8 February 2011

To: SOS_RFI@nist.gov

Re: Standardization feedback for Sub-Committee on Standards

This is in response to the Request for Information on the Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for National Science and Technology Council's Sub-Committee on Standardization that was published in the December 8, 2010 Federal Register [Docket No. 0909100442-0563-02].

Introduction and Background

The Association for the Advancement of Medical Instrumentation (AAMI) provides global leadership and programs to support the health care community in the development, management and use of safe and effective medical technology. One of the main programs of the association to support its mission is Standards Development. AAMI is accredited by the American National Standards Institute (ANSI) to develop American National Standards for healthcare technology, operates several international technical committees and subcommittees of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) on behalf of ANSI (the official U.S. member to these bodies), and also administers U.S. technical advisory groups (TAGs) to these and other ISO and IEC committees.

The medical device industry is a relatively large user of the voluntary standards system owing to the unique nature of the numerous products that fall under the general category of "medical device" as well as the complex nature of medical devices. This requires a number of device-specific standards as well as a number of standards that cover general aspects and processes such as sterilization, biocompatibility, general electrical safety, quality systems, and risk management. With the main emphasis on patient safety, input from knowledgeable users (doctors, nurses, clinical engineers, etc.) regarding both medical and human factors (usability) issues is especially helpful and important.

While AAMI members have a growing interest in healthcare informatics, AAMI specializes in the development of medical device safety and performance standards that are intended to be used in a regulatory context. Like other highly regulated industries, the medical device industry relies on voluntary standards as a means of establishing with regulators and customers what technical requirements must be met in order to demonstrate compliance with regulations affecting their products. Therefore, to ensure regulatory compliance, manufacturers must commit significant resources not only to keep track of how regulations vary from one place to the other, but also to keep track of what standards apply where, which standards requirements are identical and which are

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different, and then keep this information up-to-date as standards are reviewed and revised. As burdensome as these standards tracking costs are, they pale in comparison to the cost of designing different products for use in different markets in order to comply with the "local" standards. Development of multiple versions of a product for sale in different markets also adds the additional cost of performing multiple tests to demonstrate conformity to requirements of individual markets -- costs that are ultimately borne by the consumer.

In short, in a global marketplace, the objective of the standardization process must be a single, technically valid and globally relevant standard with a single test of conformance to that standard, and a growing number of AAMI's American National Standards are identical adoptions of ISO and IEC standards that were developed with strong input from U.S. experts, including FDA representatives. In terms of regulatory acceptance, many ISO and IEC standards for medical devices are adopted or recognized by regulators in Europe ("European Norms/Harmonized Documents"), the U.S FDA, and regulators in other major markets and can therefore be used by industry as a means of demonstrating compliance with national and/or regional regulations. Since this is a major goal of the industry's strong support for international standards, they consider active and effective participation by regulators in voluntary standards development essential, as this helps increase the likelihood that the final document will be acceptable to regulators.

Regulators also have a number of things to gain by participating in standards development activities. Committee membership is a good way to stay up-to-date on cutting-edge technology. Voluntary standards development allows manufacturers, users and regulators to discuss the risks and benefits associated with a device or process in a non-confrontational, science-based setting, with participation from a wide range of highly specialized experts on numerous topics. In addition, governments rarely have the resources to effectively and efficiently develop standards and keep them up to date (which is critical in a regulatory context). To be effective, such standards require strong input from industry and the professions, i.e., the developers and the users of technology, as well as from regulatory interests. For these reasons, the voluntary consensus standards system should be seen by governments as a viable alternative to developing their own technical standards, and active participation by regulators and other government agencies (e.g., those interested in standards from a procurement perspective) enables government to have an impact on the content of documents that they need to help fulfill their mission.

We also believe that agencies with an interest in standards – whether from a regulatory or procurement perspective – should participate in international standards development. Participation can be done indirectly by joining the U.S. technical advisory group (TAG) that is responsible for submitting U.S. votes and comments on international standards, or directly by getting nominated to an international working group by the U.S. TAG. Given the global marketplace and number of component parts as well as finished products that are traded internationally, government should be as effective in international standards development as it is in national standards development.

On a final note, as standards in the health care field rarely lead technology, their adoption as regulation may inappropriately preclude cutting edge technology and become a barrier to innovation. Such barriers do not serve the best interest of patients, manufacturers or governments. Therefore, governments should view voluntary consensus standards as a

way, but only one way, to demonstrate compliance with relevant regulatory requirements. However, when public health concerns mandate the adoption of standards, they should be incorporated by reference in regulation.

