

April 30, 2012

The Honorable Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Reference: FR Docket 2012-7602, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities"

Dear Mr. Sunstein:

SAE International (SAE) is thankful for the opportunity to comment on the above-referenced notice, which appeared in the *Federal Register* on March 30, 2012. We believe it is important to provide our input on the issue as to whether and how to supplement OMB Circular A-119.

SAE, founded over 105 years ago, is an international standards development organization that produces globally-recognized and –adopted, consensus-based standards for use in the aerospace, automotive and commercial vehicle industries. SAE follows the requirements of the World Trade Organization (WTO) with regard to Technical Barriers to Trade (TBT), and ensures an open and transparent standards development process. Membership on any of SAE's standards development committees does not require membership in SAE and is open to all interested parties throughout the world. SAE also is a member of the American National Standards Institute (ANSI).

General Comments on Issue:

The current standards development process used in the United States ensures that standards are developed by technical experts and stakeholders most familiar with the issues. The process ensures that the standards improve public safety while at the same time minimizing the public's share of the development costs. Any revision of OMB Circular A-119 should ensure that these important criteria are not compromised.

The current process enables all interested parties to participate in the standards development process in an open environment that does not favor any one sector, whether industry, government or the public, over another. Altering this proven approach could result in the perception that one sector is unduly influencing the end result.

Responses to Specific RFI Questions:

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 preamble to rulemaking?

SAE believes that the federal agencies, in the vast majority of the cases, follow the guidance set out in the Circular as it relates to rulemaking. The agencies also provide clear explanations in the preambles of regulations of their rationale for considering voluntary consensus standards.

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.

SAE believes that consensus is the cornerstone of effective standards development. Any other process subjects the end-product to possible charges of undue influence by any one party involved in the process. This could result in inferior standards, thereby compromising public safety, and higher costs in the regulatory process due to potential legal challenges.

In addition, the United States could be exposed to potential charges of unfair trade practices because the standards would not meet the criteria of the WTO's Technical Barriers to Trade. U.S. businesses could be harmed and U.S. exports and jobs reduced.

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

SAE supports addressing conformity assessment issues in Circular A-119. The issues addressed should include definitions and roles for stakeholders. The current process of consensus-based, conformity assessment processes led by end-users of inspected processes is appropriate. We welcome NIST's support and partnership in this area, but do not feel that a larger management role for NIST should be emphasized at this time.

Factors agencies should use in selecting the appropriate conformity assessment procedure, including product/sector specific issues and the level of risk of non-fulfillment of legitimate regulatory, procurement, or other mission-related objectives.

Any conformity assessment process should be based on voluntary consensus standards. End-users of procured products should have a major role in deciding which conformity assessment process to employ and what key criteria should be involved in the audit/inspection process.

Guidance for regulatory agencies on compliance with relevant international obligations pertaining to conformity assessment and accreditation activities.

Guidance should be provided in the supplement so that federal agencies comply fully with international trade agreements. And, wherever practicable, conformity assessment practices should be based on globally-accepted standards and industry-led, globally accepted conformity assessment processes.

Factors agencies should consider in determining whether to recognize the results of conformity assessment and accreditation activities conducted by private-sector bodies in support of regulation.

Factors include:

- 1) Open and transparent processes
- 2) Conformance with international agreements
- 3) Reputation and history of private-sector bodies
- 4) Industry (end user/prime contractor) participation and acceptance of assessments

Non-regulatory uses of standards (including vendor conformity for purposes of response to procurement solicitations).

Non-government standards that describe products, performance of products, and quality acceptance of products should form the basis, whenever possible, for all government procurements.

Ensuring that agencies consider how to minimize conformity assessment costs and delays for businesses, especially small and medium-sized enterprises, subject to statutory and budgetary constraints and the ability of agencies to fulfill their legitimate regulatory, procurement, or other mission-related objectives.

Conformity assessment processes should be streamlined and consolidated by industry-led groups to ensure the provision of quality products at reasonable prices and with wide availability.

Is lack of access to standards incorporated by reference (IBR) in regulation an issue for commenters responding to a request for public comment in rulemaking or for stakeholders that require access to such standards? Please provide specific examples.

SAE standards are available to any party at a reasonable cost. SAE has received only a minimal number of comments relating to a perceived lack of access to SAE standards. SAE has a demonstrated practice of working with parties that have expressed hardship related to access to standards to meet their needs, while at the same time preserving the IP rights afforded by U.S. law. SAE also provides access to its standards to federal agencies for their internal use on a case-by-case basis. Businesses consider the cost of accessing standards as a component of the cost of doing business. The cost of access is negligible compared to the total cost a business incurs in complying with a regulation.

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

SAE believes all interested parties should have the right to access standards that are referenced in regulation. SAE makes all versions (current and historic) available via its web site and third party sellers. Requests for access based on hardship from any party are considered on a case-by-case basis with a variety of customer-friendly solutions.

