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April 28, 2012

Hon. Cass R. Sunstein, Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
Washington, DC 20503

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

Re: American Nuclear Society Response to 77 *Federal Register* 19357, OMB Circular A-119

Dear Mr. Sunstein:

The American Nuclear Society (ANS) is a standards development organization (SDO) accredited under the rules of the American National Standards Institute (ANSI). ANS standards are widely used within the United States as well as internationally in all areas of nuclear science and technology. ANS considers the issues raised by the subject *Federal Register* notice to be of vital importance to its interests, and appreciates the opportunity to provide comments and responses to the questions and issues raised in the notice (see reference above).

ANS's interest in "Federal Participation in the Development and Use of Voluntary Consensus Standards (VCSs) and in Conformity Assessment Activities" lies primarily in the implementation of the policies contained therein by the Nuclear Regulatory Commission (NRC), the Department of Energy (DOE), the Defense Nuclear Facilities Standards Board (DNFSB), and the National Institute of Standards and Technology (NIST), which is part of the Department of Commerce (DOC). The NRC has regulatory authority over most of the technical areas addressed by ANS; consequently, ANS's closest interaction is with the NRC. ANS's comments related to Federal agency activities requested in the notice should be viewed as applying primarily to the NRC and somewhat less so with the DOE, NIST and the DNFSB. The questions posed in the subject notice are restated in Attachment A, followed by the ANS response.

Thank you for the opportunity to comment on this precedence-setting issue.

Respectfully submitted,

A handwritten signature in cursive script that reads "Eric P. Loewen".

Eric P. Loewen, Ph.D.  
President  
American Nuclear Society

Cc: Robert C. Fine, JD, CAE, ANS Executive Director  
Donald J. Spellman, ANS Standards Board Chair  
Rick Michal, Director, ANS Scientific Publications and Standards

**Agency Implementation of Circular A-119 in Rulemakings.**

*Question 1: Are Federal agencies generally following the guidance set out in the Circular and providing an adequate explanation of how they considered standards and conformity assessment-related issues in the preambles to rulemakings?*

**ANS Response**

Federal agencies are generally following the guidance set out in the Circular but they apply considerable latitude in their interpretation and implementation of consensus standards requirements (e.g., “shall”), recommendations (e.g., “should”), and permissions (e.g., “may”). Those interpretations are apparently based upon the agencies “policy objectives or activities” and are possibly influenced by governmental administrative goals that are at variance with the literal language and direction within the standards. Due to perceived legitimacy, those variant interpretations have been embedded in agency regulations and positions without utilizing the formal consensus standard processes for making inquiries regarding the differences between regulatory language and consensus standard language.

This issue of variances may provide a viable justification for a conformity assessment program related to the use of consensus standards within Federal agencies.

**Standardization Activities.**

*Question 2: What factors should agencies use in evaluating whether to use voluntary non-consensus standards in regulation, procurement solicitations, or other non-regulatory uses? OMB also invites comments on the respective roles of voluntary consensus standards vs. voluntary non-consensus standards for agency responsibilities in rulemaking, procurement, and other activities.*

**ANS Response**

The NRC uses non-consensus standards, reports, and other documents generated by national organizations such as the Electric Power Research Institute, the Institute for Nuclear Power Operations, the Boiling Water Reactor/Pressurized Water Reactor Owner’s Groups, and the Nuclear Energy Institute as part of stakeholder inputs relative to new or modified regulatory requirements.

While ANS is fully supportive of the work done by these organizations, and of the Federal use of such information, ANS strongly recommends that the OMB upgrade A-119 to stress that the consideration of national and international Voluntary Consensus Standards (VCSs) be given the highest priority and be given more weight in supporting regulatory activities where other non-consensus documents are available on a particular technical subject area. ANS believes that such a distinction is required to realize the policy objectives of Public Law 104-113. Precedence accorded to VCSs is justified by the broader representation of industry users in development and approval of consensus standards and in the rigorous certification process imposed by ANSI. This consensus process provides a more objective stance in the generation of standards.

In an update to A-119, agencies should be required to verify and document that there are non-consensus standards relevant to the regulation, procurement solicitation, or other non-regulatory uses under consideration. Agencies should also ensure that the intended use of specific non-consensus standards does not infringe upon other non-consensus standards nor

provide an unfair economic advantage to the developer of the non-consensus standard. Any regulation that requires the use of non-consensus standards should limit that use to the protection of "...public health, welfare, safety, and the environment while promoting economic growth, innovation, competitiveness, and job creation."

