Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary standard for a medical device recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of minimum safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A recommended practice provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance per se, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidance to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are voluntary (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important reference in responsible decision-making, but it should never replace responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the Standards Monitor Online monthly newsletter. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an official interpretation in the AAMI Standards Monitor Online.
Medical devices—Application of risk management to medical devices

Abstract: 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.

Keywords: medical device, risk management
AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI 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.
## Contents

Committee representation.......................................................................................................................................... iv

Background of ANSI/AAMI adoption of ISO 14971:2019.................................................................................................. vi

Foreword..................................................................................................................................................................... vii

Introduction ................................................................................................................................................................. ix

1 Scope .............................................................................................................................................................. 1

2 Normative references .................................................................................................................................... 1

3 Terms and definitions.................................................................................................................................... 1

4 General requirements for risk management system .................................................................................................. 7

5 Risk analysis .................................................................................................................................................................. 11

6 Risk evaluation ................................................................................................................................................ 13

7 Risk control ...................................................................................................................................................... 13

8 Evaluation of overall residual risk .......................................................................................................................... 15

9 Risk management review ...................................................................................................................................... 15

10 Production and post-production activities.................................................................................................................. 16

Annex A (informative) Rationale for requirements ........................................................................................................ 18

Annex B (informative) Risk management process for medical devices.............................................................................. 26

Annex C (informative) Fundamental risk concepts ....................................................................................................... 30


Annex ZC (informative) Relationship between this European standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered ......................................................................................................................................... 43

Annex ZD (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered .................................................................................................................. 46

Annex ZE (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered .................................................................................................................. 49

Bibliography ............................................................................................................................................................... 52
Committee representation

Association for the Advancement of Medical Instrumentation
Application of Risk Management to Medical Devices Working Group

The adoption of ISO 14971:2019 as an American National Standard was initiated by the AAMI Application of Risk Management to Medical Devices Working Group. AAMI QM/WG04 provides input to the Quality Management and Corresponding General Aspects for Medical Devices Committee which is the responsible group for providing the U.S. input to the relevant group in ISO/TC210. U.S. representatives from AAMI 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 committee Application of Risk Management to Medical Devices Working Group has the following members:

Cochairs: Christine Krenc
Melissa Torres

Members: David Amor, Pear Therapeutics Inc
Pat Baird, Philips
Pierre Barbier, Alcon Laboratories Inc
Edwin Bills, ELB Consulting
Amar Chanani, Avanos Medical
Roberto Del Cid, Conmed Corp
Tushar Dharampal, Abbott Laboratories
Elizabeth DiDonato, Department of Defense - Defense Blood Standard System Project Office
Thomas Dold, Vista Regulatory Solutions
Sherman Eagles, SoftwareCPR
Hugo Felix, Owlet Baby Care
Jason Fuller, Stryker Instruments Division
David Geraghty, Spacelabs Healthcare
Michael Glynn, Battelle Memorial Institute
Richard Granquist, NAMSA
Michael Groendyk, Arthrex Inc
Michael Gustafson, Siemens Healthineers
Casey Haley, LivaNova PLC
John Hedley-Whyte, Harvard University
Jose Justianiano, Johnson & Johnson
Patricia Krantz-Zuppan, Medtronic Inc Campus
Sonja Kraus, Draeger Medical Systems Inc.
Christine Krenc, KTA Compliance Consulting
Chad Kymal, Omnex
Dan Laelie, Nonin Medical Inc
Mark Leimbeck, UL LLC
Eduardo Martinez, Abbott Laboratories
Mercedes Massana, MDM Engineering Consultants
Dino Mavromatis, Regulatory and Quality Solutions LLC
Mike McAndrew, Getinge USA
Michael McCarthy, Baxter Healthcare Corporation
Kathleen Miller, Amgen Inc
Enio Montenegro, Cadwell Laboratories Inc
Pablo Montero, Boston Scientific Corporation
Wade Munsch, MET Laboratories Inc
Jorge Ochoa, Exponent
B Park, Christine Park & Associates
Anthony Piotrkowski, STERIS Corporation
Frank Pokrop, Sotera Wireless Inc
NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.
Background of ANSI/AAMI adoption of ISO 14971:2019

As indicated in the foreword to the main body of this document (page vii), 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, Quality management and corresponding general aspects for medical devices to specify 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.

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 Committee, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of quality management and corresponding general aspects for medical devices. Upon review of ISO 14971, the Quality Management and Corresponding General Aspects for Medical Devices Committee and the AAMI Application of Risk Management to Medical Devices Working Group decided to adopt it verbatim, as a revision of ANSI/AAMI/ISO 14971:2007.

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

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 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.

NOTE Users of this standard 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 comes 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 vii, this American National Standard is identical to ISO 14971:2019.
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).

