 is currently in the Agency Directives Clearance Process and invokes the ANSI/ASQC E4-1994 standard as the basis for EPA's quality system. This will further lead to changes in the

extramural agreement regulations pertaining to quality. For example, 40 CFR 30 for non-profit organizations receiving financial assistance has already been revised to require conformance to E4.

4. ***Evaluation of the effectiveness of the guidelines in Section 7 of the proposed revision to the Circular and recommendations for any changes.***

EPA has been an active participant in the admirably open process through which OMB and NIST have developed the revisions to OMB Circular A-119 that are necessary to implement the National Technology Transfer Act. EPA helped lead a Regulatory Agencies Workgroup considering the various drafts of the Circular; the Agency participated in meetings of the Interagency Committee on Standards Policy where features of NTTAA and the draft Circular were discussed; and EPA submitted two sets of written comments during the public comment period. The Agency is in the process of implementing the NTTAA and A-119, as we expect it will be ultimately promulgated.

We are quite satisfied with the draft procedures at the moment. We will, however, continue to coordinate with other agencies through the Regulatory Agencies Workgroup and the ICSP to compare approaches, to identify inconsistencies and problems, and to collaboratively attempt to resolve issues. As a result of this process and, with the benefit of more experience in implementing the Act and Circular, we may suggest potential improvements to A-119.

5. ***As required by P.L. 104-113, report on Agency use of government-unique standards in lieu of voluntary consensus standards.***

As explained elsewhere in this report, EPA is currently in the process of putting in place the procedures necessary to accurately track the consideration and use of voluntary consensus standards in Agency regulations. These procedures will provide for rule writers' insertions of statements about NTTAA implementation into published preambles to regulations. This will allow the Agency to capture examples of, and explanations for, those times when we use government-unique standards in lieu of voluntary consensus standards. For FY 1997, the Agency is not able to report on any instances of these decisions.

OTHER STANDARDS-RELATED ACTIVITIES

Throughout 1996 EPA employees continued to be active participants in several key U.S. Technical Advisory Groups to Committees within the International Organization for Standardization (ISO). These include ISO's Technical Committee 207 for Environmental Management Standards -- the ISO 14000 series of standards, Technical Committee 179 for Quality Management -- the ISO 9000 series and Technical Committee 146 for Air Quality.

The Agency also successfully continued its work in the Organization for Economic Cooperation and Development (OECD),with governments and private sector participants, on the development and implementation of Good Laboratory Practice Guidelines.

PLANS FOR ENHANCEMENTS

One of the most significant developments underway is the establishment of an Agency-wide electronic system which can make use of the National Standards Service Network (NSSN) developed and maintained by ANSI, through cooperative government-private sector funding. The NSSN will allow Agency rule writers to easily and accurately search for national and international voluntary standards. This includes standards that are proposed for development as well as existing, final standards. Through this process, EPA will help ensure that employees are alerted to standards and the opportunity for participation in relevant standards development activities.

In 1998 the Alert Service of the NSSN will be set up and made operational within EPA. In addition to the search capabilities of the NSSN, Agency employees can be altered, via Agency E-mail, to any activity on specific standards of interest. This will enhance the ability of both the standards bodies and the Agency to take advantage of early-as-possible collaboration on areas of critical interest.

RESPONSE TO NIST'S INVITATION TO PROVIDE SUPPLEMENTARY INFORMATION ABOUT NEW AGENCY DIRECTIVES, GUIDELINES OR POLICY STATEMENTS RELATING TO A-119 PRINCIPLES AND OBJECTIVES

EPA is actively engaged in several activities designed to ensure full implementation of the NTTAA and Circular A-119 at the Agency.

A subcommittee of the EPA's intra-Agency Regulatory Steering Committee has convened to develop guidance for the Agency's rule writers. Its first task was the creation of the "Interim Guidance on Rulemaking Requirements of the National Technology Transfer and Advancement Act (NTTAA)." The subcommittee intended this document to provide temporary guidance pending the ultimate promulgation of OMB Circular A-119. Attached is the August 6, 1997, transmittal memorandum along with the "EPA Rule Writer's *Checklist* for Voluntary Consensus Standards." These documents have since been provided to all EPA offices engaged in writing regulations. Briefings about the guidance have been provided within various divisions of the Office of General Counsel and other offices on request.

As a result of this effort, an increasing number of EPA's regulatory documents published in the *Federal Register* contain preamble sections entitled "National Technology Transfer Act." In accordance with the Interim Guidance, these sections summarize the requirements of the

NTTAA; describe the Agency's efforts to identify potentially applicable voluntary consensus standards; identify those standards EPA intends to use in the rule, or explains why the use of particular voluntary consensus standards would be inconsistent with applicable law or otherwise impractical; and, for proposed rules, solicits comments from the public both as to additional voluntary consensus standards the Agency should consider and about EPA's analysis under NTTAA. During FY 1997, there were only three direct references to NTTAA. In FY 1998, we expect a substantial increase in such references.

In an activity related to the use of voluntary consensus standards under NTTAA, the Agency plans to implement a Performance Based Measurement System (PBMS) for environmental monitoring in all its media programs, to the extent feasible. In a *Federal Register* notice signed by the Administrator and published at 62 FR 52098 (October 6, 1997), EPA explained:

> The Agency defines PBMS as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve a criteria for selecting appropriate methods to meet those needs in a cost-effective manner. Where PBMS is implemented, the regulated community would be able to select any appropriate analytical test method for use in complying with EPA regulations. It is EPA's intent that implementation of PBMS have the overall effect of improving data quality and encouraging advancement of analytical technologies. The Agency anticipates proposing amendments to certain of its regulations, as needed, to incorporate PBMS into its regulatory programs.

EPA expects the implementation of PBMS to be consistent with the expanded use of voluntary consensus standards. Where such standards meet the criteria for environmental monitoring set out in programmatic regulations, they may be used by the regulated community. The Agency expects that PBMS will reduce the problems associated with the explicit incorporation into regulations of out-of-date versions of voluntary consensus standards; setting out the criteria for selecting appropriate methods, rather than prescribing particular, dated, methods, should facilitate the use of updated, improved methods.

The subcommittee of the Regulatory Steering Committee is now developing more comprehensive, permanent guidance to implement NTTAA and A-119. Starting with a detailed analysis of the decision-making process that needs to be followed to implement NTTAA, the subcommittee will identify specific elements of the process which are to be documented in regulatory preambles. The comprehensive document will also provide expanded guidance about how to search for potentially applicable voluntary consensus standards; how to decide whether a standard can be used or must be rejected as "impractical" by the Agency; and how to use PBMS. The comprehensive guidance will also address requirements flowing from international agreements related to trade and environment and international harmonization.

Following the development of the comprehensive guidance for rule writers, EPA intends to develop guidance to employees about participating in the standard-setting activities of voluntary consensus standards bodies. This guidance will build on the provisions of A-119 and will, to the extent feasible, be coordinated with other agencies.

Attachment

August 6, 1997

MEMORANDUM

SUBJECT: Interim Guidance on Rulemaking Requirements of the National Technology Transfer and Advancement Act (NTTAA)

FROM: Thomas E. Kelly, Director /s/
Office of Regulatory Management and Information

TO: Regulatory Policy Council (see Addressees)

The National Technology Transfer and Advancement Act (NTTAA) was effective in March 1996 and requires agencies to use "technical standards that are developed or adopted by voluntary consensus standards bodies" to carry out policy objectives or activities. "Technical standards" are "performance-based or design-specific technical specifications and related management systems practices." To encourage uniform Agency-wide compliance with the rule-related aspects of NTTAA, I am asking program offices to immediately begin using the attached interim checklist for all rules under development.

This checklist, prepared by a cross-agency work group, outlines the basic requirements of NTTAA and gives enough guidance to inform and lead a rule writer through those requirements. Bear in mind that the work group that prepared this checklist is also developing a more comprehensive guidance document for rule writers. This latter document will address all of the standards-related considerations for Agency rule-making activities, as well as further clarifying our responsibilities under NTTAA. Among other things, this will include suggested language for rule preambles, additional methods for locating potentially useful standards, and means of evaluating existing standards.

OMB has proposed but not finalized a revision to *Circular A-119, Federal Participation in the Development and Use of Voluntary Standards.* A-119 will provide government-wide interpretations of the NTTAA and our comprehensive guidance will supplement the provisions established by OMB. During the interim period before Agency and OMB guidance is completed, rule writers should rely on the checklist and work with their program office's Regulatory Steering Committee Representative and their OGC representative for additional help.

Because the requirements are applicable now, we must try to implement the Act's requirements as fully as possible, even for regulations in the pipeline, and including those that have already been proposed. For example, if your comment period has already closed for a proposed rule that contains technical standards, you should still check the sources identified in the checklist to identify any potentially applicable voluntary consensus standards. If you do

identify one, or if a commenter has already suggested consideration of a particular voluntary consensus standard, be sure to address it. If you determine that a voluntary consensus standard shows promise for Agency adoption, you should consider issuing a supplemental notice, if practicable. Alternatively, if you decide not to use the standard, explain your reasons in the final rule.

As you may know, the scope of NTTAA goes beyond rule-making considerations. The Act requires Federal agencies to participate in the standards development activities of voluntary consensus standards bodies (such as ASTM) when such participation would be in the public interest and compatible with the Agency's mission, authorities, priorities, and budget resources. This would further the goals of the Agency by facilitating compliance with the rule-making aspect of the Act, complementing our commitment to reach key stakeholders, and potentially reducing the cost and burden of Federal regulation. Such firsthand involvement would also provide an opportunity to influence the outcome of these activities in a manner that meets the Agency's goals and objectives, as well as those of other participants in the process. The officially designated EPA Standards Executive, Pep Fuller of OPPTS, will be providing guidance on Agency participation in the future.

As I mentioned earlier, the comprehensive guidance for rule writers will address other important standards-related regulatory issues. For the sake of expediency and to avoid confusion, these issues were not covered in this interim checklist. The future guidance will more fully explain the rule-making requirements of the NTTAA, and deal with the rule-making implications of several other standards-related topics, as follows:

- The Deputy Administrator's recent decision concerning the implementation of the Performance Based Measurement System (PBMS) in all programs will be relevant to Agency rule writers. This policy will influence the Agency's deliberative process and will affect our consideration of alternative technical standards and approaches. (Each program has been charged with developing an implementation plan.)

- The United States is party to an increasing number of international environmental and trade agreements which explicitly require the use of international standards if they provide an acceptable level of protection. We need to take U.S. obligations under these international agreements into account when we set domestic environmental standards if we are to avoid international legal disputes.

If you have any preliminary questions about these guidelines, you can contact Michael McDavit of my staff at 260-7202, or Craig Annear in OGC at 260-5328.

Attachment

Addressees:
Fred Hansen, Deputy Administrator
Margaret Schneider, OA
Dana Minerva, OW
Mahesh Podar, OW
Cynthia Puskar, OW
Rob Wolcott, OPPE
Susan Wayland, OPPTS
Angela Hofmann, OPPTS
David Doniger, OAR
Robert Brenner, OAR
Richard Wilson, OAR
Tom Eagles, OAR
Barbara Hostage, OSWER
Michael Shapiro, OSWER
Scott Fulton, OGC
Nancy Ketcham-Colwill, OGC
Jim Nelson, OGC
Sylvia Lowrance, OECA
Jon Silberman, OECA
Jay Benforado, Reinvention Team
Shelley Metzenbaum, OROSLR
John Sandy, OARM
Lynne Ross, OCLA
Julie Anderson, OCLA
Karen Brown, OSDBU
Dorothy Patton, ORD
Kevin Teichman, ORD
Elaine Wright, CSI
Stan Laskowski, Region III

cc:
Steering Committee Representatives
Standards Coordinators

EPA RULE WRITER'S *CHECKLIST* FOR VOLUNTARY CONSENSUS STANDARDS

Interim Internal Guidance for Complying with the National Technology Transfer & Advancement Act of 1995 (NTTAA)

1. WHAT IS THE NTTAA?

Section 12 of the National Technology Transfer & Advancement Act of 1995 (Attached) is intended to avoid "re-inventing the wheel". It aims to reduce the costs to the private and public sectors by requiring Federal agencies to draw upon any existing, suitable technical standards used in commerce or industry. To comply with the Act, which went into effect in March 1996, EPA must consider and use "voluntary consensus standards" (VCS's), if available and applicable, when implementing policies and programs, unless doing so would be "inconsistent with applicable law or otherwise impractical". This checklist briefly describes how the NTTAA affects the development of new rules at EPA. OMB must report annually to Congress any decisions by EPA and other agencies to use a government-unique standard in lieu of an existing VCS, along with an explanation.