### **Conformity Assessment.**

*Question 3: In conjunction with NIST's efforts to update its conformity assessment guidance, should a supplement to Circular A-119 be issued to set out relevant principles on conformity assessment? If so, what issues should be addressed in such a supplement?*

#### **ANS Response**

Should new guidance be developed on conformity assessment, it should require, consistent with 15CFR 287, "Federal Guidance on Conformity Assessment," that the principles involved with conformity assessment be employed to help ensure more productive use of the increasingly limited Federal resources available to conduct conformity assessment activities. For instance, much of what the NRC does on a day-to-day basis is captured under the definition of conformity assessment, but the agency currently employs only a few of the range of tools that are potentially available. If a supplement to Circular A-119 on conformity assessment is pursued, it should require the agencies to consider the full range of options to reduce costs of compliance to regulatory requirements (as well as reducing regulatory uncertainty) while fulfilling their legitimate regulatory, procurement, or other mission-related objectives. The supplement should provide ready reference to a potential listing of the range of tools available.

Where an agency proposes to interpret or implement variations to literal words/meanings of consensus standards they should be required to provide substantive bases and technical cost-benefit analysis for implementing the variations. Such cost-benefit analyses should include the examination of the risk regarding the protection of the public health, welfare, and safety relative to publicly accepted risks and other societal cost-benefits.

Supplemental guidance should also include the use of U.S. consensus SDOs such as ANS, ASTM International, etc., in the proposal, review, and approval of the use or reference of international standards, guides, and glossaries (i.e., the International Electrotechnical Commission, the International Atomic Energy Agency, the International Organization of Standardization) in regulations. The U.S. has a history of not engaging international consensus standards development groups to seek harmonization of national and international requirements.

Agencies should be required to select consensus standards for use from national SDOs that meet the consensus requirements of ANSI first, before selecting from business specific non-consensus standards producers.

For circumstances where an agency identifies a need for a new standard, the agency should be required to notify the relevant SDO to describe the need and to volunteer to assist in the development of a consensus standard. In the event that there is no relevant consensus SDO, the agency should notify the relevant industry of the perceived need and invite public and industry participation in the development of a non-consensus standard.

## **Protection of Copyright Associated With Standards.**

*Question 4: Is lack of access to standards incorporated by reference in regulations an issue for commenters responding to a request for public comment in rulemaking or for stakeholders that require access to such standards?*

### **ANS Response**

ANS is not aware of any issues related to the use of ANS standards incorporated by reference. As part of the public notification process, a draft copy of the new standard or standard revision is either provided directly or notification provided on the means to obtain an electronic or paper copy.

*Question 5: What are the best practices for providing access to standards incorporated by reference in regulation during rulemaking and during the effective period of the regulation while respecting the copyright associated with the standard?*

### **ANS Response**

Two methods are routinely provided by ANS:

1. Users of ANS consensus standards are provided a convenient worldwide web application at ans.org to obtain copies of ANS standards for a reasonable price based on the effort required by the organization to competently develop and maintain both current and historic copies of those standards.
2. A complementary method is provided by ANS through a partnership with a commercial vendor that supplies copies of relevant national standards from many SDOs with certain agreed-upon copyright restrictions also at a reasonable price.

*Question 6: What are the best practices for incorporating standards by reference in regulation while respecting the copyright associated with the standard?*

### **ANS Response**

The same practice that U.S. SDOs use for incorporating documents by reference in their standards should be used for incorporated by reference in regulations. ANS procedures require that any reference made in an ANS standard must cite the specific document title and publication date of the reference. Two statements are made in the Foreword of ANS standards to the effect:

*This standard could reference documents or other standards that have been superseded or withdrawn at the time the standard is applied. References include statements in the section(s) that provide guidance on the use of references. Users may use more recent editions of those references with appropriate notations of any variances that were applied where the newer document was used.*

*Any part of this standard may be quoted. Credit lines should read "Extracted from American National Standard ANSI/ANS-53.1-201X with permission of the publisher, the American Nuclear Society." Reproduction is prohibited under copyright convention unless written permission is granted by the American Nuclear Society.*

## **Voluntary Consensus Standards and Cost-Benefit Analysis.**

*Question 7: What resource and other costs are involved in the development and revision of voluntary standards?*

### **ANS Response**

Knowledgeable, credentialed, and experienced people are the natural resource necessary for the development of VCSs. The availability of these people is tantamount to success. This resource is the most costly aspect in the development of a standard. Frequently, revisions to consensus standards can be accomplished with little additional cost; however, major revisions are nearly as costly as first-time standards. Volunteerism is becoming less enthusiastically endorsed by industry, the source of this resource. This reluctance is likely due to industry's need to pass along costs to the customers and, potentially, their frustration with the near autonomy of agency directives.

