Q&A: AAMI's Health IT Standards Initiative

For almost two decades, AAMI has developed international and domestic standards for regulated health software and health information technology (IT). AAMI also has decades of expertise in the development of risk management and quality system standards designed specifically for technology used in healthcare (historically, regulated technology). More recently, the vital role that sector-specific quality system and risk management standards can play in promoting patient safety and health with non-regulated health IT has been recognized. AAMI is launching a new Health IT initiative to develop such standards in accordance with the association's mission to "advance safety in healthcare technology."

What standards are being developed?

AAMI will develop two American National Standards—*Risk Management for Health IT,* and *Application of Quality Management Principles to Health IT*, under the auspices of the American National Standards Institute (ANSI). The first standard—HIT1000—will provide a process for managing risks to patients posed by clinical systems and health management (IT). This standard will define the roles and responsibilities of those involved in creating, implementing and using health IT; outline methods for identifying and quantifying risks; and provide guidance for establishing mitigation strategies.

The second standard—HIT2000—will define quality system principles applicable to health IT and will detail the application of quality management best practices to improve patient safety.

While the standards are being developed initially for national use, the intent is that they will be suitable for advancement as international standards through the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Why are these standards being developed?

Standards already exist for high-risk medical device health IT. However, other health IT can still pose risks to patient health and safety. The U.S. FDASIA Health IT report, jointly released by the

ONC, FDA, and FCC[1], called for the application of risk management practices and quality management principles by health IT vendors as a way to manage and mitigate risks and to promote patient safety. The importance of quality system practices and a risk-based framework in promoting the delivery and implementation of consistent, high-quality clinical health IT has been identified by various organizations.[2] Internationally, the need for these standards for health IT and health software has been recognized by an ad hoc task group on health software standards operating under the joint auspices of the ISO/TC 215, *Health Informatics,* and IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.[3]

Why not use existing standards?

While general quality system and risk management principles are covered in many existing standards, these standards do not offer the sector-specific detail needed to ensure consistent application across the health IT industry. In addition, these standards do not provide the requisite focus on patient safety, health, and security necessary for the health IT sector.

There are of course well-developed quality systems and risk management standards for medical devices[4], but these are intended for use in a highly regulated environment, which does not exist in the United States for non-medical device health IT. In addition, these standards do not take into account the very different life cycles of health IT, the special conditions created when such IT is custom implemented and configured, or the need for shorter timelines for fixes and urgent changes. These dissimilarities dictate that health IT quality systems and risk management must emphasize principles and practices different from those emphasized for medical devices.

Why are the existing risk management practices and quality management systems used by HIT vendors insufficient, and how will HIT standards help?

Standards are a way for a community to share knowledge and develop consensus on what is required to advance patient safety, health, and security. Without sector-specific standards defining what is expected of health IT vendors, it is difficult for the community to objectively ensure that practices across the industry are sufficient. In addition, the lack of specific standards means there is inconsistency across vendors. This situation hinders communication between vendors and their customers. Furthermore, given the importance of custom implementation and system evolution, such a scenario creates potential risks and complicates risk mitigation.

---

[1] U.S. FDASIA draft Final Report on Health IT (April 2014).

[2] (e.g., IOM Report on Health IT and Patient Safety, Bipartisan Policy Center: An Oversight Framework for Assuring Patient Safety in Health Information Technology).

[3] Draft Report of the ISO/TC 215-IEC/SC 62 *Joint Task Force on Health Software*

[4] ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes*, and ISO 14971, *Medical devices – Application of risk management to medical devices*, for example.

The creation of industry-specific standards or guidance is not intended to supplant existing quality management systems or risk management frameworks; it is intended to establish consistency and consensus on the minimum requirements for such frameworks and practices, enabling HIT vendors to assess their existing systems and improve them if necessary. In the absence of defined minimum standards, the industry will be judged by its worst actors by both customers and potential regulators.

Why is AAMI the right organization to develop these standards?

AAMI is an accredited standards developer under ANSI and has been developing standards for healthcare technology for almost half a century. The association has extensive experience developing both American National Standards and International Standards for quality management systems and risk management in the healthcare technology sector. AAMI administers the international committees and working groups responsible for standards covering quality management and risk for medical devices, healthcare IT networks, and health software under the auspices of ISO and IEC[5]. AAMI is an experienced convener of diverse stakeholders and has the institutional knowledge base and expertise necessary to launch this project.

Who should participate in the development of these standards?

Any stakeholder with a direct and material interest in these standards may apply to be on the committee, including the following:

- health IT producers, vendors, and manufacturers;
- healthcare providers;
- healthcare IT professionals;
- patient advocacy organizations;
- government representatives and regulators; and
- health IT association subject experts.

What is required of participants?

As detailed in the AAMI Standards Committee Code of Conduct, participants must be committed to advancing standards within their agreed scope, agree not to hinder their development, and support AAMI's goal of advancing patient safety and technology. Participants must agree to uphold the key principles of AAMI's standardization: consensus, due process, honesty, openness, transparency, fairness, effectiveness, relevance, and coherence.

[5] ISO/TC 210, IEC/SC 62A, ISO/TC 215-IEC/CS 62A JWG 7, Joint work on health informatics and electrical equipment in medical practice

Participants are encouraged to take part in meetings, in person or via the web. Participants must be engaged in providing timely input on drafts and proposals and are required to respond to every formal ballot with a vote or an abstention. In addition, participants must comply with the AAMI Antitrust Policy, Patent Policy, Conflict of Interest Disclosure Policy, and other policies as detailed in the AAMI procedures.[6]

Is there a membership requirement or other charge for participation?

Representatives of patient interests, clinical interests, academic interests, or healthcare delivery organizations: There are no fees for what AAMI calls "user or general interest" stakeholder participation, although all members must have a direct and material interest in the standards being developed. These are individuals who have no commercial interests.

Regulatory interest members: There is no fee required for regulatory interest participants; however regulatory agencies are *requested* to support AAMI by becoming a sustaining member ($7,500 per year).

*Vendor and related commercial interests***:** Representatives with a commercial interest in standards development are invited to become members, and the membership dues are published on AAMI's website.

Any health IT vendor that wishes to participate **only** in these two health IT standards activities must pay an annual participation fee based on total gross revenue from worldwide healthcare sales as detailed below:

Total gross revenue from health IT and other medical sales	**Yearly assessment for participation**
0 to $1 million	$500
>$1 million to $10 million	$1000
>$10 million to $50 million	$2000
>$50 million to $100 million	$3000
>$100 million to $250 million	$4000
>$250 million to $1billion	$6000
>$1 billion to $3 billion	$8000
>$3 billion -5 billion	$10,000
>$5 billion -15 billion	$13,000
>$15 billion	$15,000

These fees will be implemented beginning **1 January 2016.** Fees are waived for AAMI corporate members.

[6] http://www.aami.org/standards/about.forms.html

Note: Vendors that pay the above user fees are paying only for participation on these two AAMI committees. Participation on any other AAMI standards committees will require reversion back to the standard AAMI non-member corporate participation fee or full corporate membership.

Non-members of the committee may attend meetings as observers without voice or vote and submit input on proposed standards during the official public review.

How long will the development process take?

No standard can be completed without establishing consensus, but AAMI is planning a two-year target for the completion of these standards (by late 2016 or early 2017).

How do I get more information or apply for membership in the HIT standards development activities?

Contact Joe Lewelling by phone (703-253-8281) or e-mail (jlewelling@aami.org) for more information on participating in the standards work. See also:

http://www.aami.org/hottopics/interoperability/index.html

March 2015