TO: Office of Management and Budget

SUBJECT: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities – Response to Federal Register Request for Information

DATE: April 30, 2012

AAMI appreciates the opportunity to comment on *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.

Who AAMI Is

The Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization founded in 1967. It is a unique alliance of more than 6,500 members from around the world united by one mission — to provide global leadership and programs to support the healthcare community in the development, management and use of safe and effective medical technology. AAMI members include medical device manufacturers, healthcare organizations, government agencies, and various associations with an interest in medical devices, as well as individual members from the healthcare professions, industry, government, academia, and research.

The AAMI standards program includes both a national and international component. AAMI is accredited by the American National Standards Institute (ANSI) to develop American National Standards and has completed 153 technical documents to-date that are approved by ANSI, as well as an additional 30 technical information reports that meet AAMI consensus criteria. Since the medical device industry is global in nature, AAMI leadership and members prefer adoption of international standards to the extent possible, and 77% of AAMI's completed technical documents are identical adoptions of International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards, or adoptions with limited national deviations. AAMI is currently working on 20 new (first edition) American National Standards as well as a number of revision and amendment projects.

AAMI also operates, on behalf of ANSI and its US National Committee, six international secretariats of ISO and IEC, as well as 10 U.S. Technical Advisory Groups (TAGs) to ISO and IEC technical committees and subcommittees. Collectively, these committees have completed 306 international standards, technical reports and specifications and guides, and are working on 27 new (1st edition) documents as well as numerous revisions and amendments.

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In addition to its standards program, AAMI conducts one to two major summits annually on topical patient-safety issues with technology, develops and implements programs through its Foundation's Healthcare Technology Safety Institute, sponsors a scholarship program through its Foundation, conducts various educational programs, provides certification of biomedical equipment technicians, and publishes various periodicals and technical publications (in addition to standards). AAMI accomplishes all of this with less than 40 staff members, and does not engage in lobbying. AAMI is known and respected for its "neutral" role. Approximately 1,200 active volunteers provide leadership and technical support and participate in various committees and other activities.

Other Pertinent Background

The principal regulator of medical devices in the United States is the U.S. Food and Drug Administration, Center for Devices and Radiological Health. Depending on the device, other FDA centers may also have some jurisdiction (e.g., CDER for combination products). In addition, and again depending on the device, manufacturers and/or users may be affected by other governmental regulations such as OSHA (e.g., electrically powered devices; devices that could present a fire hazard such as anesthesia equipment), EPA (e.g., sterilizers that utilize ethylene oxide), CMS (e.g., reimbursement criteria for hemodialysis), and FCC (e.g., medical devices that transmit radio signals or could cause interference of same). This is by no means a comprehensive list. In addition, state or local governments sometimes enact laws and regulations impacting medical devices, such as recent legislation in California regarding medical device connectors. The Joint Commission (which accredits healthcare organizations) also has rules pertaining to medical devices. While certain federal agencies (e.g., the Veterans Administration) may utilize medical device standards for procurement purposes, the focus of our comments is use of voluntary standards and related conformity assessment activities from a regulatory standpoint.

Response to Questions

1. Agency Implementation of Circular A-119 in Rulemakings. 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 preambles to rulemakings?

   The process works well. AAMI believes that FDA and other federal agencies have made a good faith effort to enact the guidance, and CDRH as an agency definitely seems to understand the importance of the public-private partnership of standard setting for medical devices.

   Greater effort is needed for agencies to coordinate conflicting requirements where overlap of jurisdiction exists. Also, the role and use standards are not uniformly known or understood within FDA and consequently there can occasionally be situations when a duplication of effort occurs. A standardized approach to the use and value of

standards within FDA and in any Federal agency with overlapping jurisdiction is essential in reducing unnecessary requirements, enhancing regulatory responsiveness, eliminating or reducing regulatory inconsistencies and increasing predictability.

2. 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.

As a signatory to the Technological Barriers to Trade Agreement, AAMI believes that to support competitiveness of U.S. industry, the preference should be for voluntary consensus standards, and a minimum requirement for use of other types of standards should be that (a) there are no suitable standards developed by a voluntary consensus standards organization, and (b) the alternative standards developer meets the criteria for openness, due process, etc. set out in that agreement. In addition, safety and performance historically have been and should remain the focus for standards that support regulation or use of medical technologies.

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

AAMI believes that the necessary guidance already exists. That said, such a supplement could be helpful if it addresses coordination between agencies with overlapping jurisdiction in terms of what standards must be met and requirements for verifying conformance with those standards. While everyone (consumers, government, as well as responsible manufacturers) wants a system that provides some assurance that products are safe, over-regulation and over-complication of a functioning process are potential issues.

