Technical Information Report

AAMI TIR57: 2016/(R)2019

Principles for medical device security—Risk management

AAMI
Advancing Safety in Health Technology

Principles for medical device security—Risk management

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AAMI

Abstract: Provides guidance on methods to perform information security risk management for a medical device in the context of the Safety Risk Management process required by ISO 14971. The TIR incorporates the expanded view of risk management from IEC 80001-1 by incorporating the same key properties of Safety, Effectiveness and Data & Systems Security with Annexes that provide process details and illustrative examples.

Keywords: medical device, information security, risk management

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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International Standards or Technical Reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Medical Device Security Working Group

The publication of AAMI TIR57 as a new American Technical Information Report was initiated by the AAMI Medical Device Security Working Group.

At the time this document was published, the **AAMI Medical Device Security Working Group** had the following members:

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report (TIR) was developed by the Device Security Working Group.

It is widely recognized that there is little existing guidance for conducting cybersecurity risk assessment of medical devices.

The objective of this TIR is to provide guidance on how medical device manufacturers can manage risks from security threats that could impact the confidentiality, integrity, and/or availability of the device or the information processed by the device. Because medical device manufacturers are already familiar with ANSI/AAMI/ISO 14971:2007, this guidance follows the basic structure of that standard.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE This foreword does not contain provisions of the AAMI TIR57, *Principles for medical device security– Risk management* (AAMI TIR57:2016), but it does provide important information about the development and intended use of the document.

Introduction

Medical device manufacturers are familiar with the requirements of ANSI/AAMI/ISO 14971:2007/(R)2010 *Medical devices — Application of risk management to medical devices*. This standard is an integral part of the safety risk management processes required by many regulatory authorities. ANSI/AAMI/ISO 14971 specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls (see Clause 1 of ANSI/AAMI/ISO 14971:2007).

NOTE In 2012, the European Committee for Standardization (CEN) adopted EN ISO 14971:2012 as the European harmonized standard, superseding EN ISO 14971:2009. This document does not address content deviations included in Annex ZA of EN ISO 14971:2012. Specifically, the "as far as possible" requirement is not included in the evaluation of security risks. Instead, security risks are to be assessed and controlled to a level that is considered acceptable, taking into account the impact of a threat event and potential vulnerabilities.

Specific clauses of ANSI/AAMI/ISO 14971:2007 define a risk management process consisting of the following elements:

- risk analysis (Clause 4);
- risk evaluation (Clause 5);
- risk control (Clause 6);
- evaluation of overall residual risk acceptability (Clause 7);
- risk management report (Clause 8); and
- production and post-production information (Clause 9).

Figure 1 of ANSI/AAMI/ISO 14971:2007 (see Figure 1) provides a schematic representation of the risk management process. Central to the definition of risk are the concepts of probability of an occurrence of harm and the severity of that harm. Harm is defined in ANSI/AAMI/ISO 14971:2007 as "physical injury or damage to the health of people, or damage to property or the environment".