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 of 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 www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 14971:2007), which has been technically revised. The main changes compared to the previous edition are as follows:

— The defined terms are updated and many are derived from ISO/IEC Guide 63. Definitions of benefit, reasonably foreseeable misuse and state of the art have been introduced.

— More attention is given to the benefits that are expected from the use of the medical device. The term benefit-risk analysis has been aligned with terminology used in some regulations.

— It is explained that the process described in ISO 14971 can be used for managing risks associated with medical devices, including those related to data and systems security.

— The method for the evaluation of the overall residual risk and the criteria for its acceptability are required to be defined in the risk management plan. The method can include gathering and reviewing data and literature for the medical device and for similar medical devices and similar other products on the market. The criteria for the acceptability of the overall residual risk can be different from the criteria for acceptability of individual risks.

— The requirements to disclose residual risks have been moved and merged into one requirement, after the overall residual risk has been evaluated and judged acceptable.

— The review before commercial distribution of the medical device concerns the execution of the risk management plan. The results of the review are documented as the risk management report.
— The requirements for production and post-production activities have been clarified and restructured. More detail is given on the information to be collected and the actions to be taken when the collected information has been reviewed and determined to be relevant to safety.

— Several informative annexes are moved to the guidance in ISO/TR 24971, which has been revised in parallel. More information and a rationale for the requirements in this third edition of ISO 14971 have been provided in Annex A. The correspondence between the clauses of the second edition and those of this third edition is given in Annex B.

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

The requirements contained in this document provide manufacturers with a framework within which experience, insight and judgment are applied systematically to manage the risks associated with the use of medical devices.

This document was developed specifically for manufacturers of medical devices on the basis of established principles of risk management that have evolved over many years. This document could be used as guidance in developing and maintaining a risk management process for other products that are not necessarily medical devices in some jurisdictions and for suppliers and other parties involved in the medical device life cycle.

This document deals with processes for managing risks associated with medical devices. Risks can be related to injury, not only to the patient, but also to the user and other persons. Risks can also be related to damage to property (objects, data, other equipment) or the environment.

Risk management is a complex subject because each stakeholder can place a different value on the acceptability of risks in relation to the anticipated benefits. The concepts of risk management are particularly important in relation to medical devices because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients and members of the public.

It is generally accepted that the concept of risk has two key components:

— the probability of occurrence of harm; and

— the consequences of that harm, that is, how severe it might be.

All stakeholders need to understand that the use of a medical device involves an inherent degree of risk, even after the risks have been reduced to an acceptable level. It is well known that in the context of a clinical procedure some residual risks remain. The acceptability of a risk to a stakeholder is influenced by the key components listed above and by the stakeholder’s perception of the risk and the benefit. Each stakeholder’s perception can vary depending upon their cultural background, the socio-economic and educational background of the society concerned and the actual and perceived state of health of the patient. The way a risk is perceived also takes into account other factors, for example, whether exposure to the hazard or hazardous situation seems to be involuntary, avoidable, from a man-made source, due to negligence, arising from a poorly understood cause, or directed at a vulnerable group within society.

As one of the stakeholders, the manufacturer reduces risks and makes judgments relating to the safety of a medical device, including the acceptability of residual risks. The manufacturer takes into account the generally acknowledged state of the art, in order to determine the suitability of a medical device to be placed on the market for its intended use. This document specifies a process through which the manufacturer of a medical device can identify hazards associated with the medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of the controls throughout the life cycle of the medical device.

The decision to use a medical device in the context of a particular clinical procedure requires the residual risks to be balanced against the anticipated benefits of the procedure. Such decisions are beyond the scope of this document and take into account the intended use, the circumstances of use, the performance and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure. Some of these decisions can be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient or the patient’s own opinion.

For any particular medical device, other standards or regulations could require the application of specific methods for managing risk. In those cases, it is necessary to also follow the requirements outlined in those documents.

The verbal forms used in this document conform to the usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— “may” is used to describe permission (e.g. a permissable way to achieve compliance with a requirement or test);
— “can” is used to express possibility and capability; and

— “must” is used to express an external constraint that is not a requirement of the document.
Medical devices—Application of risk management to medical devices

1 Scope

This document specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices. The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of this document are applicable to all phases of the life cycle of a medical device. The process described in this document applies to risks associated with a medical device, such as risks related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.

The process described in this document can also be applied to products that are not necessarily medical devices in some jurisdictions and can also be used by others involved in the medical device life cycle.

This document does not apply to:

— decisions on the use of a medical device in the context of any particular clinical procedure; or

— business risk management.

This document requires manufacturers to establish objective criteria for risk acceptability but does not specify acceptable risk levels.

Risk management can be an integral part of a quality management system. However, this document does not require the manufacturer to have a quality management system in place.

NOTE Guidance on the application of this document can be found in ISO/TR 24971[9].

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp


3.1 accompanying documentation

materials accompanying a medical device (3.10) and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the medical device (3.10), particularly regarding safe use