It also could be helpful to provide a menu of proven conformity assessment programs that agencies must choose from to limit the variability with which industry must contend. The federal government should discourage its agencies from adopting a "one-size-fits-all" approach to conformity assessment, or placing additional burdens on industry without a concomitant reduction in federal oversight. For example, requiring that a certified third party test a product to determine whether it conforms to a standard may be a good approach for high risk products, but this could add unnecessary costs that will ultimately be borne by consumers if it is also applied to low-risk products with little or no actual benefit. Further, if a government agency requires evidence from third party testing, it also should be required to accept the results. Requiring manufacturers undergo this type of scrutiny, in addition to federal inspection, adds

redundancy (and cost) to the system in the absence of any empirical evidence that the added cost is warranted. Federal agencies already follow numerous different practices. It could be worthwhile to conduct a study using a cost/benefit approach, to determine which of these are the most effective and under what circumstance. Agencies could then be provided with a menu of "allowable" conformity assessment programs from which to choose, which would reduce the variability for manufacturers who need to conform to multiple regulations.

4. Protection of Copyright Associated With Standards.

- Is lack of access to standards incorporated by reference 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.

When the need arises, we always find a way to make copies available to those who need them during the public comment process (example provided below). Our standards are also available for viewing at various libraries and government facilities. Lack of access has not been an issue.

The cost of standards development must be paid for in some way: either through the federal government (which would be an expense to all taxpayers, not simply those who use standards); private industry (which ultimately would be an expense to all customers in that industry); or, by the standards development organizations (which ultimately is an expense that must be born in some way by the community that supports the organization). Nothing is free, and someone ultimately will pay for the development of standards.

Like many (if not most) standards developing organizations, AAMI is a not-for-profit association that, from a financial standpoint, has to continuously look for ways to remain financially viable because of the high cost of standards development.

While there are other methods for covering these costs, AAMI's method is to ask industry to bear the primary expense through participation fees, and then sell standards for a reasonable expense to help defray some of the expenses.

Intellectual property is one element of how AAMI funds standards development, so we strongly support Circular A-119 in its statement that federal agencies must respect the copyrights of standards developers. Standards sales are an important funding mechanism for the cost of standards development but they are not sufficient to cover the full development cost. AAMI tries to keep standards prices

low in order to encourage use of our documents and in keeping with our mission. AAMI is not aware of any problems or complaints regarding lack of access to standards, and customer surveys conducted by AAMI over the years indicate that our prices are considered reasonable.

It is also important to note that the cost to comply with a standard (or government regulation citing a voluntary standard) is enormous compared to the cost of purchasing a standard. It's part of the business expenses that companies bear, along with the cost of participation.

- 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?

One best practice used by AAMI is to provide for free the relevant paragraph or section related to the proposed or new rule so the context is better understood at the time of reading and can help the reader better determine if the rule applies to them or their regulated product, or if they have a public interest in what is being proposed for purposes of making comments during the public comment period.

Whether the copyright holder and other authorized sellers provide documents at a cost or for free, standards that have been cited in proposed regulation also could be made available in a "read only" format for the time that the rule is in the proposal stage, so that potential commenters have access during the comment period. Federal agencies would need to give advance notice to the standards developing organization about the proposed rule.

At least in the case of the FDA/CDRH, final standards tend to be "recognized" more than incorporated by reference, and such recognition usually occurs a year or more after publication. Thus, most parties affected by the standard have already purchased a copy before the government actually recognizes it.

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

Government agencies should respect copyrights by citing only the referenced standard and providing information on how to obtain copies.

5. Voluntary Consensus Standards and Cost-Benefit Analysis.

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

The standards AAMI writes take, on average, three to five years to develop. During this time, AAMI provides staff support to committees, which includes salaries, travel to meetings, etc., as well as other types of administrative support for committees such as covering the cost for meeting room rental, refreshments at meetings, etc. AAMI has 9 full-time staff to support this work, a technology platform to manage the process, and other typical "lean, non-profit" office expenses.

AAMI also absorbs some of the cost of participation for users and independent experts (e.g., academic experts). We do not require these independent participants to pay a participation fee. We also have a significant user travel fund ($100,000/year) to help defray the cost of participation for users.

Infrastructure support (ANSI, ISO and IEC dues greater than $60,000/year) are another significant cost of standards development, including the cost of keeping our staff current on changes to ANSI essential requirements, ISO and IEC procedures; monitoring the work of other standards developers that may duplicate or conflict with our work; participating in ANSI policy committees, etc.

In addition to AAMI's own costs to develop a standard, the total development cost must also look at the cost to committee members to participate in development. Industry committee members (or their employers) pay their own costs to attend meetings, and employers that sponsor their employees' standards participation are contributing "in-kind" services such as paying salaries of representatives for time spent at and between meetings on standards activity, costs to conduct round-robin testing of proposed new test methods and the like (e.g., Cad cam drawings).