ANS conducted a survey of its volunteers to provide accurate information of volunteer time and expenses associated with the development of consensus standards. Although there can be great variances, the following averages were found for development of a new ANS standard:

- Annual contribution of a chair (lead) of a writing group = 130 hours  
(most writing groups have a single chair)
- Annual contribution of a member of a writing group = 60 hours  
(the average ANS writing group has 11 members)
- Annual travel expense to writing group meetings for chair = \$2,200
- Annual travel expense to writing group meetings for member = \$1,800  
(roughly half of the members were generally unable to travel due to cost)
- Average length to develop a new standard and gain ANSI approval = 6.1 years

Revision of existing standards, on average, take nearly as much time and cost as developing a new standard. The average length of time to revise a standard and gain ANSI approval = 5.8 years

Using the above figures, the total contribution of time by both the chair and members for the development of a new standard is estimated at 4,800 hours. At a professional hourly labor rate of \$125.00/hour (including benefits), volunteer contributions would approach \$600,000. Associated travel expenses for chair/members are estimated at \$75,000 for a combined cost of nearly \$675,000. This cost does not include the contribution of consensus committee members that perform a separate, technical review and formally ballot the standard as required for approval as an American National Standard by ANSI. When factoring in the contribution of consensus committee members, the cost to develop one standard over a six-year period can be upwards of three-quarters of a million dollars. All of this cost is borne by the member's company, organization, or, in many cases, by the members themselves. ANS does not provide any direct travel or labor support funding for standards development volunteers.

The direct contribution of the ANS pales in comparison to the contributions of its nearly 1000 volunteers. The ANS budget provides for 1.75 staff members to support the standards program with administrative support for its higher-level committees as well as editing and publication formatting. Actual publication cost of the standards is borne by ANS through collection of reasonable prices for the documents. When reviewing revenue and expenses, significant variances have been found from year to year. Most years show a small profit from publication sales allowing the program to sustain itself. ANS considers the standards program a significant contribution to the industry.

*Question 8: What economic and other factors should agencies take into consideration when determining that the use of a voluntary standard is practical for regulatory or other mission purposes?*

**ANS Response**

The economic factor that should be considered by the Federal agency is the professional volunteer effort that is an integral part of developing and maintaining VCSs, the benefits of which the agency receives essentially for free. The other factors to be considered include such qualitative factors as representation of diverse views and the attention to detail that is part of the ANSI–required time-consuming balloting and comment resolution process. Federal agencies should also recognize that the processes that pertain to developing a VCS are quite analogous to the disciplined approach that agencies are themselves required to follow in rulemaking.

Agencies should be required to provide substantive bases and technical cost–benefit analysis for implementing variations to consensus standards. The implementation of a VCS for regulatory or other mission purposes, as worded and unadulterated with no variations, is not anticipated to be economically onerous.

*Question 9: How often do standards-developing bodies review and subsequently update standards*

**ANS Response**

ANS adheres to the ANSI–required update process, which generally requires an evaluation be conducted every five years to ensure that each standard is revised to reflect current good practice. ANS provides an annual notification to the NRC regarding new, revised, or reaffirmed standards to ensure ANS continuity with the primary regulator for the nuclear industry.

*Question 10: If standards are already incorporated by reference in regulations, do such bodies have mechanisms in place for alerting the relevant agencies and the public, especially in regard to the significance of the changes in the standards?*

**ANS Response**

Yes, see “ANSI Public Document Library Standards Action” web page:

<http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Action%2f2012%5fPDFs>

**Using and Updating Standards in Regulations.**

*Question 11: Should OMB set out best practices on how to reference/incorporate standards (or the relevant parts) in regulation? If so, what are the best means for doing so?*

**ANS Response**

Currently, regulations adequately reference and/or incorporate standards. Where the agency has extracted or revised a portion of a consensus standard for regulatory purposes, substantive bases and technical cost–benefit analysis for implementing the variations should be provided to the effective SDO and those regulated. Such cost–benefit analyses should include an evaluation of the risk regarding the protection of the public health, welfare, and safety relative to publicly accepted risks and other societal cost/benefits.



