



May 9, 2014

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

Submitted Electronically

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

Dear Mr. Administrator:

NSF International appreciates the opportunity to provide comments regarding proposed revisions to Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities published on February 11, 2014 (Federal Register 2014-02891).

NSF International is an ANSI accredited voluntary consensus standards developer and provider of conformity assessment services. NSF has published more than 80 voluntary consensus standards in the area of environmental and public health, and has certified the products and services of thousands of companies from more than 100 countries around the world. NSF has been active in this space for over 65 years and its standards and certifications are widely referenced and relied on throughout the U.S. and globally.

NSF International strongly supports OMB A119 and the NTTAA and believes they provide considerable public policy benefit. While we support these policies, we also believe there is room for improvement by federal agencies in the participation, recognition, reference, adoption, implementation and promotion of both the letter and spirit of these policy directives. The net result has been missed opportunities by the Standards Development Organizations (SDO) and the Conformity Assessment (CA) communities to support federal agency policies and mandates, especially with shrinking federal, state and local government budgets. As an ANSI accredited SDO and accredited CA body, NSF International and its stakeholders have not fully realized the potential benefits of these Federal directives. However, NSF International is encouraged that the newly proposed revisions to OMB A119 will strengthen and clarify the intent of the policy directives, and that federal agencies are more free and motivated to strongly embrace and act on these directives.

With respect to **Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities**, we strongly agree with the majority of the proposed revisions, and believe these changes will serve to significantly strengthen consensus national standards and accredited third party certification. However, we also believe some of these recommendations do

not go far enough and do not provide the necessary clarification to ensure consistent interpretations by all stakeholders.

- 1. Preference for Consensus National Standards.** We agree with the proposed revisions to establish a general preference for using voluntary consensus standards (VCS) in Federal regulations and for other Federal agency uses over voluntary non-consensus standards (VNCS). We would prefer to see the use and recognition of VNCSs by government agencies be time limited, and only be used if there is a commitment by the VNCS SDO to convert or transition VNCSs to VCSs. We believe this is important in preserving the integrity and impartiality in the standards community. To do otherwise may create incentives favoring the development of VNCSs.
- 2. Ensuring the Timely Updating of Standards:** There is a concern that a standard incorporated by reference (IBR) in a regulation can become outdated. ANSI accredited standards must comply with the ANSI Essential Requirements which require, at minimum, the reaffirmation, revision or withdrawal of a national standard every five (5) years. This assists in ensuring the standard maintains relevance and advances along with technology or other factors. Non-accredited standards are not held to this obligation. Thus, it would be beneficial to incorporate language where the IBR standard is from an accredited SDO. It is also important to mandate the participation of agencies in the VCS process. Agency participation will help ensure that a VCS meets federal requirements and be of use to the agency.
- 3. Providing Guidance on Conformity Assessment:** The proposed revision sets criteria for agencies when designing a conformity assessment procedure to consult with NIST and OMB. Agencies should also be provided guidance to consult with an internationally recognized accreditation body such as ANSI. Such a consultation could provide the agency information from an experienced body, expedience in the development process and avoid any redundancies of other programs, schemes, or other conformity assessment applications. While, NSF strongly supports agency reliance on and use of appropriately accredited conformity assessments, it would be preferable for the Circular to specifically reference accredited conformity assessments, such as those based on ISO Guide 65 (17065). Similar to the difference between VCS and VNCS, relying on accredited certifications is much more meaningful, and generally more reliable, and this should be clearly preferred in the final version of OMB A119.
- 4. Limitations on Recognition of Conformity Assessment Bodies.** NSF International believes that OMB A119 and NTTAA should be more specific when defining acceptability of Conformity Assessment Bodies and Third Party Certifiers. As an example of where this would have been helpful is in the drafting of the Food Safety Modernization Act (FSMA), which recognizes third party auditing and certification of foreign suppliers. Where FSMA mandates significant conflict-of-interest provisions for third party auditors, the law itself recognizes “foreign cooperatives” as acceptable third party auditors or certifiers. While this may have been an oversight by the drafters of FSMA, the end result is that the proposed rulemaking does not adequately address either actual or perceived conflicts of interest for “foreign cooperatives”. Similarly, the drafters of FSMA failed to exclude Trade Associations or their captive “subsidiaries” from being recognized as accredited third party certifiers. The inherent conflicts of interest of a Trade Association, whether they have created an apparent arms length corporate entity to serve its member companies or not, makes it

