

AAMI Response to Request for Comments on Incorporation by Reference

1 CFR Part 51 [NARA 12-0002]

National Archives and Records Administration, Office of the Federal Register

Thank you for the opportunity to comment on the petition submitted by Professor Peter Strauss *et al.* to the Office of the Federal Register (OFR), regarding the availability of material incorporated by reference (IBR) in the Code of Federal Regulations (CFR).

The Association for the Advancement of Medical Instrumentation (AAMI) respectfully submits the following comments addressing two main issues:

- Why IBR matters to AAMI and the standardization community
- The nine specific questions asked by the OFR in the *Federal Register* notice

Why Does IBR Matter to AAMI and the Standardization Community?

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.

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.

The U.S. Standardization System

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.

Standards are the backbone of trade, the building blocks for innovation, and the basis for quality, safety, and interoperability. Voluntary consensus standards and compliance activities are essential to the U.S. economy. Market driven and highly diversified, standards support technological innovation, build bridges to new markets, and create gateways for businesses in this increasingly complex world of global access. Standardization also helps to assure health, safety, and quality of life for individuals in the United States and around the world.

Our national standardization system is a democratic process that thrives on the active participation and engagement of all affected stakeholders. The open, market-driven, and private sector-led nature of our system is critical to achieving the widely shared policy goals of expanded U.S. leadership and innovation on the global stage.

Currently, the U.S. has the most robust standardization system in the world, which gives the nation a competitive advantage. Unlike the standards development systems of many other countries, the U.S. system considers the views of all interested parties in a balanced way. And the openness of the system to new participants means that their needs can be met quickly and through innovative, collaborative solutions.

Decisions made about our national standardization system and our priorities for action reach far beyond our borders, especially when it comes to the continued success of our products, services, and workforce on the global stage. Any decisions or actions that would fundamentally undermine this system will cause the U.S. to lose this competitive advantage. Additionally, significant changes to the system would compromise the role that standards play in protecting health, safety, and the environment.

Why Does IBR Matter to the Standardization Community?

Every standard is a work of authorship and, under U.S. and international law, is copyright protected¹, giving the owner certain rights of control and remuneration that cannot be taken away without just compensation.

Although many people working on standards development are volunteers, AAMI incurs significant expenses in the coordination of these voluntary efforts. From the time a new project is commenced until the final balloting and adoption of a standard, the drafting process draws heavily on AAMI's administrative, technical, and support services. The primary cost of a standard is the development, not the cost of printing and disseminating the document.

SDOs are – for the most part – non-profit organizations. AAMI is a non-profit organization. In order to recoup costs, AAMI relies heavily on revenue from copyright-protected sales and licensing of the standards. By funding operations at least in part through sales and licensing of standards, AAMI can minimize barriers to qualified participation and maximize independence from entities seeking to influence the outcome for commercial or political reasons. Standards sales also allow AAMI to recoup basic administrative costs while passing on to implementers all of the benefits of the voluntary and inclusive process of standards development, including openness, balance, opportunities to participate, and protection from undue influence.²

The U.S. government's announced policy under OMB Circular A-119 is to "observe and protect" the right of copyright holders when incorporating by reference into law voluntary consensus standards. The very purpose of this policy is to permit the government to benefit from the efficiencies of the voluntary consensus standards development process. When the government references copyrighted works, those works should not lose their copyright, but the responsible government agency should collaborate with the relevant SDOs to ensure that the public does have reasonable access to the referenced documents. In addition, considerations have not been given to the use of international standards and who will pay the royalty fees to the international standards developers should their standard be referenced. The only work-around for this could result in the limited use of international standards which would upset the

¹ <http://www.copyright.gov/title17/>

² ANSI Essential Requirements, <http://www.ansi.org/essentialrequirements>; World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement Principles for the Development of International Standards, http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

critical international harmonization efforts what support and enhance the medical device regulatory process.

Responses to Questions from the *Federal Register* Notice

1. Does “reasonably available”

- a) mean that the material should be available
 - i) For free and
 - ii) To anyone online?
- b) Create a digital divide by excluding people without Internet access?

AAMI believes that standards and associated documents should be available to all interested parties on a reasonable basis, which includes appropriate compensation as determined by the SDO/copyright holder. AAMI has consistently kept the price of its standards low to ensure reasonable availability.

“Reasonably available” should not be strictly defined using terms such as “for free” and “to anyone online;” rather, the definition should encompass a broad spectrum of access options.

“Reasonably available” means that the public and private sectors should work together to make standards available on a timely basis and readily accessible – either for free or at reasonable prices – to anyone who wants them. This approach is already working in the marketplace, and AAMI has not been affected by any instances where access was denied to an individual or organization. AAMI continues to actively consider further efforts that can be made to make documents available.

The internet has certainly expanded the public’s access to information. However, it has not changed the underlying protections of intellectual property, nor has it changed the need and the ability of standards developers to cover the significant costs of creating the documents that are used to further public policy goals in law and rulemaking.