In the early 1990's AAMI did an informal analysis of the cost to develop a voluntary standard and determined that the total cost per document was around $2.4M, with the cost to AAMI around $40,000-$50,000 per document. Those costs are at least 60% higher today, in the range of $55,000-$80,000 per document (average).

None of these costs would go away for standards development organizations if we were required to give away standards for free. The costs would simply have to be shifted to others. Such a model would be more unfair and imbalanced than the current structure, in which those who choose not to participate pay nothing unless they want to use a standard.

- 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?

  There are thousands of voluntary standards available for use by the federal government. It is significantly cheaper and less time consuming for the government to use standards developed by others than to develop their own. In addition, standards committees of private standards developing organizations include broad and expansive expertise – representatives of companies who actually manufacture the product being standardized and so are very knowledgeable about the product, how it is made, how it is tested, etc.; users of the product, who understand the practical considerations and risks of day-to-day use and other related issues (e.g., in the case of medical devices, users have medical expertise which is helpful in setting safety-related parameters); independent experts such as consultants, academics, and testing labs; and government representatives.

- 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 the public, especially in regard to the significance of the changes in the standards?

  AAMI reviews all of its standards, regardless of how they are used by the federal government, no later than five years from their last approval. AAMI invites and accepts comments at any time on final documents. Consequently projects to amend or revise standards often occur before the five-year mark based on comments from users of the document, or from committee members.

6. Using and Updating Standards in Regulation.
   - 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 for doing 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)?

     AAMI thinks best practices could be helpful if they are not generic practices but limited to examples that worked. One example is the reference to AAMI HE 75 as a standard to be used in making medical devices accessible as part of the Affordable Healthcare Act. The U.S. Access Board needed to write standards to facilitate the accessibility requirement of the Act and chose Chapter 16 of this human factors standard as a tool for helping to achieve the requirements. AAMI allowed the

Access Board "read only" access to the relevant Chapter 16 of the standard so the readers, and potential manufacturers, could understand the requirements being set forth and have a better understanding of the value of the standard as a tool for achieving the level of accessibility required by the Act. This practice made the requirement more understandable and AAMI did not have to make the entire 465-page document available at no cost to accomplish the goals of the government.

As previously noted, agencies should be encouraged to respect copyrights by citing standards in regulation, only, or if the agency needs to incorporate a standard in whole or in part directly into regulation, doing so only with the prior, written approval of the standards developer.

In addition, for our industry, incorporation by reference is preferred not only from a copyright standpoint, but also in terms of making updating of the regulation more efficient when standards are revised.

- 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?

Yes. Keeping regulations current with the latest edition of voluntary standards cited in regulation has been a long-standing problem. When appropriate, agencies should cite the current "or latest" edition. When that is not appropriate and they cite date-specific standards, when updating the citation some sort of transition period should be allowed when either the new edition or the previously cited edition can be used, since it takes time for industry to change to the new edition.

For medical devices, a typical transition period is three years though a shorter period may be called for in select cases based on, for example, an urgent safety need. Guidance should also include a target time-frame for considering new editions such as six months from the date of publication, and a requirement to provide a rationale directly to the standards developer if an agency decides to retain citation of a superseded standard rather than updating to the latest edition so that this can be considered by the committee that developed the standard, which may want to amend the latest edition in order to make it suitable for government use.

That said, it is highly preferable for government to actively participate in the development of standards and to clearly identify any "must have" requirements, from a government standpoint, during the development stage rather than bringing these up after a document is completed. It adds significant cost to the system to have to engage in early revisions or amendments to address comments that were not brought up during initial development, and it is inefficient for a government

agency to decide to issue a regulation when its issues could have been addressed in a standard if the agency's participation had been more proactive.

As noted earlier, for our industry, incorporation by reference should be considered a best practice, because it makes updating of the regulation more efficient when standards are revised.

7. OMB recognizes that changes in technology and the need for innovation can result in the updating of private sector standards in a turn-around time of two years or even less. Where such standards are already incorporated into regulations, these changes can suggest a need to update the relevant regulations as well and, in some cases, can result in a need for regulated entities to purchase the newly updated standards on a fairly routine basis. In addition to the costs associated with the continuing purchase of such standards, rapid update cycles may make it difficult for the regulated public to understand the nature and significance of the changing regulations.
   - 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?

     Although medical devices are considered fast-changing technology, standards-developing committees have indicated a need for "stability" of standards because the time is considerable to meet new standards and to get products approved by government regulators who use standards as evidence of conformance with regulations. That said, guidance that helps an agency understand the evolution of standards and gives them guidance on how to manage regulations in the face of changing standards, perhaps with a menu of best practices to choose from based on common parameters, could be helpful.

