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

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Thank you for the opportunity to comment on the Request for Comments on a Proposed Revision of OMB Circular A-119.

The attached comments are submitted by the Association for the Advancement of Medical Instrumentation (AAMI). AAMI is a diverse non-profit community of 7,000 professionals from many domains in healthcare, all experts on healthcare technology, especially medical devices. AAMI is a leading developer of national and international voluntary consensus standards for medical devices and other healthcare products. It specializes in standards that address safety and performance of devices and device systems, in particular as they relate to patient safety. AAMI is ANSI-accredited as a standards development organization, and its community of industry, regulators (e.g., FDA, CMS), clinicians, researchers and independent experts together develop national and international standards, technical information reports, and related information about medical devices. AAMI's focus is on the *safe and effective* development, management, and use of medical devices and related technologies. AAMI is *not* an advocacy organization. It is a neutral organization that highly values its neutrality and "honest broker" reputation.

AAMI applauds the Office of Management and Budget (OMB) for its work to clarify and update OMB Circular A-119. AAMI strongly agrees with and supports the overall conclusion that voluntary consensus standards should be preferred and supported by the federal government.

As a member of the American National Standards Institute (ANSI), AAMI had the opportunity to provide input into ANSI's comments on the revised circular and AAMI is supportive of those comments. AAMI submits these comments in order to bring forward some additional considerations that are important to the AAMI standards community.

Our comments begin with the revised Circular – Definitions section. While all definitions were improved, AAMI particularly welcomes the proposed change from balance of interest to balance of representation. AAMI agrees that appropriate representation is of greater value than interest category and would help standards development organizations better meet the balance requirement for all standards committees.

The next series of comments respond directly to the questions posed in the Policy section of the circular.

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Question 6, c: How does this policy affect my agency's regulatory authorities and responsibilities?

This proposed language seems very ASTM-specific, suggesting that in order to determine whether established regulatory limits or targets have been achieved, agencies should use voluntary consensus standards for test methods, sampling procedures, or protocols. AAMI suggests that this proposed requirement be expanded to include performance criteria and limits, methods of measurement, and acceptance criteria.

Question 6, e: When deciding to use a standard, what are some of the things my agency should consider?

As in the question above, (i) should be expanded to state "As a general matter, standards being considered for use in regulation that specify nomenclature, basic reference units, performance criteria, methods of measurement, testing, and acceptance criteria, and that are primarily empirical in their formulation, warrant less scrutiny by an agency than standards that embody factors that are less objective."

Section (iii) in evaluating whether to use a standard, an agency should also consider the following factors:

- The list mentions the cost to the government and the regulated public of the agency developing its own standards but there is no discussion or mention of the cost of developing or writing a regulation. We would suggest that that be added as a new item (e).
- Item (g) should be revised to state "The extent to which the standard establishes acceptance criteria in the standard, where feasible." It is the acceptance criteria which provides greater purpose and usability to a regulatory agency.
- This list also does not mention or consider the value of the standard to the stakeholder, such as the manufacturer seeking clearance to market. The stakeholder, whether it be an industry member, consumer, researcher or other interested party, is in essence the government's "customer" and the very reason that the government is supporting the development of standards. This value cannot be understated, and also adds predictability and process to the regulator which also adds value to the federal government overall (its reputation for consistency, fairness and the like).

Question 6, m: What if no voluntary consensus standard exists?

There are times when a suitable standard does not exist or a gap in existing standards is identified. While an agency can then consider developing its own standard or use another government-unique standard, AAMI recommends that the agency first seek out appropriate standards development organizations to suggest or request that a new standard be developed. It is likely that the SDO will be responsive to such a request and work diligently to fill the need. While this notion is suggested in the draft comment, we recommend that it be moved up to be the first sentence, giving it added emphasis.

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

AAMI supports the notion that all standards incorporated by reference or officially recognized by a federal agency should reflect the most current information and state-of-the-art technologies and approaches to help ensure the safety and efficacy of medical products and for patient safety. Having old versions of standards still in play creates confusion and concern among those who are expected to comply with the standards, especially when they know that the updated version is stronger from a safety and efficacy perspective than the old one that continues to be recognized in some way by the federal government. Therefore, we recommend that federal agencies incorporating standards by reference or officially recognized by the agency in some other way be required to update those references within one-year of the publication date of the revised standard. This timing would allow the federal agency the time needed to review the revision, reaffirm that the standard continues to be an appropriate reference, and go through the rulemaking process identifying the newly revised standard as the appropriate regulatory tool.

Question 6, p: How should my agency determine whether a voluntary standard is "reasonably available" in a regulatory or non-regulatory context?

Regarding read-only access to a standard for free during the comment period, AAMI would be able to meet this recommended requirement. All AAMI members now have full access to draft documents during the comment period and a read-only function could be added for non-member use.

AAMI follows ANSI requirements for membership and standards participation, ensuring that all stakeholders have an opportunity to participate in the standards development process.

Providing a non-copyrighted, non-technical summary that adequately explains the content of the standards is more problematic. This summary could be interpreted as a rationale for the standard which AAMI does not provide because of the possible legal exposure from misinterpretation, misapplication, or over-reliance on a summary. It would also be very difficult and resource intensive to write a summary that would be understandable to a broad audience that includes the non-technical lay public. This would require these documents to be written at the seventh or eighth grades levels of education for the U.S. and may not be interpreted correctly by any citizen where English is not their native language. AAMI standards are also at times lengthy (e.g., human factors standard that is more than 500 pages in length), and AAMI would surely miss something that is important to one reader if it were to do a summary.

Question 7: What is the Policy for Federal Participation in Voluntary Standards Bodies?

AAMI fully supports the recommendation that federal agency participation in voluntary standards bodies is an essential contribution to ensuring balance of representation and the government's perspective on an issue. For this reason, federal agency participation should be strongly supported in the priority and budgetary processes of that agency. Beyond the need to ensure balance of representation, the best way to ensure that a voluntary consensus standard will meet the needs of the agency is to have the full support and participation of that agency. AAMI

also believes that the agencies should be reminded of this important principle each year during the budget process, for the reasons stated below.

AAMI also supports the recommendation that each agency should arrange for qualified representative to participate in standards development activities as appropriate. The input of the agency should be consistent and provide the most accurate thinking of the agency. It is difficult for an SDO and the members of a standards committee to meet the needs of the agency if the input varies from meeting to meeting and/or from draft to draft. Standards development is a partnership of all participating representatives and consensus can only be achieved by working through the issues and requirements with qualified and committed stakeholders.

All of this also means that the federal government must give adequate priority to the budget needed for participation in standards work. In recent years, we have seen these budgets cut to the bone and become much more difficult to justify and secure, often viewed as competing with other scarce resources that might have more pizzazz or immediate return on investment. AAMI recommends that the OMB document include a strong reminder to all federal agencies that appropriate budgets for standards participation should be maintained and not cut short as an "easy" way to cut a budget.

As a final note, with the movement of staff in and out of federal agencies, it is easy to overlook this important guidance from the OMB. We recommend that, in addition to an annual budget reminder, OMB find an appropriate mechanism to share this circular with all of the federal agencies on a periodic basis.

In conclusion, standards in healthcare are an extremely important regulatory tool and help increase patient safety both domestically and worldwide. We should do all we can to help preserve and promote the value of standards while continually working to improve the processes to develop them. AAMI appreciates this opportunity to comment, share our thoughts, and to continue to offer relevant guidance as needed. We also thank the OMB for its hard work to update and improve the circular for all stakeholders in the standards development process.

Respectfully Submitted,

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