Executive Summary: The AAMI Health Information Technology (IT) Standards Initiative held its second meeting on 19-20 January at the AAMI offices in Arlington. Individuals representing clinicians, HIT developers and vendors, government agencies and patient safety experts met to continue work on the two draft American National Standards addressing the application of quality system (QS) practices and risk management (RM) practices to health IT and health IT systems. These standards will define the roles of those involved in developing and using health IT and related systems and the responsibilities associated with those roles with respect to QS practices and RM processes. Rather than having an organization-centric focus, these standards will apply throughout the Health IT ecosystem and across the full health IT product lifecycle.” The committee expects to complete the first editions of these standards by early 2017.

The committee also explored possible work on guidance for user-centered design processes for health IT and user-interface design guidelines.

1. Opening
   — Welcome by AAMI staff and the Committee cochairs
   The meeting was convened at 9 a.m. on 27 June 2016.

   Mary Logan, the AAMI President, welcomed the attendees and spoke about the challenges and value of this effort (the AAMI Health IT Initiative). Michael Marchlik, as cochair, welcomed everyone and expressed appreciation given that there were conflicting events. He noted that initial working had been pulled together, but much work would be needed to move the work forward.

   — Introduction of the attendees (committee members and guests)
   Attendees introduced themselves. The list of attendees is attached (Attachment A)

   — Review of AAMI Antitrust Statement (attachment A), Standards Committee Code of Conduct (attachment B) and AAMI Patent Policy (attachment C)

   The antitrust statement, code of conduct and patent policy were reviewed and explained to the attendees.

2 Approval of the agenda
   The agenda for the meeting (doc. HITN040) was reviewed and approved.
3. Approval of the minutes of the 21 October 2015 inaugural meeting of the AAMI Health IT Committee (to be distributed)

The minutes of the 21 October meeting (doc. HIT N041) were reviewed. Staff reviewed the standards development process that had been formally explained during the opening meeting. It was noted that there was an urgent need for the standards and that the work was targeted for the end of 2016 or early 2017 for initial completion (as provisional American National Standards. During review of the minutes, the attendees

- Discussed the IOM and FDASIA reports, as well as the work of ISO TC215 & Joint Working Group 7.
- Noted that the AAMI work was complementary and will be developed in tandem with the international work.
- Reviewed existing QMS Standards and risk management standards and other resources and agreed that the intent of the new work was not to change these, but to support specificity for implementing and using HIT software and systems.
- Discussed the “actors and roles” involved in health IT and noted that the new standards would not focus on industry vs. user, but rather to detail activities, roles and responsibilities
- Discussed how cultural change could be instigated through training, education and learning.

Following extensive discussion, the minutes were approved.


The committee discussed the 20 October 2016 AAMI Stakeholder Workshop.

- The AAMI Whitepaper Report produced by an AAMI Task Force has been reviewed and would be released in the following months. It addressed good quality principles, but recognized the interdependency of risks. It would provide a high-level perspective on how to address development of health software and would attempt to lifecycle implementation for all stakeholders.

- The stakeholder event had shown that the problem statement was understood. Everyone agreed that there was a problem (though not necessarily on its magnitude.) What was proposed in the new standards would be the establishment of a framework for shared responsibility, so that all actors could work from the same game sheet with clarity of understanding of their roles. This would be an iterative and evolutionary process, and culture, healthcare delivery organizations, and regulatory processes would have to change. It would also be a long term process and it is difficult to envision at an early how success would be measured. Patient safety was of utmost importance. Security was key as well.

5. Review of the plan of work for the Committee

   — Membership

Staff noted that members were being recruited and an online application form had been made available. Twenty-nine (29) applications had been received and were being processed. The membership of the committee and any working groups would be finalized for the next meeting. It was noted that there was no fee or membership requirement to be a participant for user or general interest representatives. For commercial interests (developers and vendors) there would be a participation fee. (Corporate members were exempt from the fee).

Questions were raised about outreach to stakeholders. It was noted that a long list of stakeholders that had previously been contacted and that over 120 stakeholders and organizations had received the documents for this meeting. In the future, document distribution would be to the committee only and additional outreach would be necessary at various points in the process.
— Work program

The committee had two approved work items—HIT1000 (health IT risk management) and HIT2000 (health IT risk management). Two draft work items had been received and would be considered later in the meeting. The committee would also serve to review and adopt international standards being developed by ISO/TC 215-IEC/sc 62A Joint Working Group 7

— Committee structure

At the previous meetings, the committee had agreed to create two working groups— one addressing quality management systems standards and one addressing risk management standards. It was noted that the two new work proposals addressing “usability” design processes and features would likely require the addition of a new working group if they were approved by the AAMI Standards Board. (See section 10 of this meeting report).