2. WHAT IS THE PURPOSE OF THIS CHECKLIST?

This checklist serves as interim guidance for rule writers while an Agency work group develops more detailed guidance, and OMB completes the revisions to *Circular A-119, Federal Participation in the Development and Use of Voluntary Standards*. OMB Circular A-119 will provide Government-wide interpretations of the NTTAA. In the absence of OMB guidance and until more detailed Agency guidance is produced, this checklist shall be used in the development of all EPA rules.

3. WHAT IS A VOLUNTARY CONSENSUS STANDARD?

A "voluntary consensus standard" is a technical standard developed or adopted by a legitimate standards-developing organization ("voluntary consensus standards body"). The Act defines "technical standards" as "performance-based or design-specific technical specifications and related management systems practices." According to NTTAA's legislative history, a "technical standard" pertains to "products and processes, such as the size, strength, or technical performance of a product, process or material". A legitimate standards-developing organization must produce standards by consensus and observe the principles of due process, openness, and balance of interests.

Examples of organizations generally regarded as voluntary consensus standards bodies include the American Society for Testing and Materials (ASTM), International Organization for Standardization (ISO), International Electrotechnical Commission (IEC),

American Petroleum Institute (API), National Fire Protection Association (NFPA) and Society of Automotive Engineers (SAE).

The well-known American National Standards Institute (ANSI) evaluates the standards development processes of these bodies and, when requested by one of them, certifies standards meeting the above criteria as American National Standards. Such a designation is an important indicator for determining whether a given standard qualifies as a legitimate voluntary consensus standard.

While you should search for all potentially useful standards, EPA is not required to give even limited deference under NTTAA to a standard which does not qualify as a "voluntary consensus standard." You may seek the advice of OGC in making this determination and in drafting the rationale. If you have any questions, consult with the OGC staff attorney on the rule or contact your Regulatory Steering Committee Representative (see attached list).

4. WHICH RULES ARE LIKELY TO INVOLVE VCS'S?

If your rule establishes a technical standard, like a special method for collecting a water sample, or a new field or laboratory procedure for measuring a chemical parameter, it is very likely that there are existing VCS's that you will need to consider in the development of the regulation.

For the purposes of EPA, the most common, potentially useful VCS's include field and laboratory test methods, sampling protocols and material specifications. Depending on the subject of your rule, however, there may be other less likely types of VCS's which could apply (e.g., quality and environmental management systems, business practices, definitional standards and installation safety codes).

In most cases, rule writers should seek out and consider any and all potentially-applicable VCS's, either domestic or international, which might be used to carry out some or all of the rule's objectives. If your rule, however, does not involve the establishment or modification of technical standards, you have neither an obligation to address the rulemaking requirements of NTTAA nor to discuss the matter in the preamble to your rule.

5. WHERE DO YOU FIND POTENTIAL VCS'S FOR NEW RULES?

- The National Standards System Network (NSSN), a consolidated database maintained by ANSI, provides highlights of technical standards from different standards organizations. The web-site, "http://www.nssn.org", provides basic information about more than 250,000 VCS's from over 600 standards setting bodies. Any on-line user may make simple word search queries. To make your search even simpler, the EPA Standards Network is planning to make "enhanced" NSSN services available Agency-wide in the near future. (Visit the web site for details on the scope of these services.)

- The National Center for Standards and Certification Information, a telephone service provided by the National Institute of Standards and Technology (NIST) at (301)-975-4040, provides free library research on applicable standards.

- Your program office's Standards Coordinator (see attached list) may have other ideas about how to identify standards which may be applicable to your rule.

- Seek public comment on potentially-applicable VCS's during the rule-making process (see below), both during stakeholder outreach and as part of the notice and comment phase for a proposed rule.

6. HOW SHOULD YOU ADDRESS THE NTTAA IN ADVANCE NOTICES OF PROPOSED RULE-MAKING AND PROPOSED RULES?

- Include a brief discussion of NTTAA and its rule-related requirements in the rule's preamble.

- Solicit public comment on the use of VCS's in ANPRMs and NPRMs.

- If you have identified a VCS for possible inclusion in the rule, identify the VCS and explain why EPA is considering using it. Request comment on the Agency's tentative position.

- If you have initially decided not to propose the use of an existing VCS, explain your reasoning. Request comment on the proposed decision.

- Request comments from the public on the existence of VCS's that should be considered for inclusion in your rule.

7. WHAT ARE THE REQUIREMENTS FOR FINAL RULES?

- Include a brief discussion of NTTAA and its rule-related requirements in the rule's preamble.
- Describe your efforts to find potential VCS's (specifically mention any outreach activities that you have conducted with voluntary consensus standards bodies).

- If you elect to use an existing VCS, identify the VCS and any alternatives that you considered and explain the decision. (This is in addition to the basic rulemaking requirement that EPA provide an appropriate explanation for its regulatory decisions.)

- If you elect **not** to use an existing, potentially-applicable VCS in your rule, identify the VCS and explain how the use of it would be inconsistent with applicable law or otherwise impractical.

8. WHERE IN THE PREAMBLE DO YOU PLACE THE NTTAA DISCUSSION

- In your NPRM and FRM, include any detailed NTTAA discussions in a separate section in an appropriate location within the "Supplementary Information" section of the preamble.

- Include summary information at the end of the preamble, in a section titled "National Technology Transfer and Advancement Act", along with the other Regulatory Assessment Requirements. (The summary statements will be extracted for inclusion in the annual report that OMB is required to send to Congress. The Agency work group is developing template language for this section.)

9. HOW DO YOU REFERENCE ADOPTED VCS'S?

- If a VCS was suggested by comment, you should address it in your response to comments section of the preamble and your response to comments document in the docket. A summary explanation must also be in the NTTAA Section.

- Typically, the text of a VCS may not be quoted in a rule. Rather, it must be incorporated by reference. To incorporate a VCS by reference, you must have written approval from the Federal Register Office. At least three weeks prior to signature, initiate a formal request to the Director of the Federal Register for approval to incorporate a voluntary consensus standard by reference. (Attached procedures provide additional information on this topic.)

Attachments:

List of Regulatory Steering Committee Members
List of EPA Standards Coordinators
Copy of the NTTAA, § 12
Copy of Incorporation by Reference Procedures

LIST OF REGULATORY STEERING COMMITTEE MEMBERS

(Alternates in parentheses) (as of 8/1/97)

CHAIR THOMAS KELLY (Paul Lapsley, 260-5480)
Office of Regulatory Management and Information (ORMI)
2136, W1017, 260-4001, FAX: 260-0513

ORD BURNELL VINCENT
Office of Research and Development
8105, W603, 260-0591, FAX 260-6932

OAR TOM EAGLES (Wanda Farrar, 260-5324)
Office of Air and Radiation
6103, W925, 260-5585, FAX: 260-9766

OPPE MARYANN FROEHLICH (Willard Smith, 260-2789)
Office of Policy, Planning and Evaluation
2126, M3202, 260-2789, FAX: 260-0512

OROSLR JIM WIEBER
Office of Regional Operations and State/Local Relations
1502, W346, 260-4462, FAX: 260-2159

OECA AVI GARBOW
Office of Enforcement and Compliance Assurance
2201-A, 202-564-2440, FAX: 501-3842

OARM JUDITH KOONTZ
Office of Administration and Resources Management
3102, M2632D, 260-8608, FAX: 260-9887

OW CYNTHIA PUSKAR
Office of Water
4102, E1027A, 260-8532, FAX: 401-3372

OSWER BARBARA HOSTAGE (Lynn Johnson, 260-4478)
Office of Solid Waste and Emergency Response
5103, SE306K, 260-7979, FAX: 401-1496

OPPTS ANGELA HOFMANN (Patricia A. Johnson, 260-2893)
Office of Prevention, Pesticides and Toxic Substances
7101, E629, 260-2922, FAX: 260-0951

OGC NANCY KETCHAM-COLWILL
Office of General Counsel
2322, W501D, 260-7624, FAX: 260-0586

LIST OF EPA STANDARDS COORDINATORS
(as of July 1997)

OW **Jim Horne**	OECA **Brian Riedel**	OPPTS **Mary McKiel**
OAR **Ken Feith**	OSWER **Dana Arnold**	ORD **Penny Hansen**
OIA **Greg Mertz**	OGC **Craig Annear**	OPPE **Jerry Newsome**
OCEPA **Elaine Koerner**	OARM **David Scott Smith**	
Region 1 **David Guest**	Region 2 **Jehuda Menczel**	Region 3 **Jeff Burke**
Region 4 **David Abbott**	Region 5 **Catherine Allen**	Region 6 **Robert Clark**
Region 7 **Chilton McLaughlin**	Region 8 **David Schaller**	Region 9 **Bonnie Barkett**
Region 10 **Nancy Helm**		

EPA Standards Executive
Pep Fuller (OPPTS)

Public Law 104-113
104th Congress

An Act

To amend the Stevenson-Wydler Technology Innovation Act of 1980 with respect to inventions made under cooperative research and development agreements, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Technology Transfer and Advancement Act of 1995"

* * * * *

SECTION 12. **STANDARDS CONFORMITY.**

(a) USE OF STANDARDS. Section 2(b) of the National Institute of Standards and Technology Act (15 U.S.C. 272(b)) is amended--

(1) in paragraph (2), by striking ", including comparing standards" and all that follows through "Federal Government";

(2) by redesignating paragraphs (3) through (11) as paragraphs (4) through (12), Respectively; and

(3) by inserting after paragraph (2) the following new paragraph:

"(3) to compare standards used in scientific investigations, engineering, manufacturing, commerce, industry, and educational institutions with the standards adopted or recognized by the Federal Government and to coordinate the use by Federal agencies of private sector standards, emphasizing where possible the use of standards developed by private, consensus organizations;".

(b) CONFORMITY ASSESSMENT ACTIVITIES. Section 2(b) of the National Institute of Standards and Technology Act (15 U.S.C. 272(b)) is amended--

(1) by striking "and" at the end of paragraph (11), as so redesignated by subsection (a)(2) of this section;

(2) by striking the period at the end of paragraph (12), as so redesignated by subsection (a)(2) of this section, and inserting in lieu thereof "; and"; and

(3) by adding at the end the following new paragraph:

"(13) to coordinate Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical 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.".

(c) TRANSMITTAL OF PLAN TO CONGRESS. The National Institute of Standards and Technology shall, within 90 days after the date of enactment of this Act, transmit to the Congress a plan for implementing the amendments made by this section.

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

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

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

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

(4) DEFINITION OF TECHNICAL STANDARDS. As used in this subsection, the term "technical standards" means performance-based or design-specific technical specifications and related management systems practices.

program should be spent in support of the goals of the program.

Approved March 7, 1996.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

JAN 12 1995

MEMORANDUM

SUBJECT: Use of Incorporation by Reference as a Mechanism for Shortening Federal Register Notices

FROM: Gerald H. Yamada
Principal Deputy General Counsel

TO: Regulatory Policy Council

We have been asked to provide guidance on the legal requirements that would govern EPA's use of incorporation by reference to reduce the length of Federal Register notices. This memorandum provides that information.

In recent guidance, a copy of which is attached, this office has described the minimum legal requirements for Federal Register preambles of proposed and final rules. In that guidance we indicated that the Administrative Procedure Act (APA) and the procedural; requirements of certain environmental statutes (e.g., the Clean Air Act) would permit EPA to shift much of what we customarily include in Federal Register preambles into the rulemaking dockets accompanying the Federal Register notices. Under that approach, the Federal Register preambles could then include simple references to those accompanying materials and inform the public as to how to access them.