Current government participation in AAMI national and international standards activities

Including working groups, AAMI administers133 national standards committees and TAGs. Total international committees that AAMI is involved with either as secretariat or U.S. TAG administrator, including working groups, is 113. Approximately 8% of the 1,986 individuals serving on one or more of these committees are with the federal government, primarily from the Food and Drug Administration.

Committees (non-duplicating):

Affiliation of members	**Natl Total**	**Intl Total**	**Grand Total**
All affiliations	*133*	*113*	*246*
FDA/CDRH	131	53	184
Military - VA (medical centers)	19	5	24
Military - VA (national center)	5	2	7
CDC	3	1	4
NIST	3	1	4
NIH	2	1	3
CMMS	1	0	1
FCC	1	0	1
Military - Air force (national)	1	0	1
Military - Defense Supply Ctr	1	0	1
Military - DoD	1	0	1
Military (national)	1	0	1
NIDRR	1	0	1

Individuals on AAMI committees/TAGs, and U.S. experts on international WGs (non-duplicating):

Affiliation	**Individuals (non-duplicating)**
All affiliations	*1,986*
FDA/CDRH	147
NIST	5
Military - VA (medical center)	3
CDC	2
Military - VA (national center)	2
NIH	2
CMMS	1
FCC	1
Military - Air force (national)	1
Military - Defense Supply Ctr	1
Military - DoD	1
Military (national)	1
NIDRR	1

Comments on Effectiveness of Federal Employee Participation

Generally speaking, we advise all of our committee members, regardless of interest category, that in order to be effective they should raise issues as early in the development process as possible, and be sure to review and comment on all drafts since major changes can occur from one iteration to the next.

The FDA's Center for Devices and Radiological Health has a strong and effective program for participation in standards development, their representatives hold a number of committee leadership positions and have been very effective in that role, and the agency also has shown support for the voluntary standards system by recognizing numerous national and international standards for medical devices.

If this is not already the case, we recommend that the same internal group that will determine whether to adopt or recognize a final standard should be involved in some way in developing agency positions on drafts while the document is under development -- it is not in industry's or government's interests to learn of major issues the government has with a document only after it is finalized and published.

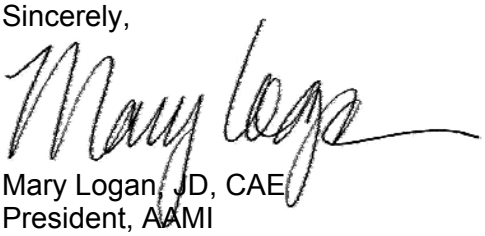
While participation by the agency with primary regulatory responsibility is, of course, extremely important and valuable, we would like to see increased participation by other agencies and Departments within the federal government. Other agencies could provide different perspectives and therefore increase the level of national (and international) consensus regarding the appropriate content of our standards. We expect that, given their different missions, there will not necessarily be agreement between representatives of different parts of the government on all matters but would hope that, through direct participation by a wider range of government interests, we can develop a broader consensus agreement and perhaps avoid the problem that occasionally arises when two different agencies adopt different, and conflicting, standards. One example of this is that the FDA (and medical device regulators around the world), which was heavily involved in the development of the third edition of IEC 60601-1, has now recognized that standard and indicated that the previous edition will no longer be recognized after a three year transition period. OSHA, which was not involved and which references the previous edition for different and much more limited purposes than FDA, is now indicating that it will not recognize the third edition. This presents some serious difficulties for industry.

Beyond providing various governmental perspectives and trying to resolve differences while documents are still in development, the federal government could provide a great service to patient safety by encouraging doctors and nurses employed by the VA or various military branches to join technical committees and actively participate in standards development. It is becoming more and more difficult to find doctors and nurses from the private sector with the time and financial resources to attend technical committee meetings and to participate between meetings by reviewing and voting on drafts. Perhaps the VA and various branches of the military could encourage their doctors and nurses to participate by providing travel support and recognizing time spent on standards development as work hours.

Similarly, it would be useful to have more participation from government researchers who work in medicine or public health on certain activities.

We hope that the above input is helpful. Please do not hesitate to contact us if we can provide any additional information.

Sincerely,



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