The regulatory framework employed by the NRC is sufficiently flexible that the agency uses the full range of options regarding citing, referencing, and incorporation. Experience of agencies other than the NRC in this area is very limited. The system that the NRC uses would be supported.

*Question 12: Are the best means of reference/incorporation context specific?*

**ANS Response**

Yes, see response to question #6.

*Question 13: Are there instances where incorporating a standard or part thereof into a regulation is preferable to referencing a standard in regulation (or vice versa)?*

**ANS Response**

Incorporating an entire standard in a regulation would leave the publication extremely vulnerable to cross-purposes created by lack of complete change control between agencies and SDOs.

Incorporation of small parts of standards word-for-word could be accommodated and this practice would lead to a more complete understanding by the user at the time the user attempts to comply with a regulation without having to spend considerable time finding access to all wholly referenced standards and then making sure that all sections that were intended to be reviewed actually got reviewed by the user.

*Question 14: Should an OMB supplement to the Circular set out best practices for updating standards referenced in regulation as standards are revised? If so, what updating practices have worked well and which ones have not?*

**ANS Response**

The Circular should emphasize the need for the Federal agency to give the same priority to amending its rules to reflect revisions that it gave to the original standard. Good practice should not permit a reference to a standard that has been superseded by a new revision.

OMB should attempt a survey to identify the best practices for updating consensus and non-consensus standards possibly by setting up a web page of lessons learned. They may want to consider use of private groups that supply commercial standards via the Internet or other means. OMB may also want to review methods used by internet-based companies such as Amazon.com and the Information Handling Services for delivering content at a very low price. These companies might seek volume discounts from standards developers.

*Question 15: Is there a role for OMB in providing guidance on how Federal agencies can best manage the need for relevant regulations in the face of changing standards?*

**ANS Response**

Yes. As an arm of the Executive Branch of the Government, OMB should monitor the effectiveness of the DOC oversight through NIST of agency implementation of Public Law 104-113 and subsequent OMB Circular No. A-119. NIST sponsors a new multi-SDO committee that would be very useful (Nuclear Energy Standards Coordination Collaborative/NESCC).

*Question 16: How should agencies determine the cost-effectiveness of issuing updated regulations in response to updated standards?*

### **ANS Response**

Cost-effectiveness of issuing updated regulations should be accomplished by ensuring that the updated consensus standards are developed with the active participation of the appropriate regulatory agency. OMB funding should be provided to these agencies as a set-aside to provide standards development/maintenance grants to the appropriate SDOs.

ANS does not believe a formal cost-effectiveness study is required. Regulations should contain precautionary comments to the effect that consensus or non-consensus standards referenced in a regulation should be checked to ensure that only the standard issue referenced in the regulation is applied. Updates to referenced standards may be used with adequate evaluation of the revised standard and comments noted where different issues of standards are applied.

Agencies should evaluate revisions to standards as they are issued unless the revision contains unacceptable technical provisions and based on that evaluation, consider an update to the regulation. Presumably the agency found the original standard to be cost effective, and that determination should apply to revisions to the extent the content of a revision continues to meet regulatory expectations.

*Question 17: Do agencies consult sufficiently with private sector standards bodies when considering the update of regulations that incorporate voluntary standards, especially when such standards may be updated on a regular basis?*

### **ANS Response**

In general, no, however ANS has been satisfied with the liaisons it has with the NRC primarily due to their high involvement in the working groups for nuclear-related standards bodies. Other relevant agencies are less routinely involved in standards development and at a much lower level of participation.

This involvement of agency technical experts puts a financial burden on those agencies to provide travel and document development and revision activities and is probably the prime reason that they participate at a lower level. There are at least eight major SDOs involved in the nuclear standards industry and many, many working groups that the SDOs rely on. Support for agency technical experts in these working groups is a continuing issue due to cost.

ANS believes that both parties share responsibility for maintaining an active communication with regard to the development of standards and their revision. ANS and other SDOs are constantly trying to improve electronic means to increase participation without unnecessary travel requirements, but again these electronic improvements are a budgetary issue for the SDOs. Some level of budgetary support from OMB to agencies and/or directly to the SDOs would greatly improve this cooperation. This could be accomplished through a new coordinating committee that has recently been established at NIST. This committee, the NESCC, would provide an excellent mechanism for OMB to directly support this need.