By contrast, "incorporation by reference" (IBR) is a term of art describing a somewhat different procedure with a narrower purpose. IBR is a mechanism for avoiding the task and cost of publishing certain materials in the rule text published in the Federal Register.

The concept of IBR stems from the requirements of the APA codified at 5 U.S.C. Section 552(a)(1). That section requires agencies to publish all substantive rules of general applicability in the Federal Register, and provides that no member of the public may be adversely affected by a matter required to be published in the Federal Register unless that person has actual notice of that matter. Finally, that section provides that matter reasonably available to the affected public

is deemed published in the Federal Register when it is incorporated by reference therein with the approval of the Director of the Federal Register.

Thus, IBR is a mechanism for applying to the regulated community, as a binding legal requirement, material that an agency chooses, for cost or other reasons, not to publish verbatim in the Federal Register. For example, EPA currently employs IBR to avoid publishing in the text of its rules certain test methods issued by independent scientific organizations. The Agency also incorporates by reference into the Code of Federal Regulations the regulatory portions of state submittals that EPA approves into Federal law (e.g., State Implementation Plan (SIP) submittals that EPA approves under the Clean Air Act).

As indicated above, however, the APA directs that an agency's incorporation by reference of any particular material is not effective unless and until the Director of the Federal Register approves it. Moreover, the decision whether to approve an agency's request for the IBR of a particular set of material is guided by, among other things, whether the material is "reasonably available" to the affected public.

The Director of the Federal Register has promulgated regulations governing when she will approve agency requests for IBR. 1 CFR Part 51. The attached summary of those requirements, prepared by the Office of Policy, Planning and Evaluation, includes all of the significant requirements contained in those regulations. As those regulations have been interpreted and applied by the Office of the Federal Register, they substantially restrict the ability of agencies to use IBR as a mechanism to shorten the regulator text to be published in the Federal Register and the Code of Federal Regulations.

Perhaps most significant for EPA's effort to shorten Federal Register notices is the rule's provision that the Director "will assume that a publication produced by the same agency that is seeking its approval is inappropriate for incorporation by reference." 1 CFR 51.7(b). Although the rule goes on to say that a publication produced by the agency may be approved it is meets certain basic requirements and "possesses other unique or highly unusual qualities," the Office of the Federal Register does not typically approve such requests. Thus, for example, we would not be able to shorten published rule text by including in the rule only short references to other rule text residing in the docket for that rulemaking. Rather, we could expect to use IBR primarily in the way EPA already uses it -- e.g., to incorporate state-generated documents like SIP submittals under the Clean Air Act, as well as other independently published materials like test methods issued by the independent scientific organizations.

Please let us know if you would like further guidance on the legal requirements for incorporating materials by reference into the Federal Register.

Attachments

Working Draft 12/8/94

MINIMUM LEGAL REQUIREMENTS FOR FEDERAL REGISTER PREAMBLES OF PROPOSED AND FINAL RULES

This description of minimum legal requirements is a limited exercise, addressing only the legal aspects and not the policy implications of including certain information in Federal Register preambles of proposed and final rules.

For particular rulemakings, many factors need to be considered in determining which material should be included in the Federal Register notice and which should be included in the public docket. OGC should therefore be consulted regarding particular rulemakings. OPPE should be consulted about specific Federal Register publication requirements of the Office of Federal Register; a summary of these requirements accompanies this outline.

PROPOSED RULES

Administrative Procedure Act section 553(b)(3) sets forth certain minimum requirements for Federal Register publication of "general notice of proposed rule making."[4]

Minimum Federal Register Publication Requirements for Proposed Rules

Statement of the time, place, and nature of public rulemaking proceedings.

Reference to the legal authority under which the rule is proposed.

Either the text of the proposal, substance of the proposal, or description of subjects and issues involved.

Description of who may be affected by the regulation.

Description of any additional information relevant to the rulemaking but not included in the Federal Register notice, and how to obtain it, such as public docket access, electronic bulletin board access, and mailing instructions.

Identification of provisions that may be changed in the final rule, solicitation of comment on controversial provisions that may change from proposal to final rule, and how to submit comments.

Description of regulatory requirements imposed by other statutes, such as the Paperwork Reduction Act and the Regulatory Flexibility Act.

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[4]Clean Air Act section 307(d) and TSCA section 411 impose additional requirements on specified rulemakings. OGC should be consulted about requirements specific to these statutes.

Under applicable case law, the notice of proposed rulemaking serves three purposes:

- improve quality of rulemaking by exposing proposed regulations to diverse public comment;
- provide opportunity to be heard and participate meaningfully in rulemaking process; and
- enhance quality of judicial review by giving parties an opportunity to develop evidence I the record.

To ensure adequate notice to the public and to fulfill the purposes of the notice, the Federal Register notice must contain certain minimum information. Additional information must either be published in the Federal Register or be available to the public in an easily accessible location, such as a public docket.[5] Although the information on which the Agency relies and the methodology used to analyze the information must be exposed to public view, the information does not necessary need to be published in the Federal Register, as long as it is easily accessible. Thus, information on which the Agency relies as the basis for a proposed or final rule may be placed in a public docket.

APA section 552(a)(1) and 553(c) require EPA to publish in the Federal Register "substantive rules of general applicability adopted as authorized by law" and to "incorporate in the rules adopted a concise general statement of their basis and purpose."[6]

Minimum Federal Register Publication Requirements for Final Rule

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[5]CAA section 307(d) requires the proposed rule to specify the period available for public comment and to state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The proposal must be "accompanied by" a statement of basis and purpose, which must include a summary of factual data on which the proposed rule is based, the methodology used in obtaining and analyzing the data, and the major legal interpretations and policy considerations underlying the proposed rule. Such data, information and documents must be included in the docket on the date of publication of the proposed rule. We interpret the phrase "accompanied by" to allow contemporaneous placement in the docket of the relevant information.

[6]Similarly, CAA section 307(d) requires the promulgated rule to be "accompanied by" a statement of basis and purpose, an explanation of the reasons for any major changes from the proposal, and a response to each of the significant comments, criticisms, and new information submitted during the public comment period. We interpret the phrases "accompanied by" and "incorporate in" to allow contemporaneous placement of the relevant material in the public docket.

Text of the rule.

Description of statement of basis and purpose and where it is available.

Description of response to comments document and where it is available.

Description of document discussing major changes from proposal and where it is available.

Description of regulatory requirements imposed by other statutes, such as the Paperwork Reduction Act and the Regulatory Flexibility Act [this list may not be complete].

Like notices of proposed rulemaking, Federal Register notices of final rules must contain certain minimum information. Additional information must either be published in the Federal Register or be available to the public in an easily accessible location, such as a public docket.

General questions concerning these requirements should be directed to Judy Tracy, (202) 260-7987. Questions concerning the fulfillment of these requirements in any specific action should be directed to the assigned staff attorney.

INCORPORATION BY REFERENCE (IBR)

"Incorporation by reference" (IBR) is a method of incorporating material into Agency regulations in the CFR by referencing the original document without publishing the full text of the material. In order for the content of the IBR to be federally enforceable, its use must be approved by the Director of the Federal Register. The Director is authorized to decide when an Agency may incorporate material by reference. The Director's office makes it determination on a case-by-case basis after review of the Agency document and materials proposed for incorporation. Material is eligible for incorporation if it:

- Is published data, criteria, standards, specifications, techniques, illustrations, or similar material;
- Is reasonably available to and usable by the class of persons affected by the publication;
- Does not reduce the usefulness of the Federal Register publication system;
- Benefits the Federal Government and members of affected classes; and
- Substantially reduces the volume of material published in the Federal Register.

The Director will not approve an Agency's request to incorporate by reference material produced by that same Agency if that material can be printed using the Federal Register/Code of Federal Regulations printing system. Also, the Director has determined that materials previously published in the Federal Register or in the United States Code are not appropriate for use as IBR. However, new Agency documents can include materials the Agency previously published in the Code of Federal Regulations through the use of a cross-reference.

Statements of incorporation by reference in regulatory text must:

- Include the words "incorporation by reference";
- Identify the standard and/or material to be incorporated, including the title, date, editing, author, and identification number of the publication;
- Contain a statement of availability stating where and how copies may be obtained and examined; and
- Refer to 5 U.S.C. 552(a) or include an approval statement that the Director of the Federal Register approves the incorporation by reference

The preamble in the final rule document must make reference to the IBR in two locations:

1. The DATES caption must include an approval statement that indicates the effective date of the incorporation by reference as approved by the Director of the Federal Register.

2. The List of Subjects in the SUPPLEMENTARY INFORMATION must include the term "incorporation by reference."

The Agency must submit a written request for incorporation by reference approval to the Director of the Federal Register. Although the Office of Federal Register (OFR) encourages submission of requests as far in advance of publication as possible, the request must be submitted no less than 20 working days before the final rule document is submitted to OFR for publication. The OFR does not consider any package for approval that does not include the following:

1. A letter requesting approval of the incorporation;
2. A copy of the material to incorporated; and
3. A copy of the final rule document.

In order to secure IBR approval prior to signature and ensure timely publication, early requests for IBR approval submissions may include an unsigned copy of the rule. The OFR will notify the Agency of its decision to approve or disapprove the request for incorporation by reference

Materials forwarded to OFR must be legible, complete, and contain identifying data including the title date, author, publisher, and identification number of the publication. The OFR stresses that:

- IBR material must be legible. It is considered unacceptable if the copy is either too light or the words are blurred and unclear. The material must be complete and have no part of the text cut off (e.g., hole punched).

- EPA must submit an official version of the material proposed for IBR; it is useful to have title pages or an official document identifying the material as the official version.

- The titles and numbers referencing the IBR material in the rule text must be identified completely and specifically. The OFR provides guidance language in the "Document Drafting Handbook" (see page 38, examples 57 and 58).

- Material should be organized. It is preferable to package it in a binder with tabs if the material is lengthy. The material should be organized in the same order as it is set out in the rule language.

Questions regarding these requirements can be addressed to Vickie Reed of the Regulatory Development Branch (RDB) in OPPE at (202) 260-7204. Further information is also available in the "Document Drafting Handbook," published by the Office of the Federal Register. The Handbook is available by contacting Bridgette Dent in RDB at (202) 260-4333.

FEDERAL COMMUNICATIONS COMMISSION (FCC)

7. The Federal Communications Commission participates in a variety of organizations that develop telecommunications standards. The actual level of participation with each organization varies depending on the need for Commission involvement and importance of the work relative to our objectives. The Commission presently has approximately 44 employees involved in more than 10 standards bodies and approximately 100 sub-groups within these bodies. The Commission uses voluntary standards in several different ways:

   To satisfy industry and user requirements where it appears that mandatory standards are unnecessary. Examples include telephone industry standards for network protocols and interfaces, International Special Committee on Radio Interference (CISPR) standards to control radio emissions from automobiles, Telecommunications Industry Association (TIA) standards for digital cellular radio protocols, and TIA/Tl standards for protocols in the personal communications service.

   To correct problems that might otherwise require regulation. For example, the Commission has strongly encouraged compliance with Electronics Industry Association (EIA) standards on television susceptibility to interference rather than moving swiftly to mandatory regulations. It has worked with the industry and local governments to develop voluntary measurement standards for testing the signal quality of cable systems, and is working with TIA to encourage development and voluntary implementation of a standard for telephone immunity to interference.

   As the basis for mandatory requirements, either by incorporating voluntary standards by reference, or including the normative portion of the standard in the FCC rules. Examples include ANSI measurement procedures for radio noise emitted by digital devices, ANSI/EIA standards on AM broadcast transmission specifications, EIA standards for telephone compatibility with hearing aids, International Telecommunications Union (ITU-R) recommendations on digital selective calling equipment for use in ship and coast marine stations, EIA task-force recommendations on standards for displaying closed-captioning information on television receivers, and an EIA/TIA standard for protection of microwave systems from interference from personal communications systems.