SAE disagrees with those individuals or organizations advocating that access to referenced standards must be free. The common use of electronic access today should not automatically translate into free access to standards. Someone or some party must pay for the development costs in the current system that uses private organizations to develop voluntary consensus standards in lieu of government funded development. If standards development costs cannot be recovered by the private sector, then government agencies would need to develop their own standards, which would prove to be financially burdensome to the public. Even more important, a government-only standards development process would deprive the government of the vast wealth of technical knowledge available from the private sector.

What resources and other costs are involved in the development and revision of voluntary standards?

Development of voluntary standards incurs cost related to:

- 1) Administration of the standards development committees during their work and balloting period (which can extend multiple years for initial development of the standard);
- 2) Research required to develop a technically sound standard;
- 3) Formatting of document in various forms to comply with various media requirements;
- 4) Creation and maintenance of web-based delivery formats;
- 5) Marketing costs associated with required awareness of document on a global basis; and
- 6) Repeat of costs of 1 through 5 for every required revision (standards are required to be reviewed for needed revisions every five years).

Participation by any individual in standards development within SAE does not require membership within SAE nor a participation fee. Standards activity within SAE is self-supporting and does not use funds from other areas within the society.

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?

Agencies should compare the cost to all parties of using voluntary consensus standards compared to those incurred if the agency would develop their own standards. Included in the cost of the agency developing their own standards would be the cost all parties would incur during added rulemaking.

The agencies should consider the process used by the standards development organization, as well as reputation and knowledge base within the development committees, when determining the suitability of a standard.

How often do standards-developing bodies review and subsequently update standards? If standards are already incorporated by reference in regulations, do such bodies have mechanisms in place for alerting the relevant agencies and public, especially in regard to the significance of the changes in the standards?

SAE has a policy to review every standard every five years at a minimum for both relevance and the need for revision. If the standard is no longer relevant, it is cancelled with historic versions being permanently and readily available. Revised standards include the rationale for the revision at the front of the document. Government personnel serve on the vast majority of SAE committees, especially those that produce standards used in regulations. As a result, they are always notified (and usually participating) when a relevant standard is being revised.

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 to do so? Are the best means of reference/incorporation context-specific? Are there instances where incorporating a standard or part thereof into a regulation is preferable to referencing a standard in regulation (or vice versa)?

OMB is encouraged to offer best practices on how to reference standards in regulation as long as it is not duplicative or in conflict with other Executive Branch entities that provide similar guidance. SAE believes that standards should be referenced in regulations and not incorporated within the text of a regulation. Incorporation within the text would violate the copyrights afforded under U.S. law. It also would result in a subsequently-revised standard having language inconsistent with that referenced in the regulation.

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?

OMB should include best practices for updating references to standards cited in regulation as those standards are revised. OMB should consult all agencies and use the most appropriate methods that have been found successful based on the needs and requirements of the agencies.

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?

OMB should work with the federal agency staffs to develop such guidance.

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

SAE does not believe that it is feasible to utilize a single approach in determining cost effectiveness across all federal agencies. OMB might need to analyze the method on an agency-by-agency basis.

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?

SAE's experience with federal agencies supports the position that the agencies do communicate in an effective manner throughout the process. In turn, SAE (and all standards bodies) is responsible for communicating with the agencies and should not rely on an agency initiating communication in all instances. Regular communication by both groups helps to ensure optimal results.

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?

OMB should provide guidance based on the input of the appropriate staff of the federal agencies. The industries that SAE serves believe in using the best standard available that meets their needs based on technical merit regardless of the origin as long as it meets the WTO TBT provisions. The same is true of conformity assessment procedures – each industry sector chooses the most appropriate process for its needs. Government agencies benefit by being part of this process and working in partnership with the industry sectors in their areas of activity.

Where an agency is requested by stakeholders to consider allowing the demonstration of conformity to another country's standard or 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?

Guidance should be considered. If such conformity is found to be suitable, the cost to the stakeholder can be reduced which in turn reduces the cost to the public while not sacrificing public safety. A public-private partnership to evaluate such requests is usually informative and helpful in such cases.

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?

Federal agencies should be encouraged to be involved in international standards development. However, it should also be made clear that "international standards development" does not restrict

participation only to organizations like ISO or IEC. Rather it should encourage participation in any standards development organization whose standards are globally recognized by the user.

Does the significant role played by consortia today in standard development in some technology areas have any bearing on (or specific implications for) federal participation?

Federal agencies should be encouraged to participate in consortia as long as such entities abide by the same requirements that private-sector standards organizations do with regard to the WTO TBT.

Thank you again for the opportunity to provide comments on this important issue. SAE International is available for further discussion as needed.

Sincerely,

A handwritten signature in blue ink, appearing to be 'D. Schutt', with a stylized flourish at the end.

David L. Schutt, PhD