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Subject:

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

CSA Group (CSA) is pleased to provide input to the latest version of OMB Circular A-119 for your consideration.

In the U.S., CSA is headquartered in Cleveland, Ohio, and accredited as a Standards Development Organization by the American National Standards Institute. We are also the largest standards developer in Canada, headquartered in Toronto, where we are accredited by the Standards Council of Canada. In addition to developing standards in both countries, CSA offers Certification and Testing and Consumer Product Evaluation services.

OMB Circular A-119

CSA is pleased that A-119 continues to adhere to the “*National Technology Transfer and Advancement Act of 1995*” (NTTAA), which directs agencies to use standards developed or adopted by voluntary consensus standards bodies; encourages agencies to consider international and private sector conformity assessment schemes and activities in lieu of those carried out by government; and states that standards incorporated by reference, while they should be accessible, should not be required to be made available for free, and that the rights of the copyright holder must be observed and protected.

The following are specific comments and recommendations regarding sections of A-119:

Section 6. What is the Policy for Federal Use of Standards?

6. a. When must my agency use voluntary consensus standards?

The second paragraph of this section makes reference to using standards developed outside the voluntary consensus process, for example in “emerging technology areas,” when a suitable consensus standard is not available. In such circumstances however, Section 6. b. talks about consensus standards that may be under development in the required areas, and suggests that agencies should wait and use these standards, and in fact encourages agencies to become involved in their development.

Recommendation: We would like to see a stronger link made between the language of sections 6. a. and 6. b. as identified above, with respect to a priority to be given to consensus standards that either exist or may be under development. In addition, and where appropriate, we would encourage A-119 to encourage the use of other approaches/products from voluntary consensus organizations to meet the needs of agencies, such as the development and use of guidelines, private standards, etc.



6. e. (ii) When deciding to use a standard, what are some of the things my agency should consider?

The second paragraph of this section indicates that in their evaluation of which voluntary standards to use, with respect to intellectual property, agencies should "...include consideration of whether such IPR policies bind subsequent transfers of patented technology incorporated into the standard." Currently, *The ANSI Essential Requirements: Due Process Requirements for American National Standards Edition: January 2014, Subsection 3.1.3*, requires patent holders whose patented technology is incorporated into standards, to make a commitment to grant a license on reasonable and nondiscriminatory terms and conditions. However, this requirement is not binding on subsequent owners of patented technology incorporated into standards.

Recommendation: The OMB may wish to consider adopting less onerous IPR language within A-119, or ANSI should consider adopting the suggested OMB language into its Essential Requirements to ensure conformance.

6. i. What factors should my agency consider when determining whether to allow the use of more than one standard?

This section refers to the potential for an agency to use more than one standard for suppliers to demonstrate that they meet a particular program, procurement or regulatory requirement, and states that in the areas of health, safety, and environmental protection, "...it may be preferable..." to allow the use of only one standard. In these fields, safety could be seriously compromised if multiple standards are applicable to the same technologies or products.

Recommendation: The language should be clarified to require that only one standard be used for regulated areas related to health, safety and environmental protection.

6. o. How should my agency ensure that standards incorporated by reference in regulation are updated on a timely basis?

The first and second paragraphs of this section talk about the need for agencies to "...update standards that have been incorporated by reference on a regular basis" and that "...regulated entities may petition agencies to update incorporated standards."

Since voluntary consensus standards bodies have copyright protection of their standards, the language above is unclear of the role the standards body, agencies and regulated entities play with respect to updating incorporated standards.

Recommendation: The language in this section should be clarified to stipulate that while advice on the content of standards can be provided by agencies and regulated entities, the responsibility of updating standards falls to the standards body that owns copyright.



6. p. How should my agency determine whether a voluntary standard is ‘reasonably available’ in a regulatory or non-regulatory context?

In providing advice regarding the standards that agencies choose to reference and make reasonably available, item *iv* raises the issue of the criteria regarding whether standards bodies would be willing to provide a freely available, non-technical summary that explains a standard to those who lack relevant technical expertise. This would constitute a standards development organization providing a service.