   The Commission continues to increase its use of voluntary standards. In many instances we have chosen not to implement regulations (or more detailed regulations) because adequate voluntary industry standards already exist or are under development. For example, the regulations for Personal Communications

Service do not include transmission protocol standards because industry has voluntarily developed these standards. In other instances, where the adoption of a standard is or may be in the public interest, we have attempted to use voluntary standards whenever possible. For example, we are allowing the industry to establish a "spectrum etiquette" policy for devices operating at millimeter wavelengths and are working with and looking to industry to develop standards for the transmission of digital radio. In addition, the Commission regularly works closely with industry through the negotiated rule making process to resolve technical compatibility issues.

2. The Commission has adopted one voluntary consensus standard since October 1, 1996. Specifically, on December 24, 1996, the Commission adopted the standard for digital television (DTV) broadcast as developed by the Advanced Television Systems Committee (ATSC).

3. No voluntary consensus standards have replaced government-unique standards as result of agency review of existing standards since October 1, 1996.

4. The Commission recognizes the benefits of using voluntary consensus standards when applicable and endeavors to comply with the guidance provided in OMB Circular A-119 and the mandates of P.L. 104-113. The Commission's current standards Executive is:

Richard M. Smith
Chief, Office of Engineering and Technology
Federal Communications Commission
1919 M Street, N.W., MS 1300
Washington, DC 20554
Telephone: (202) 418-2470

The Standards Executive will carry out his responsibilities by:

a. Providing guidance to each of the agency's Commissioners on standards-related issues;

b. monitoring the standards-setting activities of the agency's bureaus and offices, and providing guidance to each one on how its activities relate to the requirements of OMB Circular A-119;

c. producing the reports required by OMB Circular A-119;

d. developing a five-year standards review cycle to be followed by each of the Commission's bureaus and offices that will ensure compliance with OMB Circular A-119.

The Commission's Office of Engineering and Technology, which is under the leadership the Commission's Standards Executive, monitors, participates, and coordinates Commission efforts with respect to on ongoing national and international developments in the standards area. Specifically, the Office of Engineering and Technology's Standards Development Branch is tasked, in part, with coordinating standards activities within the FCC and with participating in and monitoring the work of standards committees. The Commission endeavors to increase its interaction with the private sector in the area of standards development to promote a greater use of voluntary standards where appropriate.

5. The Commission has not used any government-unique standards in lieu of voluntary consensus standards since October 1, 1996.

If you should need further information, please contact David Sylvar of my staff at (202) 418-2424 or via e-mail at *dsylvar@fcc.gov*.

FEDERAL TRADE COMMISSION (FTC)

The Federal Trade Commission does not participate in the development of voluntary consensus standards. The Commission's only contact with voluntary standards organizations is in connection with the enforcement of the Federal Trade Commission Act, which proscribes unfair methods of competition and unfair or deceptive acts or practices affecting commerce. In recent years, Commission staff has conducted several in-depth investigations of standards setting organizations and of participants in standards setting to determine whether they were engaged in unfair methods of competition or unfair or deceptive acts or practices. Based on these investigations, the Commission has filed lawsuits alleging deceptive use of standards against an accredited testing laboratory, the private standards developer that accredited the laboratory, and a product manufacturer. In each case, a settlement was approved by the Commission and the court.

Further, the Federal Trade Commission staff has not actively participated in any standards activities pertinent to OMB Circular A-119 and Commission procurement programs and regulations have not used government-unique standards in lieu of voluntary consensus standards or substituted such standards for government-unique standards.

GENERAL SERVICES ADMINISTRATION (GSA)

1. GSA has 54 employees participating in 100 voluntary consensus standards bodies.

2. GSA has used 4 additional voluntary standards since the 1996 report. Note that one of these was for the purpose of promoting environmentally sound products.

3. No additional voluntary standards have been substituted for government-unique standards during the past year, as a result of the review of existing standards.

4. We have no comments or recommendations for changes concerning the proposed revision to the circular.

5. No government-unique standards are being used in lieu of existing voluntary standards.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

1. The number of voluntary consensus standards bodies in which there is agency participation, as well as the number of agency employees participating (Sec. 9.b.(1)).

In 1997, NASA had 154 employees participating in 47 standards developing domestic and international voluntary consensus standards bodies. This compares with 148 employees participating in 45 organizations last year.

2. The number of voluntary consensus standards the agency has adopted since October 1, 1996 (Sec. 9.b.(2)).

NASA has identified 414 voluntary consensus standards and specifications for potential adoption, based on current use by one or more NASA installations; about 85% of these documents are for commonly used parts and materials. Adoption has been recommended by the Engineering Standards Steering Council and formal adoption is pending approval by the Engineering Management Council and NASA's Standards Executive.

3. Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards (Sec. 9.b.(3)).

In 1997, NASA initiated development of an Agency-wide standards management system to be used for support of Agency missions, and as a basis for reporting use of voluntary consensus standards, replacement of Government standards etc. Although this Agency system is not yet complete, elimination and replacement of Government standards is underway at component field installations. For over three years, the Kennedy Space Center, has had an aggressive program of reviewing all currently used standards and specifications for potential cancellation or replacement with voluntary consensus standards. In the past year, they have canceled and/or superseded 92 government documents with voluntary consensus standards. The NASA Jet Propulsion Laboratory has eliminated 300 internal standards and identified another 100 standards for which voluntary consensus standards are being sought. NASA also participates with the Department of Defense in its Single Process Initiative to eliminate the use of multiple Government specifications at individual facilities for meeting common requirements. As a result of SPI proposals, three NASA Centers, the NASA Goddard Space Flight Center, Lewis Research Center, and the Marshall Space Flight Center have accepted replacement of some 18 Government standards (in the areas of quality, calibration and configuration management) with national and international standards. In the coming year, NASA will consider making these replacements on an Agency-wide basis.

4. An evaluation of the effectiveness of the guidelines in the proposed revision to the Circular and recommendations for any changes (Sec. 9.b.(4)).

OMB Circular A-119 has stimulated a very useful re-examination of standards use in NASA that reinforces internal re-structuring initiatives that will enable more direct cooperation with industry and among NASA Centers. Focusing attention on national and international standards vs. locally developed technical procedures will directly support these goals. Revisions to the Circular that permit selection of a "categorical" or standards management basis for reporting are useful and important for a procurement based agency like NASA; a transaction basis for reporting would have imposed a very burdensome administrative reporting requirement on the Agency.

5. Agency use of government-unique standards in lieu of voluntary consensus standards (Sec. 9.a and 6.a.(1)).

The NASA has chosen a "categorical" (Standards Management System) based approach for reporting use of voluntary consensus standards and elimination of Government standards. That system is still under development and, at present, lists only internally developed NASA Standards.

The NASA Standards currently listed in the management system fall principally in three categories, namely information technology, safety and mission assurance, and engineering. The NASA information technology standards are for internal use only, and specify internal procedures or preferred use of COTS (Commercial off the Shelf) products; they do not duplicate voluntary consensus standards.

The safety and mission assurance standards are either (I) to document corrective procedures in the areas of electronics, which are required on the basis of failures in past space missions, or (ii) to document safety procedures in all areas required for use of NASA space systems such as the Space Shuttle and International Space Station. NASA is now in the process of identifying replacements for those government-unique engineering standards that do not relate directly to safety procedures required for the use of NASA space systems.
The NASA engineering standards, developed more recently, have been established to consolidate internal practices and generally relate to system testing and design practices for payloads to be flown on NASA systems. Until recently, no national or international standards were available in many of the specific areas covered, but Voluntary Consensus Standards bodies are now beginning to address these needs. NASA is participating with industry, plus domestic and international voluntary consensus standard bodies, to identify relevant voluntary consensus standards for possible adoption by NASA, and to develop standards of common interest.. The NASA Standards development activity will continue to consolidate internal practices but will target standards with external application for eventual transition to voluntary consensus standards. The NASA Standards Management System is key to this effort.

In the coming year, the NASA Standards Management System will be completed to permit more complete reporting on other government-unique standards still in use.

6. NASA Implementation of OMB Circular A-119

(a) The NASA Standards Executive is:

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Washington, D.C. 20546-0001
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(b) NASA implements the provisions of OMB Circular A-119 through NASA Policy Directive NPD 8070.6A, "Technical Standards", which was revised in 1997 to reflect pending revisions to OMB Circular A-119. References to the Circular and its provisions have also been added to a new, major policy guideline on "Program and Projects Management" (NASA NPD 7120.5A). NASA NPD 8070.6A establishes the policy and organizational responsibilities for the development, management, and use of technical standards on NASA programs, including the adoption and use of voluntary consensus standards.

(c) NASA NPD 8070.6A delegates to the NASA Marshall Space Flight Center the authority to serve as the NASA Lead Center for Standardization, in support of the NASA Standards Executive. The Lead Center is responsible for developing program initiatives and operating procedures, and administration of the NASA Standards Management System. The Lead Center operates through an Agency-wide Engineering Standards Steering Council which reports to the NASA Standards Executive and the NASA Engineering Management Council, which consists of the senior engineering and safety management officials from each of the NASA Field Centers.

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION (NARA)

The National Archives and Records Administration (NARA) has continued this year to be active in the area of voluntary standards. NARA staff members are active on a number of standards committees. In addition, the agency continues, where possible, to cite voluntary standards in its regulations and procurement documents.

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

A total of eighteen National Archives and Records Administration employees are active on a variety of voluntary consensus standards organizations, committees, and subcommittees either as official NARA representatives or alternates. In addition, a number of other staff review drafts of various standards that may have an impact on our work. The eighteen individuals serve on approximately twenty voluntary standards bodies at the organization, committee, or subcommittee level. This standards work assists in the development of a common set of methods, processes, materials, and products that we, other Federal agencies, and our colleagues in the information and preservation world can share. Moreover, our participation helps foster standards that further our central mission of ensuring, for the citizen and the public servant, for the President and the Congress and the Courts, ready access to essential evidence.

2. The number of voluntary consensus standards the agency has used since October 1, 1996:

The agency currently uses twenty voluntary standards which have been incorporated by reference in our regulations outlined in 36 CFR Chapter 12.

3. Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards:

Although members of NARA staff have actively worked on standards activities during the past year, no voluntary standards were substituted for government-unique standards during the reporting period.

4. An evaluation of the effectiveness of the guidelines in the proposed revision to the Circular and recommendations for any changes:

Responsibility for standards activities shifted to another organization in NARA at the end of the reporting period. Therefore, we were not able to do a careful analysis of proposed revisions to OMB Circular A-119.

5. As required by P.L. 104-113, when the agency used government-unique standards in lieu of voluntary consensus standards.

We are not aware of any government-unique standards used by NARA. The agency actively pursues adoption of voluntary standards. NARA has adopted standards by the American National Standards Institute (ANSI), National Fire Protection Association (NFPA), and the National Information Standard Organization (NISO). However, NARA has just signed an agreement with Department of Defense in which NARA will review the government-wide usefulness of a DoD standard has been established for electronic records-management software. Hopefully successful implementation of this standard throughout the Federal Government will lead to adoption of a voluntary standard.

As previously stated, responsibility for Standards Executive has shifted to the Policy and Communications Staff which is part of the Office of the Archivist. The new Standards Executive is Mary Ann Hadyka, Policy and Communications Staff (NPOL), National Archives and Records Administration, Suite 4100, 8601 Adelphi Road, College Park, Maryland 20740-6001. Telephone: 301-713-7360. Fax: 301-713-7270. E-mail address: maryann.hadyka@arch2.nara.gov

Voluntary standards continue to be important to the work of the National Archives and Records Administration. The agency will continue to provide time and travel support for staff members who contribute to the work of standards organizations.