impossible for the appearance of conflict of interest to be erased. Recognizing Trade Associations as certifiers will raise significant public doubt about the integrity of third party certifications, resulting in diminished confidence in any federal program that relies on such certifications. Government recognition of Trade Associations or their captive “subsidiaries” will undermine the not only OMB A119 and NTTAA, but legitimate third party certifiers as well. OMB revisions should raise the bar on conflict of interest provisions by explicitly excluding Trade Associations and their captive certification body “subsidiaries” from any type of U.S. government agency recognition as third party conformity assessment bodies.

5. **Federal Regulatory Participation on Standards Development.** As an ANSI accredited SDO, we fully appreciate the degree to which federal agency staffs have participated in the development of VCSs. However, not all relevant agencies are willing to participate on committees, and not all participating agency staff feel compelled to vote on standards. Some instead behave more as observers to the standards development process, which is appreciated, yet is not necessarily as helpful as a vote. NSF International strongly supports the new language stating that an Agency Standards Executive (ASE) should be a senior level official. Additional guidance should be provided to ASEs clearly granting them the authority and obligation to vote on VCSs, on behalf of their agencies. This will increase stakeholder recognition of VCSs and increase the recognition of CA activities related to these standards.
6. **Expenses Related to Federal Regulatory Participation on Standards Development.** Occasionally, federal agency staff will indicate that budgets prevent them from traveling to the standards development committee meetings. Additionally, and understandably, most if not all agencies are prevented from accepting travel reimbursement. We would like to see OMB A119 address the issue of travel budgets, and to explore the possibility of federal agency staff travel expenses being reimbursed directly or through a central, transparent clearinghouse. We realize this is a difficult issue, but state and local regulators do not appear to have the same obstacles, but since most ANSI VCSs are national in scope, federal agency participation is imperative.
7. **Federal Endorsement of VCSs.** Especially in new and emerging areas, such as “green” and “sustainable”, the proliferation of VNCSs has resulted in a confused, conflicted and otherwise counterproductive environment for many stakeholders who want to do the right thing. This proliferation of VNCSs, some of which are proprietary in nature, has slowed progress on generally recognized public policy mandates. The Federal government can help clarify these situations by recognizing and endorsing specific VCSs early in the process. A clear and strong position by the appropriate federal agency will encourage cooperation among competing SDOs, conserve valuable resources and expedite the adoption of standards benefitting the public.
8. **Federal Regulatory Promotion and Adoption of VCSs.** It has been our experience that a specific government agency (FDA), with representation on the NSF VCS committee for many years, and an active voter, has been reluctant to reference the NSF food equipment sanitation standards into a normative or informative annex to the FDA’s Model Food Code, which is only advisory to States. We believe FDA’s reluctance may be due to its reluctance to endorse a specific SDO, however the 20+ NSF VCSs for food equipment are the only ones that have been used in the U.S. for over 60 years. The FDA’s Model Food Code tends to be adopted by States in its entirety, with minor

revisions. We believe the ANSI Project Initiation Notification System (PINS) appropriately deters development of redundant standards; hence, there should be no reluctance to reference the NSF International standards which they, FDA, helped to develop. This action would not prevent recognition or listing of other SDO's standards in the Model Food Code Annexes as they were developed and recognized. As it stands now, the major drawback to FDA's reluctance is that States fail to be specific in their codes about the Standards that everyone relies on. The end result is weaker adherence and compliance with the VCSs, especially from foreign product manufacturers.

In summary, we strongly support the proposed changes to OMB A119 and believe OMB's proposed revisions, along with the recommendations above, will increase the adoption and use of VCSs and related CA activities.

Sincerely,

Stan Hazan
Sr. Director, Scientific & Regulatory Affairs
NSF International
789 N. Dixboro Road
Ann Arbor, Michigan 48105
Office 1-734-769-5105
hazan@nsf.org
www.nsf.org