American National Standard

ANSI/AAMI HIT1000-1: 2022

Safety and effectiveness of health IT software and systems—Part 1: Fundamental concepts, principles, and requirements

AAMI
Advancing Safety in Health Technology

Safety and effectiveness of health IT software and systems—Part 1: Fundamental concepts, principles, and requirements

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Abstract: Identifies the fundamental concepts and principles for creating, integrating, and implementing health IT software and health IT systems to maintain safety and effectiveness.

Keywords: health software, health IT, quality, quality systems, risk, risk management, usability, human factors engineering, safety, effectiveness, security, assurance case, safety assurance case, health IT system, sociotechnical system

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Association for the Advancement of Medical Instrumentation

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The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this recommend practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203-1853 or by email to standards@aami.org.

NOTE This foreword does not contain provisions of the HIT1000-1:2022, *Safety and effectiveness of health IT software and systems—Part 1: Fundamental concepts, principles, and requirements*, but it does provide important information about the development and intended use of the document.

Introduction

The vital role that standards for quality systems, risk management, and human factors engineering can play in enhancing the safety and effectiveness of health IT (HIT) has been recognized both in the United States [17] and globally) [21]. Safety and effectiveness are properties of health IT software or systems that directly impact patient outcomes; quality systems, human factors (usability) engineering, and risk management are tools to support that safety and effectiveness of these systems across the full lifecycle.

This triad (quality systems, risk management, and usability) is used successfully in many high-risk industries, including medical devices, nuclear engineering, and aeronautics. Existing general standards addressing elements of this triad (e.g., ISO 31000:2018 [6] or ISO 9001:2015 [7]), however, are organization-focused and do not sufficiently address the complexities of the health IT world, where responsibility for safety and efficacy is shared among many different organizations and stakeholders across the product lifecycle [19]. Standards for regulated healthcare technology (e.g., medical device standards, such as ANSI/AAMI/ISO 13485:2016 [3] or ANSI/AAMI/ISO 14971:2007 [4]) provide very useful concepts and direction but are developed to support regulatory compliance; applying them in the health IT sector is difficult as the regulatory status of components and systems (especially health software) and the regulatory responsibilities of stakeholders vary by product and jurisdiction [16]. There is a pressing need for standards specific to health IT that integrate key concepts and best practices from across this triad and apply them to the sociotechnical context in which health IT software and systems are deployed and used.

The AAMI HIT1000 series is intended to address this need. The standards in this series supplement existing quality management systems, risk management frameworks, and human factors engineering processes. They also facilitate shared responsibility among all stakeholders by identifying specific roles and defining the responsibilities needed to ensure health IT safety and effectiveness. The AAMI HIT1000 series provides a common framework for cooperation and collaboration among the many organizations and individuals that develop, implement, and use health IT software and systems.

NOTE 1 See Report of the ISO/TC 215-IEC/SC 62 Joint Task Force on Health Software (available from International Organization for Standardization ISO/TC 215 or IEC/SC 62A, Geneva. International Standards for health IT are under development in a Joint ISO/IEC Joint Working Group (ISO/TC 215-IEC/SC 62A Joint Working Group 7). AAMI manages this Joint Working Group and is ensuring coordination between the international work and the development of the HIT1000 series. The International Standards will take several years to complete and may be considered for adoption at that time if they may reflect the specific needs of the U.S. health IT sector.

NOTE 2 See Clinical Decision Support Software: Draft Guidance for Industry and Food and Drug Administration Staff, September 2019 (available from the FDA). [15] In the U.S., health IT may or may not fall under medical device regulation, depending on a product's function and the risk posed to patients. The 21st Century Cures Act, for example, removed 5 categories of software from FDA jurisdiction. [21] In Europe, it is likely that most health IT products will fall under the European Medical Device Regulations and be treated as medical devices.

The AAMI HIT1000 series *(Safety and effectiveness of health IT software and systems)* is initially comprised of the following parts:

- Part 1: Fundamental concepts, principles, and requirements;
- Part 2: Application of quality systems principles and practices;
- Part 3: Application of risk management;
- Part 4: Application of human factors engineering.

In recent years, awareness of the need for security management in ensuring the safety and availability of health IT has increased substantially, especially in response to serious and widespread security breaches (such as the WannaCry virus attacks) [18]. The AAMI HIT1000 series of provisional standards is concerned with security risks related to patient safety and effectiveness. These are addressed in the AAMI HIT1000 provisional standards as part of "safety" risk management. (See AAMI (PS)HIT1000-3:2019) [1]. Other types of security risks may be mitigated as a by-product of

this risk management, but that does not obviate the need for a comprehensive security management program to ensure that the full spectrum of security-related risks is adequately addressed. Annex B of this document offers more information and useful guidance on security management.

Safety and effectiveness of health IT software and systems—Part 1: Fundamental concepts, principles, and requirements for patient safety

1 Scope

This series of standards and provisional standards (AAMI HIT1000 series) provides a framework for managing the safety and effectiveness of health IT (HIT) software and systems, for the purpose of promoting better patient outcomes.

NOTE 1 Safety and effectiveness are key properties of a system. The ultimate goal of this standard is to promote patient safety and better patient outcomes. Patient safety requires systems and software that are safe and effective.

NOTE 2: Safety and effectiveness directly impact patient outcomes. Other attributes of software or systems, such as usability and quality, are essential to assuring safety and effectiveness and are addressed in that context by the HIT1000 series of provisional standards.

NOTE 3: Security-related risks are dealt with in the AAMI HIT1000 series as part of risk management. This does not obviate the need for a more comprehensive security management program to address other security risks. See Annex B for more information.

This part of AAMI HIT1000 (*Part 1: Fundamental concepts, principles, and requirements*) identifies the core concepts and principles needed to maintain safe and effective health IT software and systems. It also identifies roles and defines responsibilities, activities, and best practices that are necessary for managing that safety and effectiveness.

This standard applies throughout the whole lifecycle of health IT software and systems and to all sizes and types of actors involved with that system—from developers and system integrators who create the systems, to healthcare delivery organizations (HDOs) who own, configure, implement, and use the systems, and to those responsible for operating and ultimately decommissioning health IT systems or health IT system components.

This standard defines the points in the lifecycle where different roles—*Top Management, Business Owner, Developer, Integrator, Implementer, Operator,* and *User* (see Table 1)—assume primary responsibility for maintaining safety and effectiveness and identifies the communication necessary among the different roles at those points.

NOTE Roles in this standard are activity-based and not dependent upon the entity or organization involved. For example, a health delivery organization may be the *Business Owner* but may also create or substantively modify health IT system components during certain stages of the health IT software and systems lifecycle. At those stages, the HDO would have the role of a *Developer* and would assume the appropriate responsibilities of that role.

It is recognized that not all incorporated parts of health IT software and systems will have used this series of standards or applicable medical device software standards throughout the lifecycle. Where this is the case, the safety, quality, and usability impacts of these parts must be considered and addressed so as to appropriately mitigate potential negative consequences.

NOTE Other parts of the AAMI HIT1000 series can provide guidance on applying requisite vigilance to software or components that have not met the requirements of this part of AAMI HIT1000.

2 Normative references

There are no normative references in this document.