NATIONAL SCIENCE FOUNDATION (NSF)

1) there are two voluntary consensus standards bodies in which there is agency participation, with three employees participating;

2) the number of voluntary consensus standards the agency has used since October 1, 1996 is zero;

3) the number of voluntary consensus standards that have been substituted for government-unique standards is zero;

4) an evaluation of the effectiveness of the guidelines in Section 7 of the proposed revision of the Circular and recommendations for any changes;

The proposed guidelines allow appropriate agency participation in standards activities. No changes are recommended.

5) the National Science Foundation has not used any government-unique standards in lieu of voluntary consensus standards.

U.S. NUCLEAR REGULATORY COMMISSION (NRC)

The NRC developed and issued a strategic plan for FY 1997 - 2002. The strategic plan establishes a strategic framework that will guide future decision-making and will help the NRC continue to meet its responsibility for protecting public health and safety, promoting the common defense and security, and protecting the environment. This plan includes general goals consistent with the NRC's mission in specific strategic arenas that include nuclear reactor safety and nuclear materials safety. In these two arenas, the strategy is to increase the involvement of licensees and others in the NRC regulatory process consistent with the provisions of Public Law 104-113, "National Technology Transfer and Advancement Act of 1955." NRC will encourage industry to develop codes, standards, and guides that can be endorsed by the NRC and carried out by the industry. In this regard procedures are being developed to further promote the efficiency and effectiveness of the NRC process for implementing P.L. 104-113 and the supporting OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Standards."

Following is the NRC response to the reporting provisions of OMB Circular A-119.

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

   165 NRC staff participate on 16 standards development organizations (SDOs). NRC staff participate on a total of 350 standards writing, consensus, and board level committees.

2) The number of voluntary consensus standards the agency has used since October 1, 1996 (or, as appropriate, those based on the procedures set forth in Section 8 of the proposed revision of the Circular)

   During FY 96, the NRC "incorporated by reference" 2 standards into 1 final NRC regulation, endorsed 15 standards in 8 final regulatory guides, and endorsed 37 standards in 8 draft regulatory guides which were issued for comment. Table 1 identifies these standards, with applicable date, and the specific method of endorsement.

3) Identification of voluntary consensus standards that have been substituted for government-unique standards as a result of an agency review of existing standards (or as outlined under paragraph 7c (6) of the proposed revision to the Circular)

   None.

4) An evaluation of the effectiveness of the guidelines in Section 7 of the proposed revision to the Circular and recommendations for any changes

The policy guidelines provided in Section 7 for using voluntary consensus standards and participating in voluntary consensus standards bodies are generally consistent with longstanding NRC staff practices. The staff believes that these guidelines provide appropriate direction and encouragement for Federal agencies to use voluntary consensus standards, while at the same time providing sufficient flexibility for each agency to make an independent case-by-case determination as to the usability of a particular standard within that agency's scope and responsibility.

5) As required by P.L. 104-113, when the agency used government-unique standards in lieu of voluntary consensus standards

None.

TABLE 1

Standards Endorsed by NRC
October 1, 1996 - September 30, 1997

SDO	Standard Number	Year	Title	Method of Endorsement
ANS	3.4	1996	Medical Certification and Monitoring of personnel Requiring Operator Licenses for Nuclear power plants	RG[7] (draft)
ANS	8.21	1995	Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors	RG (final)
ANS	58.8	1994	Time Response Design Criteria for Safety-Related Operator Actions	RG (draft)
ASME	B&PVC[8] Section XI Subsection IWE	1995 Ed, 1996 Add.	Requirements for Class MC and Metallic Liners of Class CC Components of Light-Water Cooled Plants	Regulation (final)
ASME	B&PVC Section XI Subsection IWL	1995 Ed, 1996 Add.	Requirements for Class CC Concrete Components of Light-Water Cooled Plants	Regulation (final)
ASME	B&PVC Section XI Code Cases	CC[9]	18 code case that address inspection, repair and replacement of nuclear power plant components	RG (draft)
ASME	B&PVC Section III Code Cases	CC[3]	16 code cases that address materials and design for nuclear power plant components	RG (draft)
IEEE	7-4.3.2	1993	Std Criteria for Digital Computers in Safety Systems of NP Gen Stas	RG (final)
IEEE	279	1971	Criteria for Protection Systems for NP Gen Stas	RG (final)

[7]RG: Regulatory Guide. RGs frequently endorse consensus standards. They are issued by the NRC to describe acceptable methods for implementing regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data used by the NRC staff in its review of applications for permits and licenses. RGs are not substitutes for regulations, and compliance with them is not required. Draft RGs are typically issued for 60 - 90 day public comment. Following a review of comments received, the draft RG may be revised and issued final.

[8]B&PVC: Boiler & Pressure Vessel Code

[9]CC: Code cases are new or revised, and have various dates

SDO	Standard Number	Year	Title	Method of Endorsement
IEEE	450	1987	Recommended Practice for Maintenance, Testing, and Replacement of large Lead Storage Batteries for Generating Stations and Substations	RG (final)
IEEE	610.12	1990	IEEE Std Glossary of Software Engineering Terminology	RG (final)
IEEE	729	1983	IEEE Std Glossary of Software Engineering Technology	RG (final)
IEEE	828	1990	IEEE Std for Software Configuration Management Plans	RG (final)
IEEE	829	1983	IEEE Std for Software Test Documentation	RG (final)
IEEE	830	1993	IEEE Recommended Practice for Software Reqs Specs	RG (final)
IEEE	610L12	1990	IEEE Standard Glossary of Software Eng Terminology	RG (final)
IEEE	1008	1987	IEEE Std for Software Unit Testing	RG (final)
IEEE	1012	1986	IEEE Std for Software Verification and Validation Plans	RG (final)
IEEE	1028	1988	IEEE Std for Software Review and Audits	RG (final)
IEEE	1042	1987	IEEE Guide to Software Configuration Management	RG (final)
IEEE	1074	1991	IEEE Std for Developing Software Life Cycle Processes	RG (final)
ISA	S67.04	1994	Setpoints for Nuclear Safety-Related Instrumentation	RG (draft)

U.S. OFFICE OF CONSUMER AFFAIRS (OCA)

STANDARDS EXECUTIVE: Howard Seltzer, Director for Policy
(202) 565-0051
Fax: (202) 565-0065
Email: hseltzer@os.dhhs.gov

1) USOCA participates in 4 voluntary standards bodies through one agency employee, as follows:

American National Standards Institute
Member, Board of Directors
Member, Consumer Interest Council
Member, International Affairs Committee

ASTM
Member, Committee F15 Executive Committee

International Organization for Standardization (ISO)
Consumer Policy Council (COPOLCO)
Representative to the Ad Hoc Advisory Group on Privacy

Underwriters Laboratory
Member, Consumer Advisory Council

2) N/A.

3) N/A

4) As USOCA's mission relates entirely to consumer advocacy and consumer policy analysis, it is too early to judge what effect, if any, the revisions to the Circular will have on consumers.

Appendix C: Charter of the Interagency Committee on Standards Policy

DEPARTMENT OF COMMERCE

CHARTER
of the
Interagency Committee on Standards Policy

ESTABLISHMENT

1. The Interagency Committee on Standards Policy (herein after referred to as the Committee) is established to advise the Secretary of Commerce and the heads of other Federal agencies in matters relating to standards policy.

2. The Committee fulfills the mandates set out in paragraph 8.a.2 of the Office of Management and Budget (OMB) Circular No. A-119, "Federal Participation in the Development and Use of Voluntary Standards," in its revision of October 20, 1993.

3. The Committee reports to the Secretary of Commerce through the Director of the National Institute of Standards and Technology.

PURPOSE

The purpose of the Committee is to ensure effective participation by the Federal Government in domestic and international standards activities and to promote the adherence to uniform policies by Federal agencies in the development and use of standards. Well-considered Federal policies reflecting the public interest can expedite the development and adoption of standards that stimulate competition, promote innovation, and protect the public safety and welfare. The establishment and application of appropriate standards for the characteristics or performance of goods, processes, and services can contribute significantly to national and international prosperity, economic growth, and public health and safety. The establishment of such standards can also further national goals for environmentally sound and energy efficient materials, products, systems, services, or practices. Heightened national and international awareness of the importance of standards activities, as reflected by enactment of the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113, signed into law March 7, 1996), and recommendations presented in the National Research Council's report "Standards, Conformity Assessment, and Trade into the 21st Century" (National Academy Press, 1995) call for the Committee to intensify its efforts to identify the broad roles and appropriate interactions of agencies in exercising the Government's authority.

OBJECTIVE

The objective of the Committee shall be to promote effective and consistent standards policies in furtherance of U.S. domestic and foreign goals and, to this end, to foster cooperative participation by the Federal Government and U.S. industry and other private organizations in

standards activities, including the related activities of product testing, quality system registration, certification, and accreditation programs.

FUNCTIONS

1. As appropriate, the Committee shall gather, analyze, and maintain current information about standards, product testing, quality system registration, accreditation and certification, and related regulations, rules, policies, and activities:

   (a) conducted within or established by Federal agencies;
   (b) conducted by private domestic and foreign national standards bodies and by regional and international private and intergovernmental organizations engaged in such programs; and
   (c) pertaining to the relationships among agencies of the Federal Government with industry and the various national, regional, and international organizations engaged in such programs.

2. On the basis of such information and when appropriate with respect to the activities named in paragraph one above, the Committee shall make recommendations to the Secretary of Commerce to:

   (a) strengthen coordination of the standards-related policies and activities among the Federal agencies;
   (b) improve the efficiency within the Federal Government of standardization efforts with the U.S. private sector, as well as with regional and international organizations, both private and governmental;
   (c) promote standards-related policies, including directory of personnel participating in standards activities, within the Federal Government consistent with statutory obligations in regard to interactions with non-federal government organizations;
   (d) ensure effective representation of the Federal Government at significant regional and international standards-related meetings and conferences;
   (e) promote the use of internationally acceptable standards and related activities with a view to increasing trade and economic integration and development;
   (f) monitor U.S. technical obligations as a signatory to the World Trade Organization, the U.S.-Canada Free Trade Agreement, the North American Free Trade Agreement, and other treaties encompassing standards-related trade issues;
   (g) encourage the development of agency strategic plans for managing and monitoring use of voluntary standards and participation in standards-related activities;
   (h) promote the use of standards that serve national goals related to increased use of the metric system of measurement and environmentally sound and energy efficient materials, products, systems, services, and practices; and
   (I) assess and improve the adequacy of such agency plans and activities.

MEMBERSHIP

1. Together with the Department of Commerce the following agencies constitute the membership of the Committee:

Department of Agriculture
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of the Interior
Department of Justice
Department of Labor
Department of State
Department of Transportation
Department of the Treasury
Department of Veterans Affairs
Office of Consumer Affairs
Consumer Product Safety Commission
Environmental Protection Agency
Federal Communications Commission
Federal Emergency Management Agency
Federal Trade Commission
General Services Administration
International Trade Commission
Office of Management and Budget
National Aeronautics and Space Administration
National Archives and Records Administration
National Communications Systems (Dept. of Defense)
(non-voting member)
National Science Foundation
Nuclear Regulatory Commission
U.S. Agency for International Development
U.S. Government Printing Office (legislative liaison -
non-voting member)
U.S. Postal Service
Office of the U.S. Trade Representative

The head of each member agency shall ensure representation by a responsible high level policy official (Senior Executive Service or higher) who serves as the agency representative on the Committee. Such agency representative shall also serve as the "Standards Executive"

as defined in section 8.b.2 of OMB Circular No. A-119. Appointments to the Committee shall be for an indefinite term.

2. Agency representatives may designate alternates of equivalent senior status to serve in their absence.

3. Experts from organizations within the member agency may be designated by agency representatives to serve on task groups established by the Committee.

4. Other Federal agencies may become members of the Committee upon application to or invitation by the Secretary of Commerce.

ADMINISTRATIVE PROVISIONS

1. The Director of the National Institute of Standards and Technology (NIST) or the Director's designee shall chair the Committee.

2. NIST shall provide administrative arrangements for the Committee including secretarial services, calling of meetings, arranging for a meeting place, and preparation of an agenda, discussion material, and reports.