It should be noted that in the Notice of Proposed Rulemaking posted by the Office of the Federal Register, 1 CFR Part 51 [OFR-13-0001], Incorporation by Reference, the following statement is made: “...we don’t have the authority to require that they [standards development bodies] give away assets, products, or services.”

Recommendation: Item *iv* should be removed, or modified to delete “freely available” in reference to providing a non-technical summary.

Section 8: What is the Policy on Conformity Assessment?

The first paragraph of this section indicates that Section 12 (b) of the NTTAA requires the National Institute of Standards and Technology (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”.

It should be noted that there are currently States and Municipalities that have their own additional requirements related to conformity assessment and acceptance of conformity assessment bodies. In most cases these are an unnecessary duplication of conformity assessment activities, and result in increased accreditation or recognition costs and potential duplication in testing to unique requirements.

Recommendation: NIST should report quarterly regarding those Federal, State and Local jurisdictions that have their own conformity assessment requirements, and activities underway to reduce unnecessary duplication.

8. b. What considerations should my agency make when it is considering the type of conformity assessment procedure(s) to use?

This section indicates that agencies should consider both domestic and international conformity assessment organizations to ensure that products meet appropriate requirements for the U.S. market, and that the use of international standards and/or guides should be adhered to.

While the use of these standards and/or guides will ensure consistency in basic conformity requirements, further action needs to be taken when considering acceptance of product accreditation from conformity assessment bodies outside the U.S. For example, technical competency to unique requirements of U.S.-only codes and standards must be demonstrated. In addition, reciprocity should also be considered to ensure equal access to foreign markets by U.S. conformity assessment bodies.



Recommendation: It is recommended that for regulated areas, products should be tested and certified by independent third-party conformity assessment bodies, to provide the required levels of independence and impartiality. Should conformity assessment activities be considered under a first- or second-party, it is recommended that a formal level of assurance needs to be implemented to ensure proper quality measures are in place and that technical requirements of the standards/guides are being adhered to. NIST should encourage, and assist Federal agencies where necessary, to utilize the international standards and/or guides for all conformity assessment activities. In addition, Federal agencies should be encouraged to implement reciprocity provisions and consult with the United States Trade Representative when considering all requests for recognition of foreign conformity assessment bodies.

8. c. What obligations does my agency have when considering whether to recognize a conformity assessment procedure in use in the market of a trading partner?

Please see the comments and recommendations under section 8. b. above.

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

This section states that "This policy does not preempt or restrict agencies' authorities and responsibilities to make regulatory decisions authorized by statute."

Recommendation: When considering conformity assessment activities, regulatory authorities should be required to ensure that unique requirements or procedures are not being inserted into statutes or regulations that could be in conflict, or cause inconsistencies, with other recognized national or international conformity assessment requirements or programs.

Administrative Conference of the United States (ACUS)

The OMB has also requested input on whether Administrative Conference of the United States (ACUS) Recommendation 2011-5, *Incorporation by Reference*, 77 Federal Register 2257 (January 17, 2012), should be adopted within A-119 with certain modifications. In this regard, CSA offers the following comments and suggestions.

In the section of the Recommendation dealing with "Ensuring Incorporated Materials are Reasonably Available," item 3. places an apparent emphasis on making material available for free or at low cost.

Recommendation: If adopted within A-119, and keeping in mind the language referenced above in OFR, 1 CFR Part 51, the reference to "low cost" should be removed, and replaced with the expectation that agencies will work with the providers of material to ensure reasonable availability on a case-by-case basis.

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In item 4. (d) of this same section, the point is made that the types of parties that need access to incorporated material, and their ability to bear the associated costs, should be considered by agencies in determining material to incorporate by reference. In 1 CFR Part 51, the Office of the Federal Register states the following: *"We are not proposing a definition [of 'class of persons'] so that agencies maintain the flexibility to determine who is within a class of persons affected by a regulation or regulatory program on a case-by-case basis to respond to specific situations."*

Recommendation: If adopted within A-119, item 4. (d) should be removed.

Respectfully submitted,
CSA GROUP

A handwritten signature in black ink that reads 'B Rose'.

Bonnie Rose
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