


# American National Standard

**ANSI/AAMI/ISO 14971:2007**

*(Corrected 4 October 2007)*



**Medical devices—Application of risk  
management to medical devices**



Association for the Advancement  
of Medical Instrumentation

# The 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 health care 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 guidelines 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 and resources 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.

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## **Medical devices— Application of risk management to medical devices**

Approved 5 December 2006 by  
**Association for the Advancement of Medical Instrumentation**

Approved 1 February 2007 by  
**American National Standards Institute**

**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

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

| International designation                | U.S. designation   | Equivalency                             |
|--|--|---|
| IEC 60601-1:2005                         | ANSI/AAMI ES60601-1:2005   | Major technical variations              |
| IEC 60601-1-2:2001 and Amendment 1:2004  | ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004                  | Identical                               |
| IEC 60601-2-2:2006                       | ANSI/AAMI/IEC 60601-2-2:2006                                       | Identical                               |
| IEC 60601-2-4:2002                       | ANSI/AAMI DF80:2003  | Major technical variations              |
| IEC 60601-2-19:1990 and Amendment 1:1996 | ANSI/AAMI I136:2004  | Major technical variations              |
| IEC 60601-2-20:1990 and Amendment 1:1996 | ANSI/AAMI I151:2004  | Major technical variations              |
| IEC 60601-2-21:1994 and Amendment 1:1996 | ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts) | Identical                               |
| IEC 60601-2-24:1998                      | ANSI/AAMI ID26:2004  | Major technical variations              |
| IEC 60601-2-50:2001                      | ANSI/AAMI/IEC 60601-2-50:2006                                      | Identical                               |
| IEC/TR 60878:2003                        | ANSI/AAMI/IEC TIR60878:2003  | Identical                               |
| IEC/TR 62296:2003                        | ANSI/AAMI/IEC TIR62296:2003  | Identical                               |
| IEC 62304:2006                           | ANSI/AAMI/IEC 62304:2006   | Identical                               |
| IEC/TR 62348:2006                        | ANSI/AAMI/IEC TIR62348:2006  | Identical                               |
| ISO 5840:2005                            | ANSI/AAMI/ISO 5840:2005  | Identical                               |
| ISO 7198:1998                            | ANSI/AAMI/ISO 7198:1998/2001/(R)2004                               | Identical                               |
| ISO 7199:1996                            | ANSI/AAMI/ISO 7199:1996/(R)2002                                    | Identical                               |
| ISO 10993-1:2003                         | ANSI/AAMI/ISO 10993-1:2003   | Identical                               |
| ISO 10993-2:2006                         | ANSI/AAMI/ISO 10993-2:2006   | Identical                               |
| ISO 10993-3:2003                         | ANSI/AAMI/ISO 10993-3:2003   | Identical                               |
| ISO 10993-4:2002 and Amendment 1:2006    | ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006                    | Identical                               |
| ISO 10993-5:1999                         | ANSI/AAMI/ISO 10993-5:1999   | Identical                               |
| ISO 10993-6:1994                         | ANSI/AAMI/ISO 10993-6:1995/(R)2001                                 | Identical                               |
| ISO 10993-7:1995                         | ANSI/AAMI/ISO 10993-7:1995/(R)2001                                 | Identical                               |
| ISO 10993-9:1999                         | ANSI/AAMI/ISO 10993-9:1999/(R)2005                                 | Identical                               |
| ISO 10993-10:2002 and Amendment 1:2006   | ANSI/AAMI BE78:2002<br>ANSI/AAMI BE78:2002/A1:2006                 | Minor technical variations<br>Identical |
| ISO 10993-11:2006                        | ANSI/AAMI/ISO 10993-11:2006  | Identical                               |
| ISO 10993-12:2002                        | ANSI/AAMI/ISO 10993-12:2002  | Identical                               |
| ISO 10993-13:1998                        | ANSI/AAMI/ISO 10993-13:1999/(R)2004                                | Identical                               |
| ISO 10993-14:2001                        | ANSI/AAMI/ISO 10993-14:2001/(R)2006                                | Identical                               |
| ISO 10993-15:2000                        | ANSI/AAMI/ISO 10993-15:2000/(R)2006                                | Identical                               |
| ISO 10993-16:1997                        | ANSI/AAMI/ISO 10993-16:1997/(R)2003                                | Identical                               |
| ISO 10993-17:2002                        | ANSI/AAMI/ISO 10993-17:2002  | Identical                               |

