



May 9, 2014

The Honorable Howard Shelanski
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Dear Administrator Shelanski:

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

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 on the proposed revisions to Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."

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 U.S. Nuclear Regulatory Commission (NRC), the U.S. 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. Comments to the notice from the ANS Standards Board are provided in Attachment A.

Thank you for the opportunity to comment on this important issue.

Respectfully submitted,

A handwritten signature in cursive script that reads "Donald J. Spellman".

Donald J. Spellman, Chair
ANS Standards Board

Attachment

CC: Donald R. Hoffman, ANS President
Michaele C. Brady Raap, ANS Vice President/President-Elect
Robert C. Fine, JD, CAE, ANS Executive Director
Steven L. Stamm, ANS Standards Board Vice Chair
Rick Michal, ANS Director of Scientific Publications and Standards

ANS Standards Board Comments on a Proposed Revision to OMB Circular No. A-119, “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”

Preference for voluntary consensus standards (VCS) – The revised Circular provides good direction for maintaining agency preference for using voluntary consensus standards in Federal regulations and procurement. The ANS Standards Board recommends the following additional concept be added:

When a VCS is not available, the agency should identify the need for such a standard to the appropriate SDO and work with that SDO to develop the standard. A non-consensus standard (NCS) may be used until such time as a VCS is made available or if an SDO is unable to develop a VCS.

Guidance on use of standards and participation in standards development – In addition to the guidance included, the revised Circular should encourage agencies to identify standards needs as early as possible and to notify the appropriate SDO to allow the SDO the opportunity to evaluate its ability to support a VCS.

The Circular should caution agencies that prior to the use of international standards, they should provide other agencies, U.S. industry participants, and SDOs an opportunity to identify concerns regarding the use of a specific international standard that might provide an unfair advantage to international suppliers.

Guidance on conformity assessment – The revised Circular should encourage agencies that do not have their own conformity assessment programs to recommend that conformity assessments performed by SDOs or an organization certified by the SDO be used. Nuclear liability protection should be extended to the SDO and SDO certified nuclear related conformity assessment organizations.

Enhanced transparency – It should be identified that ANSI national standards requirements provide an adequate approach to public participation and transparency for SDOs that are ANSI members. Other SDOs and NCS not associated with ANSI should be encouraged to ensure public participation and transparency is incorporated in their standards development policies and procedures where possible at the same time protecting business sensitive and intellectual property information.

Incorporating standards by reference in regulations – The Circular should include the following:

1. Clarify that “incorporation by reference” in a regulation is the preferred approach to endorsing VCS rather than extracting standards sections in whole or in part. Extraction of whole sections or paragraphs is not allowed by SDO copyright protection without a clear reference to the VCS in the body of the standard and in the reference section with title, version, and date noted.
2. If only a portion of a standard is applicable, a reference to the specific portion of the standard may be used with appropriate notation in the body of the standard and in the reference section with title, version, and date noted. Intellectual property rights and copyright protection must be protected by prior negotiation with the SDO or NCS developer.

3. If a standard is acceptable with some exceptions, the standard shall be referenced and the exceptions indicated in the body of the text or in a footnote. Intellectual property rights and copyright protection must be provided by prior negotiation with the SDO or NCS developer.

Intellectual property – The Circular shall clearly indicate that intellectual property rights and copyright protection remain the property of the SDO or NCS developer. In the case of the NCS developer, use of intellectual property in a regulation is allowed only after negotiation and release of the information from the NCS developer. VCS, due to their consensus nature and required public comment period, do not include intellectual property rights, however, VCS are protected by copyright and the VCS SDO must approve of any use of information in a regulation.

Ensuring the timely updating of standards – It should be noted in the Circular that ANSI policies (for those SDOs who are members of ANSI) provide an acceptable approach to maintaining standards current. Non-ANSI SDOs and NCS developers should require maintenance of standards currency in their internal standards development and maintenance policies and procedures.

Determining whether a voluntary standard is “reasonably available” – The Circular should make it clear that the SDO consensus process provides adequate opportunity for public input and review and are “reasonably available” during the approval process for a nominal fee (Unapproved VCS or NCS may not be used or quoted in agency regulations). Where standards development is being performed in support of an agency request, the agency should attempt to synchronize its regulation public review period so that it coincides with the public review period for the related standard.

“Reasonably available” for copyright VCS is meant to imply that VCS are available on commonly used electronic media to the general public for a minimal cost that is used to cover the SDO cost of development, maintenance, and publication of the VCS.