*Question 18: Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions?*

### **ANS Response**

ANS would not be able to support a conformity assessment group within the current ANS management structure that could accommodate agency assessments, again due to budget impacts on the organization unless there is a means to develop a profit center to carry out such assessment activities.



ANS recommends that preliminary guidance be developed by OMB and proposed to the SDOs for acceptability through the NESCC for nuclear industry programs.

*Question 19: Where an agency is requested by stakeholders to consider allowing the demonstration of conformity to another country's standard or the use of an alternate conformity assessment procedure as adequate to fulfilling U.S. requirements, should OMB provide guidance to agencies on how to consider such requests?*

**ANS Response**

ANS supports OMB's developing such guidance, particularly in the international arena.

With globalization of nuclear technology, U.S. leadership in this technology can be maintained by including third-party participation in establishing conformity to a greater extent than is currently possible within the current regulatory framework. Such practices are apparently commonplace in Europe. The greatest opportunity for "harmonizing" safety standards with non-consensus documents lies with documents issued by the IAEA. This harmonization could and should be coordinated through the ISO Technical Committee 85. Harmonization of U.S. and international SDOs should be addressed to show consistency in expected safety outcomes.

OMB should direct agencies that consider national or international consensus or non-consensus standards for regulatory development or update to directly engage the appropriate SDO that developed the standard(s). That interaction should include consideration of the substantive technical bases and cost-benefit analysis for conforming to another country's standard. Such cost-benefit analyses should include evaluation of the risk regarding the protection of the public health, welfare, and safety relative to publicly accepted risks and other societal cost-benefits as well as promotion of economic growth, innovation, and competitiveness.

**Other Developments**

*Question 20: Have there been any developments internationally—including but not limited to U.S. regulatory cooperation initiatives—since the publication of Circular A-119 that OMB should take into account in developing a possible supplement to the Circular?*

**ANS Response**

The commendable initiatives taken by the NRC with the Organisation for Economic Co-operation and Development Nuclear Energy Agency Multinational Design Evaluation Program should be probed for lessons that may be relevant to preparation of any supplement to Circular A-119.

*Question 21: Does the significant role played by consortia today in standards development in some technology areas have any bearing on (or specific implications for) Federal participation?*

**ANS Response**

ANS believes that including conformity assessment within its scope should strengthen the consortium approach being attempted with the NESCC, with NIST and ANSI as co-chairs. This would preclude the need to have a separate conformity assessment program within each SDO.

Development of Federal regulations without participation and adoption of the consensus standards by regulators creates regulations by perception of need/justification without sound, knowledgeable, and experience judgment.

*Question 22: Are there other issues not set out above that OMB might usefully seek to address in a supplement?*

**ANS Response**

1. The assessment of Federal employee participation in the consensus standards process needs to be better monitored by NIST or OMB. There needs to be some sort of criteria for including the name of a Federal or contractor employee participating in the consensus standards process. A cursory review of NIST's agency employee listings demonstrates that numerous people are affiliated with membership, but have limited to no actual participation in the consensus standards development processes. This creates the false illusion that agencies are broadly and deeply engaged in the consensus process.
2. There is a current push toward "performance-based" standards by many SDOs and Federal agencies. These efforts are not well understood. The uncoordinated push for these regulations and standards, where they are NOT appropriate, has a potential to create unacceptable confusion. The American Society of Mechanical Engineers has a useful four-page policy discussion on performance-based standards. Performance-based standards are no panacea and not appropriate for many standards activities, including process and administrative standards. In many activities it is necessary to give people explicit guidance, such as an algorithm, that guarantees them an acceptable answer ("prescriptive standards"). Likewise, an inclusion of the concept of "risk-based" standards is fraught with the same issues. At some point, definitions of and clear guidance needs to be provided to distinguish between prescriptive (procurement, calibrations, etc.), performance-based (outcome specific), and risk-based (occurrence specific) standards.
3. China, South Korea, India, and third world countries are expanding their nuclear enterprises at "break-neck" speeds. The quality of workmanship and operations are imperative to any safe operation. The application of high-quality, prescriptive standards and the means for verification of compliance can do much to avoid across-boundary injuries, especially from large-hazard potential events due to poor quality. The goal for reactor technology safety requires carefully developed standards based on their intended applications. These standards are those that have been developed through a consensus process to facilitate easy compliance and provide difficult non-compliance. Intergovernmental agency specifications are influenced by national objectives that may not be biased with sound safety considerations, whereas the consensus process offers a broad balance of interests during the standard development deliberation process.