2. Does “class of persons affected” need to be defined? If so, how should it be defined?

AAMI does not believe that this term needs to be defined. CFR language states that a document incorporated by reference must be “reasonably available to and usable by the class of persons affected by the publication.” But depending upon the standard being referenced, the “class of persons affected” may vary significantly.

3. Should agencies bear the cost of making the material available for free online?

AAMI would discourage agencies from bearing the cost of making materials available for free online. If agencies subsidize the costs of standards, then budgets will need to be substantially increased in order to pay such costs, either through taxes or additional interest on the national debt. As it currently exists, the FDA budget does not fully support the regulatory mandate of the agency and could not be relied on to consistently support standards development even though they rely heavily on the documents in the

premarket review process. FDA should continue on the path that has already proven successful – working with the AAMI in order to determine the best mechanism for making those documents reasonably available.

4. How would this impact agencies budget and infrastructure, for example?

As indicated above, agency budgets would be significantly impacted by undertaking the responsibility to provide all referenced standards for free online. In addition, new contracting mechanisms could be required to negotiate with AAMI on appropriate compensation for standards development and dissemination. This could actually cost more due to the potential need to develop additional national standards in lieu of international standards significantly used by the FDA. A separate but equally significant issue would be the real or perceived undue influence by a single stakeholder – the U.S. government – in the consensus-based standards development process.

5. How would OFR review of proposed rules for IBR impact agency rulemaking and policy, given the additional time and possibility of denial of an IBR approval request at the final stage of the rulemaking?

Both in the development of voluntary consensus standards and the federal rulemaking process, stakeholders have adequate opportunity to review pending standards and regulations and provide feedback. As a member of the national body that facilitates standards development, AAMI follows strict guidance for the standards development process and provides monthly notices of upcoming development activities and requests for comments. Further, the OFR does not maintain expertise in the subjects FDA identifies for rulemaking. If OFR were to circumvent the development of rules and regulations by agencies with the statutory expertise and obligation, OFR would essentially drive the development of rules and regulations, which is not part of its mission.

6. Should OFR have the authority to deny IBR approval requests if the material is not available online for free?

For the many reasons outlined above, OFR should not have the authority to deny IBR approval requests solely on free availability of the referenced document. Requesting such authority would likely place OFR in the midst of a contentious fight involving numerous federal agencies and many private-sector entities over copyright limitations. See the response to question 8 below.

7. The Administrative Conference of the United States recently issued a Recommendation on IBR. 77 FR 2257 (January 17, 2012). In light of this recommendation, should we update our guidance on this topic instead of amending our regulations?

ACUS speaks with the authority of the General Counsels of U.S. government departments and independent agencies. It is both an independent federal agency and a federal advisory committee. Updating OFR guidance on IBR based upon the ACUS recommendation, which was passed on a voice vote at the December 2011 ACUS Plenary, may be useful. But not all agencies were included in the

development of the recommendations and the ACUS recommendations could impact those agencies significantly. In addition, one recommendation included “read only” access to standards online. While this seems a reasonable approach on the surface, it also presents other issues. There is no such thing as “read only” access. All documents can either be downloaded or photographed to provide the reader with free access to the entire document. Most, if not all, SDOs provide free access to the scope and table of contents to standards documents. Where appropriate, AAMI has also provided free access to a chapter or relevant section to a document to provide more clarity and relevance to the rulemaking. This is a reasonable approach without jeopardizing the revenue of the document. AAMI recommends more work be done before implementing the ACUS recommendations.

8. Given that the petition raises policy rather than procedural issues, would the Office of Management and Budget be better placed to determine reasonable availability?

As described above, the SDO community has already been working in partnership with agencies to make standards available as appropriate. AAMI works very closely with the FDA and will continue to do so. This issue is already the subject of policy in OMB Circular A-119; it is unclear that there is any new need to escalate this issue to a policy level. But if that course of action is pursued, then OMB could be the appropriate office to set the parameters of acceptable agency use of IBR, including recognition of copyright protections.

9. How would an extended IBR review period at both the proposed and final rule stages impact agencies?

An extended review period at various stages of rulemaking at agencies would almost certainly further slow this already complex and time-consuming process. This could have a chilling effect on agencies’ willingness to refer to voluntary standards in support of regulatory actions, which would undermine the federal policy set forth in OMB Circular A-119. Medical device technology is fast-moving and the standards are in constant revision and update. If an additional layer of review was added to this delicate process the result could negatively impact the availability of current standards for the medical device premarket review process.

Conclusion

Standards are inextricably linked to all facets of our national economy and are vital to the continued global competitiveness of U.S. medical device industry and the maintenance of appropriate health and safety protection mechanisms. AAMI appreciates this opportunity to share more information about our role in the U.S. standardization system, and welcomes further dialogue on this critical issue.

We thank you for this opportunity to provide comments.