3. The Committee shall meet at least three times each year. Other meetings may be called at the discretion of the Chair or at the written request of five (5) members of the Committee.

4. The Committee may establish task groups as appropriate.

5. Attendance at Committee meetings by at least one half of the designated members of the Committee shall constitute a quorum. Decisions internal to the Committee's operations, such as formation of a task group, shall be made by a majority of those present and voting. Voting on Committee business and proposals shall be limited to designated agency members. Decisions concerning Committee recommendations to the Secretary of Commerce on governmental policy or other matters set out in paragraph two of the section entitled "Functions" shall require ratification by two-thirds of the members present and voting. Dissenting positions of the decision may be made a matter of record. The Chair shall not vote except in the case of a tie vote.

6. The annual cost of operating the Committee is estimated at $31,000 (with overhead) which includes 0.20 staff year for staff support.

7. The Committee shall submit an annual report to the Secretary of Commerce so that the Secretary may satisfy the reporting requirements set forth in OMB Circular No. A-119, as applicable to the Secretary, and in P.L. 104-113, as applicable to the head of each agency. Each such report shall also summarize the Committee's activity during the period covered

and shall include a listing of all recommendations formulated by the Committee during that period.

DURATION

The need and mission of the Committee shall be reexamined three years after the date of this Charter to determine the need for the Committee's continuation.

/signed/
Secretary of Commerce

Dated: October 29, 1997

Appendix D: Membership of the Interagency Committee on Standards Policy

Interagency Committee on Standards Policy Members - FY 97

AGENCY MEMBER	REPRESENTATIVE
Agency for International Development, U. S. (USAID)	Mr. James Murphy Deputy Director, Office of Procurement 13000 Pennsylvania Ave Washington, DC 20523-7900 Phone: 202-712-0610 Fax: 202-216-3395
Agriculture, Deparment of (USDA)	Ms. Anne F. Thomson Reed Acting Chief Information Officer Room 416-W Jamie L. Whitten Federal Building 1400 Independence Avenue, SW Washington, DC 20250-7603 Phone: 202-720-8833 Fax: 202-720-1031
Commerce, Department of	Dr. Belinda L. Collins Director, Office of Standards Services National Institute of Standards and Technology Building 820, Room 282 Gaithersburg, MD 20899 Phone: 301-975-4000 Fax: 301-963-2871 Email: belinda.collins@nist.gov
Consumer Affairs, Office of (OCA)	Mr. Howard Seltzer Director for Policy 808 17th Street NW Washington, DC 20006 Phone: 202-565-0051 Fax: 202-565-0065 Email: hseltzer@os.dhhs.gov
Consumer Product Safety Commission (CPSC)	Mr. Colin B. Church Voluntary Stnds & International Activities Coordinator 4340 East-West Highway Room 604-C Bethesda, MD 20207 Phone: 301-504-0554 x 2229 Fax: 301-504-0407 Email: cchurch@cpsc.gov
Alternate:	Ms. Jacquie Elder Room 702 Bethesda, MD 20207 Phone: 301-504-0554 x 2254 Fax: 301-504-0407

Defense, Department of (DOD)

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Federal Communications Commission (FCC)

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Federal Trade Commission (FTC)

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General Services Administrations (GSA)

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International Trade Commission (ITC)	Mr. Stephen A. McLaughlin Acting Director, Office of Administration Room 212 500 E Street, SW Washington, DC 20436 Phone: 202-205-3131 Fax: 202-205-2034
Justice, Department of (DOJ)	Ms. Mary Ellen Condon Director, Information Management and Security Staff Justice Management Division Suite 850 WCTR Washington, DC 20530 Phone: 202-514-4292 Fax: 202-514-1534 Email: condonma@justice.doj.gov
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Labor, Department of (DOL)	Ms. Patricia Lattimore Assistant Secretary for Administration and Management Room S 2203 200 Constitution Avenue, NW Washington, DC 20210 Phone: 202-219-9086 Fax: 202-219-1270 Email: plattimo@dol.gov
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National Archives and Records Administration (NARA)	Mr. Reynolds Cahoon Assistant Archivist for Policy and Info. Resources Mgt. Services National Archives at College Park 8601 Adelphi Road College Park, MD 20740-6001 Phone: 301-713-6730 Fax: 301-713-6497
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State, Department of (STATE)	Mr. Earl S. Barbely Director for Telecommunications and Information Standards Room 5820 Washington, DC 20520 Phone: 202-647-0197 Fax: 202-647-7407
Transportation, Department of (DOT)	Mr. Frank Turpin Director of International Harmonization National Highway Traffic Safety Administration 400 Seventh Street, SW Suite 5220 Washington, DC 20590 Phone: 202-366-2114 Fax: 202-366-2106
Treasury, Department of (Treasury)	Mr. James J. Flyzik Deputy Assistant Secretary (Information Systems) & Chief Information Officer 1500 Pennsylvania Avenue, NW Room 2464 Washington, DC 20220 Phone: 202-622-1200 Fax: 202-622-2224 Email: jim.flyzik@cio.treas.gov
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U. S. Trade Representative (USTR)	Ms. Suzanne Troje Director, Technical Trade Barriers Washington, DC 20508 Phone: 202-395-9444 Fax: 202-395-5674
Veterans Affairs, Department of (VA)	Mr. Gary J. Krump Deputy Asst Secretary for Acquisition & Materiel Management (90) 810 Vermont Avenue, NW Washington, DC 20420 Phone: 202-273-6029 Fax: 202-273-6163 Email: krugar@mail.va.gov

Appendix E: List of NIST Publications Related to P.L. 104-113

Publications on Standards and Conformity Assessment Activities

Office of Standards Services
National Institute of Standards and Technology
Gaithersburg, Maryland 20899

o TBT Agreement Activities of the National Institute of Standards and Technology

This annual report describes the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) activities conducted by NIST. NIST receives notifications of proposed foreign technical regulations related to trade, responds to inquiries on proposed technical regulations, participates in various bilateral and multilateral standards-related trade discussions, and respond to inquiries on the existence, source and availability of standards and standards-related information.

o The National Technology Transfer and Advancement Act - Plan for Implementation (NISTIR 5967)

The National Technology Transfer and Advancement Act (P.L. 104-113) gives NIST responsibility to coordinate standards and conformity assessment activities with other Federal agencies, state and local governments, and with the private sector. Congress required NIST to submit a plan for implementing the coordination activities. Specific activities in strategic standards management, responsiveness to international trade concerns, greater use of voluntary standards, and conformity assessment procedures are described. Responsibilities of governments, standards developers, and private sector interests are outlined, as are a number of specific tasks.

o Standards Setting in the European Union - Standards Organizations and Officials in EU Standards Activities (NIST SP 891, 1997 Edition)

The guide is designed to help U.S. manufacturers, exporters, and other interested persons in locating contact points for important information on the development of standards and conformity assessment issues. The report includes a history of the role of standards in the European Union (EU) and the latest information on the EU's harmonization directives for implementing the "New Approach" and the "Global Approach" for harmonizing technical regulations and standards to reduce barriers to trade.

o ABC's of the U.S. Conformity Assessment System (NISTIR 6014)

This report is designed to provide the reader with an introduction to conformity assessment and information on how the various conformity assessment activities are interlinked. It highlights some of the field's more important aspects and serves as background for using available documents and services.

o Profiles of National Standards-Related Activities (NIST SP912)

This directory describes the metrology, standardization, testing and quality (MSTQ) activities of more than 70 countries. Each entry includes basic data on the country's economy and trade; agencies and institutions responsible for metrology and calibration, standards development, testing, product certification, quality and environmental system registration and accreditation; and key contacts and information sources. Entries are formatted to facilitate access to specific information. An introductory section provides general information on development of the directory and an overview of world-wise MSTQ activities.

o Report on the Open Forum on Establishment of the National Council for Laboratory Accreditation (NACLA) at the National Institute of Standards and Technology January 7, 1997 (NISTIR 6008)

The forum was jointly sponsored by NIST, ACIL (formerly the American Council of Independent Laboratories), and the American National Standards Institute (ANSI). It was attended by more than 300 representatives from private industry and the government. The purpose of the Forum was to discuss a proposal to establish the National Council for Laboratory Accreditation (NACLA), which would be a cooperative partnership between the public and private sectors designed to provide a national infrastructure for laboratory accreditation in the United States.

o Examination of Laboratory Accreditation Programs in the United States and the Potential Role for a National Laboratory Accreditation System (NIST GCR 97-714)

This report presents an initial study of existing U.S. laboratory accreditation programs, with a focus on government programs, particularly at the Federal level. The study was conducted in two phases: Phase I established categories of existing laboratory accreditation programs in the Federal government, at the state and local level, and in the private sector. Phase II compared technical standards used by five Federal government laboratory accreditation programs with general standards for laboratory accreditation established by ISO.

o Using Voluntary Standards in the Federal Government (NISTIR 6086)

This report is a compilation of presentations given at a NIST-sponsored conference held on September 8, 1997 to foster better understanding among Federal agencies of the private sector standardization process. The conference took place as part of a major effort by NIST to implement the National Technology Transfer and Advancement Act which gives NIST responsibility to coordinate standards and conformity assessment activities with other Federal agencies, state and local governments, and with the private sector.

o The U.S. Certification System from a Government Perspective (NISTIR 6077)

This report is designed to provide the reader with an introduction to the U.S. certification system from a governmental perspective. It highlights some of the relationships that exist between federal and state agencies and the private sector and discusses some of the history and philosophy behind the U.S. system.

Breitenberg, Maureen, Conformity Assessment, ASTM Standardization News, Nov. 1997. This article defines the term, highlights the importance of conformity assessment in maintaining the economic competitiveness of U.S. industry, and explains the relationship between standardization and conformity assessment.

USDA

United States
Department of
Agriculture

Office of the Chief
Information Officer

1400 Independence
Avenue SW

Washington, DC
20250

TAB C

AUG 28 1998

Ms. Virginia Huth
Information Policy Branch
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C.

Dear Ms. Huth:

Attached is a Report on the Department of Agriculture's implementation during fiscal year 1997 of Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards."

Because this is a delayed report, we send it directly to you, as was agreed in phone conversations between you and Dr. Ron Garbin of my staff, and with the agreement of Dr. Collins at the Department of Commerce. Thank you for agreeing to receive the submission at this time.

If you have questions, please contact Ron Garbin at (202) 720-8026.

Sincerely,

Anne F. Thomson Reed
Chief Information Officer

Enclosures

Tab C-2

DEPARTMENT OF AGRICULTURE
Annual Agency Report on Circular A-119 Compliance
1997

The following information was prepared for the National Institute of Standards and Technology (NIST) by the Department of Agriculture (USDA) as required annually under Office of Management and Budget Circular A-119, "Federal Participation in the Development and Use of Voluntary Standards."

BACKGROUND

In the Department of Agriculture, the Standards Executive serves also as the Chief Information Officer (CIO), a position established in August 1996. This has made the Office of the CIO (OCIO) the coordinating organization within USDA for reporting on A-119 activities. The present report was compiled, however, only after a delay.

METHOD

To prepare this report, OCIO sought information from USDA Agency Heads. The CIO requested accounts of A-119 activities, and for information on the number of agency employees engaged in at least one standards-developing group; the resulting number of voluntary standards therefore adopted since the previous year; and the number of government-unique standards adopted during fiscal 1997, together in each such instance with some explanation of why such a standard was chosen in lieu of a voluntary consensus standard. To facilitate responses, OCIO also placed telephone calls to selected agency members to determine, where possible, if at least no change had occurred in the agency's information for FY 1996.

DEPARTMENTAL VIEWS

The reorganization of USDA in late 1994, the effect of ITMRA, and the advent of a CIO have shifted emphasis from information technology (IT) to examination of fundamental factors like mission, prior identification of program needs, management strategies, and the making of decisions. In this broader context, USDA still sees IT infrastructure as a key to comprehensive progress. Standards, IT and otherwise, will play a part. Neither of these things is primary; each is subordinate to agency programs and must support them. We understand that this point of view accords completely with Circular A-119.