Staff noted that the AAMI HIT Committee’s role in providing U.S. input on the work of ISO/TC 215 and IEC/SC62A Joint Working Group 7 could require the formation of another working group in the future, given the expected increase in international work and the need to include medical device manufacturers in the process. (The AAMI HIT Committee addressed only health software and health IT systems, not medical device software or systems. The work of JWG 7 addressed both).


Sherman, co-convener of Joint JWG 7 and Neil Gardner gave a report of the November 2015 Bern meeting of Joint Working Group 7. (AAMI served as the secretariat of JWG7 and AHIMA served as the international secretariat TC-215. It was reported that the JWG 7 was proposing to initiate revision of IEC/ISO 80001 series on health IT incorporating health software or medical devices. JWG7 was also expected to propose new work on safety, effectiveness and security of health software and health IT and to begin revision of IEC 62304 which would address health software life cycle processes. Finally the final text of IEC 82304 which addressed safety of health software would also be issued sometime in 2016. The AAMI Health IT Committee would be asked to consider all of these document and proposals when they were issued.


The draft prepared by the drafting task group (doc. HITN042) was presented and discussed. This draft was created by leveraging four documents from U.K. National Health Service which oversaw HIT products in that country, but did not regulate them as medical devices. The focus of the draft was risk management— determining what can go wrong, how can it go wrong, what can be done about it, and who is responsible for doing it.

It was noted that there was a different philosophical view of risk management between some health care provider organizations that focused on loss prevention and damage control and those that focused on safety. This draft focused on safety, but it was important to stress the connection between safety and enterprise risk management.

It was reported that the Joint Commission and CMS were also trying to change the philosophy of health care providers to ensure that safety was the focus and to promote proactive risk assessment as opposed to reactive risk management. The recent sentinel event alert on HIT was noted as an example of this.

The draft required the appointment of a safety officer who was a clinician for both developer and user organizations. In development organization this may not be feasible or necessary. A multidisciplinary officer might be more productive and it was agreed that there needed to be more clarification of this role. Among the other issues that needed to be addressed or considered where

- The importance of skills and capabilities.
- The need for raining and understanding of the role and “go live” responsibilities.
- Roles or principles.
- Using a team-based approach.
- The possibility of developing a safety case across the lifecycle which would allow organizations flexibility in use and transparency through the process on how and what to document (and would improve
communication among different “roles”).
- The scope of HIT addressed (e.g., Does it cover CDS or not)?
- Should there be an appendix to provide examples?
- The development of maturity models could be helpful in clinical environment.
- The focus should be on “least burdensome” approaches.
- The standard needs to address or be applicable to LEAN development methods and agile, cloud and other non-waterfall development environments.
- The entire data lifecycle should be considered.
- Consideration must be given to various healthcare delivery models (e.g., neonatal, emergency, hospice or surgical environment).

The challenge will be to determine the general principles without diving too deep—to provide a level of specificity and flexibility to support all stakeholders.

Attendees were invited to send in comments on the document The drafting task group would meet again to prepare a more detailed document for comment by HIT and HIT/WG 01 before the next meeting.


The draft prepared by the drafting task group (doc. HITN042) was presented and discussed

Points of discussion included the following
- It was noted that lot of elements in RMS that should be included in the QMS document (e.g.; controls, feedback to support changes, life cycle).
- It was also noted that the scopes of the two documents (HIT1000 and HIT2000) should be aligned.
- As HIT matured, it moved from a standard implementation model to a fast pace model-more of a waterfall approach that no longer has phase gates. How will a standard address that model and be applicable to anyone that develops, implements or uses HIT?
- Normative references need to either be publically available or published.
- Validation that the design meets the needs of the customers is essential. HIT must meet customer (user) expectations for the use environment.
- Best practices examples are needed.
- Examples should be provided and included as a part of the learning environment. Examples could focus on roles of stakeholders in the process as well as type/size/maturity of the organization(s) in those roles.
- The document must take into consideration data management considerations, examples of varying scope levels to implement – large hospital, individual, etc.
- Quality management system processes must be consistent with life cycle process.
- Down time must be addressed. It is NOT just an IT activity as there are clinical implications that affect patient safety.
- The titles of each section need to consider the different users.
- Clinical use should have a separate section.
- The governance framework needs to be addressed.
- Overall change management must be fully addressed.
- Training is NOT just focused on who is involved in the development but also who is using it.
- How will HIT safety events reporting be dealt with? There are already LOTS of reporting systems with varying levels of access and confidentiality. Errors aren’t always reported as safety.

Attendees were invited to send in comments on the document The drafting task group would meet again to prepare a more detailed document for comment by HIT and HIT/WG 02 before the next meeting.