| International designation                       | U.S. designation                                     | Equivalency                |
|---|--|----------------------------|
| ISO 10993-18:2005                               | ANSI/AAMI BE83:2006                                  | Major technical variations |
| ISO/TS 10993-19:2006                            | ANSI/AAMI/ISO TIR10993-19:2006                       | Identical                  |
| ISO/TS 10993-20:2006                            | ANSI/AAMI/ISO TIR10993-20:2006                       | Identical                  |
| ISO 11135:1994                                  | ANSI/AAMI/ISO 11135:1994                             | Identical                  |
| ISO 11137-1:2006                                | ANSI/AAMI/ISO 11137-1:2006                           | Identical                  |
| ISO 11137-2:2006 (2006-08-01 corrected version) | ANSI/AAMI/ISO 11137-2:2006                           | Identical                  |
| ISO 11137-3:2006                                | ANSI/AAMI/ISO 11137-3:2006                           | Identical                  |
| ISO 11138-1:2006                                | ANSI/AAMI/ISO 11138-1:2006                           | Identical                  |
| ISO 11138-2:2006                                | ANSI/AAMI/ISO 11138-2:2006                           | Identical                  |
| ISO 11138-3:2006                                | ANSI/AAMI/ISO 11138-3:2006                           | Identical                  |
| ISO 11138-4:2006                                | ANSI/AAMI/ISO 11138-4:2006                           | Identical                  |
| ISO 11138-5:2006                                | ANSI/AAMI/ISO 11138-5:2006                           | Identical                  |
| ISO/TS 11139:2006                               | ANSI/AAMI/ISO 11139:2006                             | Identical                  |
| ISO 11140-1:2005                                | ANSI/AAMI/ISO 11140-1:2005                           | Identical                  |
| ISO 11140-5:2006                                | ANSI/AAMI ST66:1999                                  | Major technical variations |
| ISO 11607-1:2006                                | ANSI/AAMI/ISO 11607-1:2006                           | Identical                  |
| ISO 11607-2:2006                                | ANSI/AAMI/ISO 11607-2:2006                           | Identical                  |
| ISO 11737-1:2006                                | ANSI/AAMI/ISO 11737-1:2006                           | Identical                  |
| ISO 11737-2:1998                                | ANSI/AAMI/ISO 11737-2:1998                           | Identical                  |
| ISO 11737-3:2004                                | ANSI/AAMI/ISO 11737-3:2004                           | Identical                  |
| ISO 13485:2003                                  | ANSI/AAMI/ISO 13485:2003                             | Identical                  |
| ISO 14155-1:2003                                | ANSI/AAMI/ISO 14155-1:2003                           | Identical                  |
| ISO 14155-2:2003                                | ANSI/AAMI/ISO 14155-2:2003                           | Identical                  |
| ISO 14160:1998                                  | ANSI/AAMI/ISO 14160:1998                             | Identical                  |
| ISO 14161:2000                                  | ANSI/AAMI/ISO 14161:2000                             | Identical                  |
| ISO 14937:2000                                  | ANSI/AAMI/ISO 14937:2000                             | Identical                  |
| ISO/TR 14969:2004                               | ANSI/AAMI/ISO TIR14969:2004                          | Identical                  |
| ISO 14971:2007                                  | ANSI/AAMI/ISO 14971:2007                             | Identical                  |
| ISO 15223:2000, A1:2002, and A2:2004            | ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004       | Identical                  |
| ISO 15225:2000 and A1:2004                      | ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006 | Identical                  |
| ISO 15674:2001                                  | ANSI/AAMI/ISO 15674:2001                             | Identical                  |
| ISO 15675:2001                                  | ANSI/AAMI/ISO 15675:2001                             | Identical                  |
| ISO 15882:2003                                  | ANSI/AAMI/ISO 15882:2003                             | Identical                  |
| ISO/TR 16142:2006                               | ANSI/AAMI/ISO TIR16142:2006                          | Identical                  |
| ISO 17664:2004                                  | ANSI/AAMI ST81:2004                                  | Major technical variations |
| ISO 17665-1:2006                                | ANSI/AAMI/ISO 17665-1:2006                           | Identical                  |
| ISO 18472:2006                                  | ANSI/AAMI/ISO 18472:2006                             | Identical                  |
| ISO/TS 19218:2005                               | ANSI/AAMI/ISO 19218:2005                             | Identical                  |
| ISO 25539-1:2003 and A1:2005                    | ANSI/AAMI/ISO 25539-1:2003 and A1:2005               | Identical                  |

<sup>1</sup>In production

<sup>2</sup>Final approval pending

## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Quality Management and Corresponding General Aspects for Medical Devices Committee

The adoption of ISO 14971:2007 as a new American National Standard was initiated by the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Application of Risk Management to Medical Devices Working Group (U.S. Sub-TAG for ISO/IEC JWG1), chaired by Harvey Rudolph, PhD, of Underwriters Laboratories, Inc. and Tony Chan of Agile Pharmaceuticals, played an active part in developing the ISO standard.