USDA PARTICIPATION BY FUNCTIONAL AREA

Natural Resources and Environment

Natural Resources Conservation Service (NRCS) has an Engineering mission to provide quality engineering products to its customers. Many of its employees have participated in organizations for the development of voluntary standards.

This year the agency reports that at least three of its members participate in the Open Geographic Information Systems (GIS) Consortium, a public/private partnership operating through a nonprofit entity, and one that focuses on GIS's. The report indicates that the Consortium has done some work in the area of standards, especially regarding standards to facilitate the interoperability of geographic information systems. These standards may become de facto standards for the GIS industry, or possibly ones that the GIS industry agrees to adopt.

NRCS has at least five people involved with the Federal Geographic Data Committee, which has a focus on geospatial data. They are cited as having done some work in the area of geospatial data standards, seeking to attain commonality among the federal agencies to facilitate geospatial data sharing. However, this committee is composed primarily, perhaps entirely, of federal agency representatives.

For FY 1996, NRCS had reported employees working with several committees within the American Society for Testing and Materials (ASTM). The Society develops standards on materials, products, systems, and services. These ASTM standards have not replaced existing conservation practices adopted by NRCS; but NRCS has used many ASTM standards as reference specifications, and cited them as guidance for many design and construction activities throughout the whole range of NRCS conservation programs. The present report has no information on the extent of participation during FY 1997.

Through fiscal 1996, NRCS employees were involved in developing industry specifications within the American Society of Agricultural Engineers (ASAE). Although the practice standards or specifications developed through ASAE have not been adopted for use with the NRCS workload, much of the agricultural community applies these specifications for construction and for provision of quality products.

In previous years NRCS members took part in developing industry voluntary standards with the American Concrete Institute (ACI). No further information is available for FY 1997 at this time.

Although none of the above standards developed with NRCS involvement had in FY 1996 yet replaced the agency's existing practice standards or specifications, NRCS said it was moving toward their adoption. For FY 1997 NRCS provides no information on this. The report for FY 1998 will have to address it.

Farm and Foreign Agricultural Services

Farm Service Agency indicated that in FY 1997 no interactions or activities occurred under Circular A-119.

Research, Education, and Economics

Neither the Agricultural Research Service, nor the Cooperative State Research, Education, and Extension Service, nor the National Agricultural Statistics Service reported interactions with voluntary standards bodies. The Economic Research Service (ERS) did report such interactions.

During FY 1997, ERS participated in or followed consensus standards for seven standards. These activities involved twelve employees. There has been no substitution of voluntary consensus standards for government-unique standards in response to agency reviews, nor any use of government-unique standards in lieu of voluntary standards.

Three ERS analysts participated on technical advisory teams associated with the creation of the North American Industry Classification System (NAICS). The analysts participated on both the Agriculture, Forestry, Fishing and Hunting and the Manufacturing sector teams. The NAICS creates a common industry classification system to replace the current individual systems of Canada, Mexico, and the United States. Common industry definitions for collecting and publishing data and information on both inputs and outputs will improve inter-country measuring of productivity, unit labor costs, and the capital intensity of production, estimating employment-output relationships, constructing input-output tables, and other uses that imply the analysis of production relationships in the economy.

ERS has one analyst who maintains contact with the Conservation Technology Information Center (CTIC) and attends its annual meeting. CTIC periodically coordinates the definition and standards for crop residue management systems. Various crop residue management systems used to reduce wind and water erosion are often part of farm conservation plans that must be implemented by farmers to be eligible for most Federal Farm Program benefits. USDA agencies, including NRCS, ERS, and CSREES, along with representatives from other natural resource organizations and private industry establish criteria for different classes of crop residue management. These criteria are used in surveys conducted by CTIC to measure the adoption of conservation tillage. The criteria are also applied to USDA's Agricultural Resource Management Study to analyze economic and environmental effects of alternative crop residue management systems.

ERS has one analyst who was a cooperator on an EPA Environmental Stewardship Program (PESP) project, completed last year, that developed draft voluntary standards for potato Integrated Pest Management (IPM). The steps for building the national definition included developing a comprehensive listing of State-level potato IPM practices, making a tentative rating of the practices in terms of their value in an IPM program, and conducting an

extensive review of the draft definition. State Extension IPM specialists and commodity associations provided information on State-level potato pest management practices, and the rating system was based on the University of Massachusetts "Partners with Nature" IPM certification system model. The draft IPM definition was reviewed by soliciting comments from EPA, land-grant university IPM specialists, food processors and commodity associations, chemical industries and other input suppliers, environmental groups and others.

ERS has one analyst who participated in the Current Research Information System (CRIS) enhancement effort. The CRIS Enhancement group was charged with evaluating and improving the CRIS system, which is used to classify all publicly-funded agricultural research. A national advisory steering committee guided the effort, and included representatives from major science and agricultural foundations, government agencies, Congressional staff, and university cooperators. Members of the Working Group and Task Groups included USDA personal and representatives from the State Agricultural Experiment Station system and the Land Grant Universities. Accomplishments included revising the current classification structure to more accurately and efficiently capture the research of USDA and its partners. An implementation team has begun work to execute the recommendations of the enhancement effort.

ERS has one analyst who participates in the USDA Ecological Risk Assessment Working Group, charged by the Secretary to develop standards and guidelines for USDA program managers to follow in conducting risk assessments for their programs. Activity involves working with representatives from other USDA agencies to define terms and develop practical guidelines to assist program managers.

ERS analysts monitor materials released by the Farm Financial Standards Council for developments in the measurement of financial indicators for farm businesses. FFSC standards are used in the development of questionnaires and in preparing summary financial statements connected with farm financial performance.

ERS analysts interact with the American Agricultural Economics Association Commodity Costs and Returns Accounting Task Force. The Task Force published its report on July 20, 1998, establishing standards for university, government, non-profit institute, private sector and other analysts to consider when developing estimates of agricultural commodity costs and returns. ERS has always sought consensus with the American Agricultural Economics Association and the agricultural economics profession in measuring costs and returns.

Marketing and Regulatory Programs

The Agricultural Marketing Service (AMS) reports that 20 employees participated in 8 national voluntary consensus standards bodies, and 17 employees participated in 17 international voluntary consensus standards bodies.

Since October 1, 1996, the agency has used the following voluntary consensus standards:

Agreement on the International Carriage of Perishable Foodstuffs and the Special Equipment to be Used for Such Carriage; Certification Standards of the American Association of Seed Certifying Agencies; Codex Alimentarius International Grade Standards; Universal Cotton Standards Agreement; Analytical Standards of the American National Standards Institute (ANSI); Test Standards of the American Society for Testing and Materials; International Meat Purchase Specifications (IMPS). In addition, AMS, at the request from and with the full participation of the industry, has developed and currently uses 584 grade and classification standards that are generally recognized by the industry for use in the marketing of 230 agricultural commodities. While developed and maintained by AMS, these standards were created in response to a need expressed by industry for uniform standards that could be recognized and certified to nationwide. The usage of these standards by the industry is voluntary.

The American Dairy Products Institute has published a series of milk and dry milk standards that are usually referenced when USDA certification is not requested by the buyer or seller. These standards are based on the USDA standards and contain basically the same requirements as the U.S. Grade Standards. We see no reason to adopt these standards because they are the same as those of USDA and the majority of the industry utilizes USDA certification services, recognizing the value of official certification.

The IMPS mentioned above are voluntary standards for meat cuts and meat products for the U.S. livestock and meat industry.

ANSI and ASTM standards are used for testing and analysis required to provide AMS certification activities.

AMS believes the guidelines in Section 7 are reasonable and effective, and recommends they be adopted.

As noted above, AMS has developed numerous grade standards and classifications in response to requests from industry. They do not view these standards and classifications as government-unique since they were developed with full consultation and participation of the industry and their usage by the industry is voluntary. AMS uses government-unique specifications for purchases of some commodities for distribution to the School Lunch Program and other domestic feeding programs when voluntary consensus standards do not meet the nutritional or program requirements of the USDA programs.

National Appeals Division

Under the mandate of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354), the Secretary's Memorandum No. 1010, of October 20, 1994 created the National Appeals Division (NAD). The Act consolidated the appellate functions and staffs of several former agencies (Agricultural Stabilization and Conservation Service, Farmers Home Administration, Federal Crop Insurance Corporation,

Soil Conservation Service) to provide for independent hearings and reviews of adverse agency decisions. NAD assumed transfer of employees previously assigned to appeal functions in their former agencies. On December 29, 1995 were published interim final regulations governing NAD appeals. On May 14, 1996, the Secretary approved NAD's organizational structure.

In last year's Report, NAD declared that a number of NAD employees belong to certain National or State professional organizations founded for the general purpose of educating, and improving the adjudication of cases, but asserted also that NAD's statutory appeal process cannot properly depend on voluntary standards. To this year's Report NAD had no response.

Assistant Secretary for Administration

From the Office of Procurement and Property Management (OPPM), one staff member participates on one standards setting body. Since October 1, 1996, one set of standards is used. The organization stated that no prior standards were used by OPPM for procurement which involved electronic commerce. Nor did OPPM comment on the effectiveness of guidelines in Section 7 of the proposed revision to Circular A-119.

Office of the Chief Information Officer

A member of the OCIO continues to take part on a Subcommittee of the Electrical Industries Association/Telecommunications Industry Association (EIA/TIA). The Subcommittee deals with Commercial and Residential Building Cabling Systems, and functions under the EIA/TIA Engineering Committee on User Premises Telecommunications Requirements. The Subcommittee meets quarterly and, afterward, information from the sessions circulates to relevant parties in the Department.

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-0001

September 25, 1998

Ms. Virginia A. Huth
Office of Management and Budget
Office of Information and Regulatory Affairs
NEOB, Room 10236
Washington, DC 20503

RE: Annual Report to the Office of Management and Budget on the Implementation of OMB Circular A-119; October 1, 1996 through September 30, 1997

Dear Virginia:

In response to your request, enclosed is the supplementary information from the Department of Health and Human Services regarding the five government - unique standards that the Office of Cosmetics and Colors used in lieu of voluntary consensus standards.

Sincerely,

Belinda L. Collins, Ph.D.
Director, Office of Standards Services
Technology Services

Enclosure

NIST

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date September 3, 1998

From Acting Director, Office of Cosmetics and Colors, HFS-100

Subject OMB Annual Standards Report - update

To John Gordon, Executive Operations Staff, HFS-22

This is in response to your request of September 1, 1998 for additional information on the 5 government unique standards that the Office of Cosmetics and Colors (OCAC) uses in lieu of voluntary consensus standards in the certification of color additives, as reported in our memorandum of November 18. 1997.

OCAC uses 5 government-unique standards in lieu of voluntary consensus standards in the certification of color additives. For all of these standards, the voluntary consensus standard methods are based on old technology and determine impurities found in frequently certified color additives. The Color Certification Program developed and uses government unique standards in lieu of these voluntary consensus standards because the government unique standards utilize newer, more accurate and more cost-effective technology. A search of all available standards is routinely done before developing a new standard.

The voluntary consensus standards, and their replacement standards are:

1. AOAC Official Method 981.13
   Cresidine Sulfonic Acid, Schaeffer's Salt, 4,4'(Diazo-amino)bis(5-methoxy-2-methyl-benzenesulfonic Acid), and 6,6'-Oxybis(2-naphthalenesulfonic Acid) in FD&C Red No. 40

   Liquid Chromatographic Method - Final Action 1982

   The voluntary consensus standard uses ion exchange LC with gradient elution and determines 4 sulfonated impurities in FD&C Red No. 40; the replacement government unique standard uses reversed phase HPLC with gradient elution and determines 7 sulfonated impurities in FD&C Red No. 40.

2. AOAC Official Method 982.28
Intermediates and Reaction By-Products in FD&C Yellow No. 5

Liquid Chromatographic Method - Final Action 1983

The voluntary consensus standard uses ion exchange LC with gradient elution and determines 5 sulfonated impurities in FD&C Yellow No. 5; the replacement government unique standard uses reversed phase HPLC with gradient elution and determines 7 sulfonated impurities in FD&C Yellow No. 5.