9. Review of the adoption strategy for HIT1000 and HIT 2000

The committee reviewed discussions that had occurred earlier about need for engagement of stakeholders and difficulty of getting the buy-in of health care provider personnel. Clinicians noted that it was hard to get their organizations or other clinicians (doctors nurses) to focus on these systems, yet the reliability of these system and
the availability and trustworthiness of the data were critical to their work.

The committee reiterated the need for tools, guidance and education to promote uptake and implementation of these standards and QS/risk management in HIT.

It was noted that the ONC was not interested in developing standards, but rather in coordinating them. The ONC’s plans for the HIT Safety Center and the "collaboratory", had not yet been funded and its future role in this area was uncertain. CMS, however, was working on electronic safety measures for HIT and this could be a new “fact” of regulation.

It was agreed that a formal task group should be formed to further develop an adoption strategy when the work was more mature.

10. Discussion of possible proposal(s) to develop AAMI standards or guidance documents addressing HIT usability and usability testing

AAMI had received two draft new work item proposals (doc HITN048 and HITN049) from Michael Wiklund of Underwriters’ Laboratories. Mr. Wiklund gave presentation on the need for standards addressing usability processes in the design of electronic health records. He noted such standard would be helpful in encouraging good human factors processes and practices and good usability practices when creating EHRs. The intent was not to create "requirements" but to provide tools that promote best practices and processes. Mr. Wiklund reviewed the history of the development of voluntary standards and guidance for human factors engineering and usability for the medical devices area that the standards process for medical devices has helped improve usability and safety. Still the EHR environment is much different in terms of the development environment and regulatory oversight. The medical device standards, while informative, were not directly applicable.

A question was raised as to how the new standards would be different than what NIST has already done?

Lana Lowry responded that the NIST report was not a standard, but guidance for standardization. What NIST produced was not a consensus-based document, but was intended as a beginning—something to be built on and modified by a consensus process to ensure that the efficacy and accuracy of the NIST recommendations were maximized and extended. The NIST work needed to evolve and advance. There was still a need guidance on design and benchmarks to prevent unsafe product from reaching market,

David Classen noted that "security" affects usability greatly (especially when it prevents access to, or use of, HIT). This should be considered. Lana responded that a separate team at NIST was working on this. David suggested that this should still be included in the committees work.

Matt Weinger noted that the design process standard would be the priority work item. This process scaled out based on risk management (and the process needed to be scalable). It should not be constraining in order to allow to innovation and migration to new platforms, technologies, etc. Second "usability" must be addressed early in the process. The design process guidance would be the critical piece. The design "recommendation" could follow.

It was agreed that the new work proposals would be sent to the AAAMI HIT Committee and placed on public review so stakeholder could provide input and comments. Any comments would be sent to the proposer who would respond and possibly modify them before they were considered by the AAMI Standards Board for approval at their on 5 June 2016.

11. Additional business

There was no additional business.
12. Review of target dates and plans for next meeting

The committee considered when to meet next. It was agreed that the drafting groups should continue to develop the drafts and these could be considered at meetings of HIT and its working groups in June. The meeting could take place either at AAMI, during the AAMI Annual Meeting in June or at another location.

STAFF NOTE: The follow-up meetings of the committee and affiliated working groups were subsequently set for 27-29 June 2016 at the AAMI offices.

Adjournment
Attachment A—Attendance

Daphine Bascom, Cerner
Steve Binion, Becton Dickinson
Gerry Castro, TJC
David Classen, XXX
Kelly Cochran, ANA
Greg Cory, athenahealth
Maureen Dailey, ANA
Sherman Eagles, AAMI
Chris Emper, NextGen
Marilyn Flack, AAMI Foundation
Angela Franklin, Pew Charitable Trusts
Neil Gardner, COACH
Elisabeth George, Philips
Peter Goldschmidt, WDG
Doiug Grindstaff, CMMI Institute
Carol Herman, AAMI
Frederick Hill, athenahealth
Michelle Jump, Stryker
Priti Lakhan, Cerner
Joe Lewelling, AAMI
Lana Lowry, NIST
Mary Logan, AAMI
Mike Marchlik, McKesson
Ellen Makar, AHRQ
Michael J. McCoy, ONC
Morgan Opie, Maryland Dept. of Health
Erick P. Murrel, USAF
Anna Orlova, AHIMA
Mala Ramaiah, NIST
Srinivas, Sabbella, athenahealth
Mark Segal, GE Healthcare
Elliot Sloane, CHIRP
Jeff Smith, AMIA
Lisa Spellman, AHIMA
Mike Stinson, PIAA
Gretchen Tegethoff, CHIME
Jeme Wallace, GE Healthcare
Matt Weinger, Vanderbilt
Mike Willingham, Caradigm
Michael Wiklund, UL