This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
Medical devices — Guidance on the application of ISO 14971

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

Keywords: risk management

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

CAUTION NOTICE: This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

ANSI Technical Report

This AAMI TIR has been registered by the American National Standards Institute as an ANSI Technical Report.

Publication of this ANSI Technical Report has been approved by the accredited standards developer (AAMI). This document is registered as a Technical Report series of publications 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 the content of this document should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.
Contents

Glossary of equivalent standards ............................................................................................................. v
Committee representation ......................................................................................................................... vi
Background of US adoption of ISO/TS 24971:2013 .............................................................................. viii
Foreword ..................................................................................................................................................... ix
Introduction ................................................................................................................................................. x
1 Scope .................................................................................................................................................. 1

2 The role of international product safety and process standards in risk management ..................... 1
   2.1 Overview .................................................................................................................................... 1
   2.2 Use of international product safety standards in risk management ................................... 2
   2.3 International process standards and ISO 14971 .................................................................... 5

3 Developing the policy for determining the criteria for risk acceptability .................................... 7

4 Production and post-production feedback loop ............................................................................ 8
   4.1 Overview .................................................................................................................................... 8
   4.2 Observation and transmission ................................................................................................ 8
   4.3 Assessment ............................................................................................................................. 11
   4.4 Action ....................................................................................................................................... 11

5 Differentiation of information for safety and disclosure of residual risk ...................................... 12
   5.1 Difference between “information for safety” and “disclosure of residual risk” .............. 12
   5.2 Information for safety ............................................................................................................. 12
   5.3 Disclosure of residual risk ..................................................................................................... 13

6 Evaluation of overall residual risk ................................................................................................. 13
   6.1 Overview .................................................................................................................................. 13
   6.2 Inputs and other considerations for overall residual risk evaluation................................. 14

Figures

Figure 1 — Use of international product safety standards and example of such standard that specifies requirements and provides specific test acceptance criteria ........................................... 4
Figure 2 — Production and Post-Production Feedback Loop ........................................................... 10
Glossary of equivalent standards

International Standards 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

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document, contact AAMI at +1-877-249-8226 or visit www.aami.org.
Committee representation

Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee


At the time this document was published, the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee had the following members:

Cochairs
Scott Colburn, MS, BSN, RN, FDA/CDRH
Charles B. Sidebottom, PE, Medtronic Inc. WHQ Campus

Members
Scott Colburn, MS, BSN, RN, FDA/CDRH
Ed R. Kimmelman, BME, JD, (Independent Expert)
Sherry M. Leichtweis, Abbott Laboratories
Emmanuel Nyakako, Zimmer Inc.
David G. Osborn, Philips Electronics North America
Harvey Rudolph, PhD, Underwriters Laboratories Inc.
Charles B. Sidebottom, PE, Medtronic Inc. WHQ Campus
Al Van Houdt, Spacelabs Medical Inc.

Alternates
David J. Geraghty, Spacelabs Medical Inc.
Mike Hudon, Philips Electronics North America
Luann M. Pendy, Medtronic Inc. WHQ Campus
Kimberly A. Trautman, FDA/CDRH

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.

At the time this document was published, the Application of Risk Management to Medical Devices Working Group had the following members:

Cochairs
Charles B. Sidebottom, PE, Medtronic Inc.
Harvey Rudolph, UL LLC

Members
Aryan Amsalu, PhD, Hill-Rom Holdings
Pat Baird, Baxter Healthcare Corporation
Edwin L. Bills, RAC, CQE, CQA, Hill-Rom Company
Sherman Eagles, SoftwareCPR
Rich Eaton, MITA
David Geraghty, Spacelabs Medical Inc.
Gottlieb Glauninger, Eli Lilly & Company
Casey Haley, Cyberonics
Lia Haley, Philips Electronics North America
John Hedley-Whyte, MD (Independent Expert)
David Hengl, Draeger Medical Systems Inc.
Bill Hintz, Medtronic Rice Creek Campus
Christine Krenc, Abbott Laboratories
Background of ANSI/AAMI adoption of ISO/TS 24971:2013

As indicated in the foreword to the main body of this document (page ix), 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.

International Technical Specification 24971:2013 was developed by Joint Working Group (JWG) 1 Application of risk Management to Medical Devices, of ISO Technical Committee (TC) 210, Quality management and corresponding general aspects for medical devices, and IEC Sub Committee (SC) 62A, Common aspects of electrical equipment used in medical practice provide guidance that addresses specific areas that are problematic for those implementing a risk management system.

U.S. participation in this ISO/IEC JWG 1 is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). AAMI administers the International Secretariat for ISO/TC 210 on behalf of the United States, and U.S. experts made a considerable contribution to this technical specification.


AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI that gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this document 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.

As used within the context of this document, “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 standard. “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.

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

NOTE—This background does not contain provisions of the ANSI/AAMI/ISO Technical Information Report TIR24971:2013, but does provide important information about the development and intended use of this TIR.

NOTE—Beginning with the foreword on page ix, this AAMI TIR is identical to ISO/TS 24971:2013.
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. www.iso.org/directives

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. 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.

ISO/TR 24971 was prepared jointly by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices and Technical Committee IEC/SC 62A, Common aspects of electrical equipment used in medical practice. The draft was circulated for voting to the national bodies of both ISO and IEC.
Introduction

Experience indicates that manufacturers have difficulty with practical implementation of some clauses of the risk management International Standard, ISO 14971:2007, Medical devices — Application of risk management to medical devices. This Technical Report provides guidance to assist in the development, implementation and maintenance of risk management for medical devices that aim to meet the requirements of ISO 14971. It provides guidance for specific aspects of ISO 14971 for a wide variety of medical devices. These medical devices include active, non-active, implantable, and non-implantable medical devices and *in vitro* diagnostic medical devices.

This Technical Report is not intended to be an overall guidance document on the implementation of ISO 14971 for organizations. It supplements the guidance contained in the informative annexes of ISO 14971 related to the following areas:

— Guidance on the role of international product safety and process standards in risk management

— Guidance on developing the policy for determining the criteria for risk acceptability

— Guidance on how the production and post-production feedback loop can work

— Guidance on the differentiation of information for safety as a risk control measure and disclosure of residual risk

— Guidance on the evaluation of overall residual risk

This Technical Report provides some approaches that an organization can use to implement and maintain some aspects of a risk management system that conforms to ISO 14971. Alternative approaches can be used if these satisfy the requirements of ISO 14971.

When judging the applicability of the guidance in this Technical Report, one should consider the nature of the medical device(s) to which it will apply, the risks associated with the use of these medical devices, and the applicable regulatory requirements.
Medical devices — Guidance on the application of ISO 14971

1 Scope

This Technical Report provides guidance in addressing specific areas of ISO 14971 when implementing risk management.

This guidance is intended to assist manufacturers and other users of the standard to:

— understand the role of international product safety and process standards in risk management;
— develop the policy for determining the criteria for risk acceptability;
— incorporate production and post-production feedback loop into risk management;
— differentiate between “information for safety” and “disclosure of residual risk”; and
— evaluate overall residual risk.