3. AOAC Official Method 980.24
Sulfanilic Acid, Schaeffer's Salt, 4,4'-(Diazoamino)-dibenzene-sulfonic Acid and 6,6'-Oxybis(2-Naphthalene Sulfonic Acid) in FD&C Yellow No. 6

Liquid Chromatographic Method - Final Action 1981

The voluntary consensus standard uses ion exchange LC with gradient elution and determines 4 sulfonated impurities in FD&C Yellow No. 6; the replacement government unique standard is a reversed phase HPLC method with gradient elution that determines 6 sulfonated impurities in FD&C Yellow No. 6.

4a. AOAC Official Method 947.12
Lead in Color Additives (Applicable to colors not containing Ca, Ba, or Sr)

4b. AOAC Official Method 948.24
Lead in Color Additives (Applicable to Al Lakes)

4c. AOAC Official Method 948.25
Lead in Color Additives (Applicable to Ca, Ba and Sr lakes)

The replacement government unique standard for Methods 947.12, 947.24 and 928.25) is an X-ray fluorescence spectrometry method that determines lead in all color additives.

5. AOAC Official Method 950.79
Chlorides in water-Soluble Color Additives

Potentiometric titration with silver nitrate - final action 1981.

The voluntary consensus standard is still used as a confirmatory method; however the government unique standard, which uses an automated ion chromatograph, is routinely used for chloride analyses.

John E. Bailey, Ph.D.

cc: HFS-100 (Bailey)
HFS-105 (Decker, Barrows)
HFS-106 (Richfield-Fratz)
HFS-125 (Dennis)
HFS-126 (Bell)

Drafted:HFS-125:DADennis:9/3/98
Init:HFS-106:NRichfield-Fratz:9/3/98
F/T:9/3/98

United States
Office of Government Ethics
1201 New York Avenue, NW., Suite 500
Washington, DC 20005-3917

August 10, 1998

Beth Nolan
Deputy Assistant Attorney General
Office of Legal Counsel
U.S. Department of Justice
Washington, DC 20530

Dear Ms. Nolan:

I recently met with representatives of the Office of Management and Budget (OMB) and the Department of Commerce to discuss their concerns about impediments to Federal employees participating in the activities of private voluntary standards organizations. One of the issues discussed at the meeting was whether the enclosed language from the National Technology Transfer and Advancement Act of 1995 (Act), Pub. L. No. 104-113, § 12(d)(2), 110 Stat. 775, provides the requisite statutory authority, as discussed in your November 19, 1996 memorandum, to permit employees to serve as officers or directors of outside standards bodies in their official capacities.

The legislative history of the Act describes the importance of developing standards appropriate to rapidly changing technology, and acknowledges that Federal agencies should be major participants in the United States standards system. H.R. Rep. No. 104-390, at 24 (1995), *reprinted in* 1996 U.S.C.C.A.N. (110 Stat.) 493, 510. It details a recommendation made by the National Research Council, in a March 1995, report which recommended that Congress amend the National Institute of Standards and Technology's (NIST) organic act to "clarify NIST's lead role in the implementation of a government-wide policy of phasing out the use of federally-developed standards wherever possible, in favor of standards developed by private sector, consensus standards organizations, with input from affected agencies." *Id.* Congress adopted this recommendation, as reflected in section 12 of the Act. The Report of the House Science Committee states that section 12 "will have the effect of assisting agencies in focusing their attention on the need to work with these voluntary consensus standards bodies, whenever and wherever appropriate." H.R. Rep. No. 104-390, at 25 (1995), *reprinted in* 1996 U.S.C.C.A.N. (110 Stat.) 493, 512.

The Act also codified existing policies in OMB Circular A-119, dated October 20, 1993, which required Federal agencies to adopt and use standards, developed by voluntary consensus standards bodies, and to work closely with these organizations to ensure that developed standards are consistent with agency needs. Revised OMB Circular A-119, also enclosed, was published in the Federal

Register on Thursday, February 19, 1998, and replaced the previous Circular No. A-119, to make the terminology consistent with the Act, and to provide other guidance consistent with the Act. Question 7 of the Circular sets forth guidance with respect to participation of agency personnel in voluntary consensus standards bodies. More specifically, it addresses issues on authorization to participate and limitations on participation.

In order to provide definitive guidance to OMB and other agencies, I am interested in your views on whether the Act provides sufficient authority for employees to serve, consistent with the requirements of 18 U.S.C. § 208, as officers or directors of standards organizations. In discussing this issue with members of your staff, I understood that your office's preliminary view was that, notwithstanding the prohibition in § 208(a), section 12 of the Act would authorize employees to serve as officers or directors of voluntary standards bodies, if participating in setting the standards were an integral part of the duties of officers or directors of the particular organization. As I understand it, however, performing only the administrative duties of officer or director would not be authorized by the Act.

Finally, the OMB and Commerce employees with whom I met mentioned that some agencies appeared to be concerned that employees were barred by § 208 from serving in an official capacity as Chairpersons of working committees or subcommittees of the standards organizations. I explained that, to the extent that those positions do not impose a fiduciary responsibility on employees serving in them, or do not create an employer-employee relationship, the prohibition of § 208 does not apply. Please let me know if you disagree with this conclusion.

Thank you for reviewing this matter. Please let me know if any additional information is necessary.

Sincerely,

Marilyn L. Glynn
General Counsel

Enclosures

U.S. Department of Justice

Office of Legal Counsel

VIA FAX

Office of the Deputy Assistant Attorney General — *Washington, D.C. 20530*

August 24, 1998

MEMORANDUM FOR MARILYN L. GLYNN
GENERAL COUNSEL
OFFICE OF GOVERNMENT ETHICS

From: Beth Nolan
Deputy Assistant Attorney General

Subject: Application of 18 U.S.C. § 208 to Service on Boards of Standard-Setting Organizations

This responds to your request of August 10, 1998 for our opinion whether, absent a waiver, 18 U.S.C. § 208 would forbid employees of the executive branch from serving, in their official capacities, as members of the boards of private voluntary standards organizations. We believe that, to the extent necessary to permit the federal employees to take part in the standard- setting activities, § 208 does not bar such service.

Section 208 prohibits an officer or employee from taking part as a government official in any "particular matter" in which he or she has a financial interest. The statute imputes to the employee the financial interests of certain other persons and entities, including an "organization in which he is serving as officer, director, trustee, general partner or employee." 18 U.S.C. § 208(a). In an earlier opinion, we observed that when an employee is acting in his or her official capacity as a director or officer of an outside entity, the work for that entity necessarily entails official action affecting the entity's financial interests. We therefore concluded that, under 18 U.S.C. § 208, the "broad prohibition against conflicts of interest within the federal government would prevent a government employee from serving on the board of directors of an outside organization in his or her official capacity, in the absence of: (1) statutory authority or a release of fiduciary obligations by the organization that might eliminate the conflict of interest, or (2) a waiver of the requirements of § 208(a), pursuant to 18 U.S.C. § 208(b)." Memorandum for Howard M. Shapiro, General Counsel, Federal Bureau of Investigation, from Beth Nolan, Deputy Assistant Attorney General, Office of Legal Counsel, Re: Service on the Board of Directors of Non-Federal Entities by Bureau Personnel in Their Official Capacities, at 1 (Nov. 19, 1996) ("FBI Opinion"). In particular, if "Congress has authorized the service by statute, the official 'serves . . . in an ex officio rather than personal capacity,' owes a duty only to the United States, and does not violate section 208." Memorandum for J. Virgil Mattingly, Jr., General Counsel, Federal Reserve Board, from Richard L. Shiffrin, Deputy Assistant Attorney General, Office of Legal Counsel, Re: Directorships of Bank for International Settlements, at 2 (May 6, 1997) (citation omitted) ("FRB Opinion").

Since the FBI Opinion, we have had a number of occasions to consider whether particular statutes confer authority for service on outside boards. We have found such authority in a range of circumstances. Sometimes the statutes expressly contemplated official service on an outside board. See Memorandum for Files, from Daniel Koffsky, Re: Foundations and Commissions Under Fulbright Program (Oct. 24, 1997); Memorandum for Files, from Daniel Koffsky, Re: Service on Outside Board (Feb. 27, 1998) (United States-India Fund for Cultural, Educational, and Scientific Cooperation). In another instance, the statute was less explicit, but we found the authority because service on the outside entity was a means by which the United States negotiated with foreign governments and "the breadth of the President's power [in that area] counsels a broad reading of congressional authorization for particular means by which the power may be exercised." FRB Opinion at 3 (citation omitted). In one other instance, where the agency largely conducts its operations in secret and had to create the outside entity to preserve the secrecy of its work, we concluded that the outside organization was, for relevant purposes, a part of the federal government, and thus no conflict existed.

As this experience in applying the principles of the FBI Opinion has made clear, Congress has enacted a variety of arrangements contemplating, directly or indirectly, that federal employees will participate in outside organizations, including by serving on their boards, and it would frustrate these arrangements if such service were considered a disqualifying "director[ship]" under 18 U.S.C. § 208. See Memorandum for Kenneth R. Schmalzbach, Assistant General Counsel, Department of the Treasury, Re: Applicability of 18 U.S.C. § 208 to the Proposed Appointment of the Deputy Assistant Secretary to the Board of the College Construction Loan Insurance Association, at 3 (June 22, 1994) (categories of service considered outside statute). We believe that there are circumstances in which statutory authority for service on an outside board can be found even though Congress has not expressly addressed that service. When Congress has specifically provided for participation in outside organizations and such participation, to carry out the statutory purposes, entails service on a board, statutory authorization may be inferred.

Here, Congress has provided that, in general, federal agencies and departments "shall use technical standards that are developed or adopted by voluntary consensus standards bodies" and, in carrying out this requirement, "shall consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate with such bodies in the development of technical standards." Pub. L. No. 104-113, § 12(d)(1) & (2), 110 Stat. 775, 783 (1996), 15 U.S.C. § 272 note (emphasis added). As the legislative history explains, Congress desired and anticipated that federal agencies would "work closely" with voluntary standard-setting organizations, that these organizations would "include active government participation," and that agencies would "work with these voluntary consensus standards bodies, whenever and wherever appropriate." H. R. Rep. 104-390, at 15, 25 (1995). When the board of an outside organization plays an integral role in the process of setting standards, it would therefore frustrate the statute to forbid federal employees from being on the board. They could not then take the "active" role that Congress mandated. To carry out the statute, therefore, employees may serve on these outside

boards without running afoul of 18 U.S.C. § 208, if the boards are engaged in the standard-setting activities in which Congress directed federal agencies to participate.

To be sure, § 208 allows for waivers when the employee's "interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect," 18 U.S.C. § 208(b)(1), and thus a conclusion that § 208 generally would bar employees from serving on standard-setting bodies in their official capacities would not necessarily have prevented the service in every instance. Nevertheless, reliance on the waiver procedure would not be consonant with the statutory scheme here. Congress itself has resolved the possible conflict between duties to the organization and duties to the United States, at least to the extent that the criminal prohibition may be at issue.

We would not reach the same conclusion, however, if the board of an organization had only administrative responsibilities and was not directly involved in standard-setting. In that event, the congressional direction to "participate . . . in the development of technical standards" would not apply. Consequently, in accordance with the FBI Opinion, § 208 would bar the service on the board, absent a waiver or an effective release from fiduciary duty.

Finally, you also ask us to confirm your view that an employee's service in an official capacity as the chair of a working committee or subcommittee of a standard-setting organization, to the extent the position imposes no fiduciary duty and creates no employer-employee relationship, would not implicate 18 U.S.C. § 208. We agree that service in such a position would not itself trigger the statute. Indeed, we are far from certain that a position other than one specified in § 208 – "officer, director, trustee, general partner or employee" – could be the basis for imputing an organization's financial interest to the employee, even if that other position created a fiduciary duty to the organization. In any event, the positions you describe would not give rise to an imputed disqualification.

Please let us know if we may be of further assistance.