American National Standard

AAMI HIT1000-4 (PS):2020

Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering

AAMI
Advancing Safety in Health Technology

Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering

Approved as a Provisional American National Standard on 7 July 2020 by
AAMI

Abstract: Describes how to apply human factors engineering to HIT system and software user interface throughout the HIT product lifecycle to ensure such systems are reasonably safe and effective.

Keywords: human factors engineering, human factors, usability, health software, health IT, safety, effectiveness, security, health IT system, sociotechnical system, use error

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Published by

AAMI
901 N. Glebe Rd., Suite 300
Arlington, VA 22203
www.aami.org

Printed in the United States of America

IBSN 978-1-57020-759-4

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Foreword

This standard, HIT1000-4, *Safety and effectiveness of health IT software and systems—Part 4: Application of human factors engineering,* is published as a provisional National Standard—a standard for trial use—and must be processed as a full American National Standard within 2 years of its publication date (see front cover).

This document has been processed in accordance with ANSI's requirements for a Provisional American National Standard. The Provisional Standards will undergo the standards development process set forth in AAMI's accredited procedures. This Provisional ANS or pertinent Provisional Amendment(s) shall be withdrawn on or before 7 July 2020.

Comments on this standard or suggestions for improving it are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or by email to standards@aami.org.

Introduction

Note: This introduction does not contain provisions of AAMI HIT1000-4 (PS), *Health IT Software and Systems – Part 4: Application of human factors,* but it does provide important information about the development and intended use of the document.

The vital role that standards for quality systems, risk management, and usability can play in enhancing the safety and effectiveness of health IT has been recognized both in the United States[1] and globally.[2] Safety and effectiveness are properties of heath IT software or systems that directly impact patient outcomes; quality systems, human factors (usability) engineering, and risk management are tools, in turn, that support safety and effectiveness.

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 this triad (e.g., ISO 9001:2015 or ISO 31000:2018), 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. Standards for regulated healthcare technology (e.g., medical device standards, such as ANSI/AAMI HE75:2009 or ANSI/AAMI/IEC 62366-1:2015) 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.

High-risk industries routinely employ best practices and expertise in user-centered design and human factors engineering, quality systems, and risk management as essential components of software development and implementation. There is therefore a need for standards specific to health IT that address the full range of stakeholders across the health IT lifecycle. The AAMI HIT1000 series is intended to address this need. The standards supplement existing quality management systems, risk management frameworks, and human factors engineering processes. They also facilitate shared responsibility among stakeholders by identifying specific roles and defining the responsibilities needed to ensure health IT safety and quality. Although most of these practices are not consistently implemented across the healthcare software lifecycle, this series is intended to provide a firm basis for accelerated adoption of these practices and building organizational capacity. It provides a common framework for cooperation and collaboration among the many organizations and individuals that develop, implement, and use health IT.

The AAMI HIT1000 series (*Safety and effectiveness of health IT software and systems*) is envisioned to initially comprise 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.*

This part of the series, HIT1000-4, describes how to apply human factors engineering to HIT systems and software user interfaces throughout the HIT product lifecycle to ensure such systems are reasonably safe and effective. Throughout this document, the term “HIT system” refers to both HIT systems and software.

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[1] See especially, the April 2014 *FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework.*

[2] 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. (See note 4 below.)