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

*Cochairs:* Carol L. Herman  
Charles B. Sidebottom, PE

*Members:* Leighton W. Hansel, Abbott Laboratories  
Carol L. Herman, U.S. Food and Drug Administration  
Edward R. Kimmelman, BME, JD, Roche Diagnostics Corp.  
Dave Osborn, Philips Medical Systems  
Harvey Rudolph, PhD, Underwriters Laboratories, Inc.  
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At the time this document was published, the committee's **Application of Risk Management to Medical Devices Working Group** had the following members:

*Cochairs:* Tony C. Chan  
Harvey Rudolph, PhD

*Members:* Krisann M. Anderson, St. Jude Medical, Inc.  
Barbara Barbeau, Baxter Healthcare Corporation  
Edwin L. Bills, RAC, CQE, CQA, Independent Expert  
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## Background of AAMI adoption of ISO 14971:2007

As indicated in the foreword to the main body of this document (page x), 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 Standard ISO 14971:2007 was developed by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices. In this new edition the requirement sections have been streamlined and clarified without fundamentally changing the process, and the informative annexes and guidance have been improved and expanded.

Annex A (Rationale for requirements) has been updated to reflect the revised requirements and should be the first section reviewed by users. Annex D (Risk concepts) has been extensively updated to provide additional guidance. Annex E has been extensively revised to explain the concept model used to develop the standard and the relationship between hazards, foreseeable sequences of events, and hazardous situations. Annex F (Risk management plan) has been added to provide guidance when developing the risk management plan. Annex H has been expanded by the ISO committee on *in vitro* diagnostics (ISO/TC 212). Annex J has been added to provide guidance on the use of information for safety and disclosure of residual risk.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation on behalf of the American National Standards Institute. The U.S. made a considerable contribution to this International 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 14971:2007, 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 14971:2000 and Amd1:2003.

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.

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

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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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NOTE—Beginning with the ISO foreword on page x, this American National Standard is identical to ISO 14971:2007.

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## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

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. International Standard ISO 14971 was prepared by 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*. Annex H, "Guidance on risk management for *in vitro* diagnostic medical devices," was prepared by ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

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This second edition cancels and replaces the first edition (ISO 14971:2000) as well as the amendment ISO 14971:2000/Amd.1:2003.

For purposes of future IEC maintenance, Subcommittee 62A has decided that the contents of this publication will remain unchanged until the maintenance result date<sup>1)</sup> indicated on the IEC web site under <http://webstore.iec.ch> in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition or
- amended.

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1) IEC National Committees are requested to note that for this publication the maintenance result date is 2014.

## Introduction

The requirements contained in this International Standard 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 International Standard was developed specifically for medical device/system manufacturers using established principles of risk management. For other manufacturers, e.g., in other healthcare industries, this International Standard could be used as informative guidance in developing and maintaining a risk management system and process.

This International Standard deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment, and the environment.

As a general concept, activities in which an individual, organization, or government is involved can expose those or other stakeholders to hazards which can cause loss of or damage to something they value. Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and its severity.

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- a) the probability of occurrence of harm;
- b) the consequences of that harm, that is, how severe it might be.

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.

All stakeholders need to understand that the use of a medical device entails some degree of risk. The acceptability of a risk to a stakeholder is influenced by the components listed above and by the stakeholder's perception of the risk. Each stakeholder's perception of the risk can vary greatly depending upon their cultural background, the socio-economic and educational background of the society concerned, the actual and perceived state of health of the patient, and many other factors. The way a risk is perceived also takes into account, for example, whether exposure to the hazard 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. 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 judgments should take into account the intended use, performance, and risks associated with the medical device, as well as the risks and benefits associated with the clinical procedure or the circumstances of use. Some of these judgments 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.

As one of the stakeholders, the manufacturer makes judgments relating to safety of a medical device, including the acceptability of risks, taking into account the generally accepted 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 International Standard specifies a process through which the manufacturer of a medical device can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of that control.

For any particular medical device, other International Standards could require the application of specific methods for managing risk.



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# Medical devices — Application of risk management to medical devices

## 1 Scope

This International Standard 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.

The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.

This International Standard does not apply to clinical decision making.

This International Standard does not specify acceptable risk levels.

This International Standard does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.