Technical Information Report

AAMI/ISO TIR24971: 2020

Medical devices—
Guidance on the
application of ISO 14971

AAMI
Advancing Safety in Health Technology

Medical devices—Guidance on the application of ISO 14971

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Abstract: Provides guidance that addresses specific areas that are problematic for those implementing a risk management system.

Keywords: risk management, 14971, medical devices

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AAMI Technical Information Report

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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 22203-1633.

ANSI Registration

Publication of this Technical Report that has been registered with ANSI has been approved by the Accredited Standards Developer (AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203). This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

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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Committee representation

Association for the Advancement of Medical Instrumentation

Application of risk management to medical devices Working Group

The adoption of ISO/TR 24971, Medical devices—Guidance on the application of ISO 14971 as an AAMI Technical Information Report was initiated by the AAMI Application of risk management to medical devices Working Group. AAMI Application of risk management to medical devices Working Group provides input to the Quality management and corresponding general aspects for medical devices Working Group which is the responsible group for providing the U.S. input to the relevant group in the International Organization for Standardization (ISO). U.S. representatives from Application of risk management to medical devices Working Group and the TAG played an active part in developing the ISO document.

At the time this document was published, the **AAMI Application of risk management to medical devices Working Group** had the following members:

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Melissa Torres

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David Amor, Pear Therapeutics Inc
Pat Baird, Philips
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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.

Background of AAMI adoption of ISO TR 24971 Ed.2.

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO/TC210 to provide guidance to ISO 14971:2019.

U.S. participation in ISO/TC210 is organized through the U.S. Technical Advisory Group to Quality management and corresponding general aspects for medical devices, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI/ISO TR24971 was registered by the American National Standards Institute (ANSI) on February 2, 2020.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication. AAMI procedures require that technical information reports are reviewed every three years.

AAMI (and ANSI) have adopted other ISO standards and technical reports.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

NOTE Users of this technical information report are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the ISO foreword on page viii, AAMI/ISO TIR24971:2020, *Medical devices—Guidance on the application of ISO 14971* is identical to ISO TR 24971:2020.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The *procedures* used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives-and-policies).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.

This second edition cancels and replaces the first edition, which has been technically revised. The main changes compared to the previous edition are as follows:

— The clauses of ISO/TR 24971:2013 and some informative annexes of ISO 14971:2007 are merged, restructured, technically revised, and supplemented with additional guidance.

— To facilitate the use of this document, the same structure and numbering of clauses and subclauses as in ISO 14971:2019 is employed. The informative annexes contain additional guidance on specific aspects of *risk management*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides guidance to assist *manufacturers* in the development, implementation and maintenance of a *risk management process* for *medical devices* that aims to meet the requirements of ISO 14971:2019, *Medical devices — Application of risk management to medical devices*. It provides guidance on the application of ISO 14971:2019 for a wide variety of *medical devices*. These *medical devices* include active, non-active, implantable, and non-implantable *medical devices*, software as *medical devices* and *in vitro diagnostic medical devices*.

The clauses and subclauses in this document have the same structure and numbering as the clauses and subclauses of ISO 14971:2019, to facilitate the use of this guidance in applying the requirements of the standard. Further division into subclauses is applied where considered useful. The informative annexes contain additional guidance on specific aspects of *risk management*. The guidance consists of the clauses of ISO/TR 24971:2013 and some of the informative annexes of ISO 14971:2007, which are merged, restructured, technically revised, and supplemented with additional guidance.

Annex H was prepared in cooperation with Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This document describes approaches that *manufacturers* can use to develop, implement and maintain a *risk management process* conforming to ISO 14971:2019. Alternative approaches can also satisfy the requirements of ISO 14971:2019.

When judging the applicability of the guidance in this document, one should consider the nature of the *medical device(s)* to which it will apply, how and by whom these *medical devices* are used, and the applicable regulatory requirements.