     AAMI suggests the OMB put together a panel of ANSI, SDOs, and agencies that rely on standards and need to manage their revisions, etc. to develop the guidance, since it is unlikely that a single approach would work given the differences between products as well as differences in rulemaking authority of various agencies.

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

     In FDA/CDRH this does not seem to be necessary. CDRH has a robust recognition program that updates the recognized standards list twice a year and links the relevant regulation or regulatory authority to that recognition. This is another best practice that could be used to better manage the use of standards in support of regulations government-wide. It is efficient and cost effective – in short, it works and should be recognized and supported.

- 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?

  This probably varies significantly from agency to agency. AAMI would note that some standards developers, including AAMI, have policies that preclude them from actively soliciting adoption of their standards by government regulators because of concerns about maintaining objectivity, potential restraint of trade claims or for other reasons. This does not mean that AAMI is opposed to such use, only that AAMI considers this a matter best decided between industry (and its various trade associations) and the government. That said, AAMI would be happy to discuss any coordination issues with FDA or other government agencies considering citing AAMI standards in regulation as necessary.

8. Use of More Than One Standard or Conformity Assessment Procedure in a Regulation or Procurement Solicitation.
   - 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?

     As noted in the full question, recognition of a single standard versus multiple acceptable standards will vary depending on the product covered by the standard, whether the standard covers safety of a product versus being a standardized specification or test method, or whether the standard is being used by the government for regulatory purposes as compared to use for procurement. The panel approach suggested above might also be an appropriate mechanism for developing guidance on conformity assessment, which would necessarily involve several different best practices. In the case of medical devices, both industry and the government have a preference for a single, standard and, to the extent possible, one that is recognized worldwide. With regard to conformity assessment activities, ideally industry would like the need for multiple testing to be minimized, so it would be helpful if various U.S. governmental agencies with jurisdiction would accept the same test results, as well as coordination between U.S. and foreign regulators regarding acceptable conformity assessment protocols and evidence of conformity. The lack of consistency between agencies can be expensive, duplicative, and confusing, for both the federal government and industry.

   - Where an agency is requested by stakeholders to consider allowing the demonstration of conformity to another country's standard or the 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 in this area would be helpful. On the one hand, mutual recognition can have a positive impact on U.S. competiveness, keeping costs for products (and regulatory costs borne by taxpayers) low, etc. At the same time, there must be appropriate safeguards in place to ensure that conformity assessments by approved parties, whether they are first-party declarations, done by private third-party entities, or performed by government employees, are consistent and of high quality, thereby affording adequate protection to consumers/the public, and also giving manufacturers whose products are tested a level playing field.

9. Other Developments
   - 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?

     Both nationally and internationally, the growing complexity of technology, and the cross-over between industries and within industries (product systems), are major changes that should be considered, in addition to the rapid growth of industry in developing countries such as the BRICK nations (Brazil, Russia, India, China, and Korea). OMB changes related to use of standards in regulatory agencies could potentially upset some of the growth and regulatory cooperation currently on-going. As a result of the work of the Global Harmonization Task Force (now evolving into The International Medical Device Regulators Forum) and other international efforts to harmonize standards and regulations, changes made to the development and utilization of medical device standards could have global implications and significantly change the way this industry is managed and regulated around the world.

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

     Some so-called "consortia" standards are widely used and represent the international standard, and government should be prepared to participate in these activities as needed. But others are not even standards and are not well developed or have private, angular agendas. ANSI accreditation of organizations developing consortia standards is a useful filter for ensuring that a standard is in fact, consensus based.

- Are there other issues not set out above that OMB might usefully seek to address in a supplement?

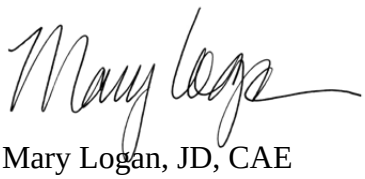
  The questions seemed quite comprehensive. AAMI appreciates being asked for its input.

Closing

If the OMB makes changes that negatively impact a SDO's intellectual property rights and ability to defray some of their expenses through the sale of standards, this would definitely turn upside down a carefully developed and well-accepted business model for a small non-profit organization like AAMI. It also could have global implications. Standards are never free. Those who do not participate in the development cost of standards – and yet believe they are entitled to free copies of standards that are incorporated by reference into regulations – misunderstand the real expenses of developing standards. Ironically, a different rule could have a greater negative impact on the access to standards and the standards development process than the current rule – and ultimately could impact the strength of the standards development process by making it cost prohibitive for users, academics, independent experts, and small or start-up companies.

Thank you for the opportunity to comment on these important matters. If you have any questions regarding our remarks, AAMI would be happy to meet with you to discuss.

Respectfully,



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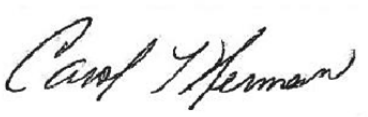

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