Technical Information Report

AAMI/ISO TIR16142: 2005

Medical devices—
Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

AAMI
Advancing Safety in Healthcare Technology

A Technical Report prepared by AAMI and registered with ANSI

AAMI/ISO TIR16142:2005
(Revision of AAMI/ISO TIR16142:2000)

Medical devices—
Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

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Abstract: Considers and identifies certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance.

Keywords: essential principles, conformity assessment, medical device safety

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AAMI Technical Information Report

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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.

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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 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	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 TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	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 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	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	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
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	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical

International designation	U.S. designation	Equivalency
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO TS 10993-20:200x[1]	ANSI/AAMI/ISO TIR10993-20:2005	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO TS 13409:2002	AAMI/ISO TIR13409:1996 and A1:2000	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	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 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	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 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:2001	AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1] In production

Committee representation

Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee

The adoption of ISO Technical Report (TR) 16142:2005 as an AAMI Technical Information Report and revision of AAMI/ISO 16142:2000 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 General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group (U.S. Sub-TAG for ISO/TC 210/WG 2) played an active part in developing the ISO Technical Report.

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

Cochair:	Charles B. Sidebottom, PE
Members:	Leighton W. Hansel, Abbott Laboratories
	Edward R. Kimmelman, BME, JD, Roche Diagnostics Corp.
	Harvey Rudolph, PhD, Underwriters Laboratories Inc.
	Charles B. Sidebottom, PE, Medtronic Inc.
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At the time this document was published, the AAMI General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group had the following members:

Members:	Krisann M. Anderson, St Jude Medical Inc.
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	Tracie Capozzio, Steris Corporation
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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 AAMI adoption of ISO/TR16142:2005

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

International Technical Report 16142 was developed by Working Group (WG) 2 *General Aspects Stemming from the Application of Quality Principles to Medical Devices,* of ISO Technical Committee (TC) 210, *Quality management and corresponding general aspects for medical devices*, to identify certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance.

U.S. participation in this ISO/TC 210/WG 2 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 report.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of ISO/TR 16142, the Quality Management and Corresponding General Aspects for Medical Devices Committee and the AAMI General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group decided to adopt ISO/TR 16142:2005 verbatim as an AAMI Technical Information Report and as a revision of AAMI/ISO TIR 16142:2000.

The significant changes to this edition of ISO/TR 16142 are the reformatting of Table A.1; the addition of a new annex listing website addresses for standards, beyond those listed in Table A.1, that are suitable for medical device assessment purposes; and the inclusion of additional guidance on recognition of and reference to standards.

AAMI has adopted other ISO documents. 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 into this technical information report should not be considered inflexible or static. This technical information report, 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.

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

NOTE Beginning with the ISO foreword on page xi, this AAMI Technical Information Report is identical to ISO/TR 16142:2005.

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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this Technical Report may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 16142 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices.*

This second edition cancels and replaces the first edition (ISO/TR 16142:1999), which has been technically revised.

Introduction

Standards and standardization processes can be made more effective by developing a better understanding of the needs and requirements of those who use or who are affected by standards. Improvements in standards will contribute to global harmonization efforts at all levels.

Continuous innovation is key to the advancement of medical device technology, contributing to more effective healthcare. Standards supporting or referenced in regulatory requirements need to be developed and applied in such a way as to allow product innovation by industry while assuring safety and effectiveness.

Timely development and periodic revision makes medical devices standards effective and efficient tools for supporting regulatory systems and for moving toward globally compatible regulation.

Voluntary standards and guides can assist manufacturers to comply with legal requirements. If the standards are accepted within a given regulatory system, compliance with such standards may be deemed to satisfy the legal requirements. The regulatory acceptance does not, of itself, imply that such standards are mandatory.

Medical device standards represent a consensus on requirements that foster innovation while protecting public health.

Harmonized compliance with the regulations, a key element of timely market introduction of advance technology, can be facilitated by the appropriate use of relevant medical device standards.

This should be based on the premise that:

— standards are based on experience or, in other words, are retrospective;

— innovation may present unanticipated challenges to experience;

— rigid, mandatory, application of standards may deter innovation;

— operation of a quality management system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health;

— quality management systems include provisions that address both innovation and experience;

— such provisions of quality management systems include field experience, risk analysis and management, phased reviews, documentation and record keeping, as well as the use of product and process standards.

Medical devices—Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

1 Scope

This Technical Report considers and identifies certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance.

This Technical Report is intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes.

2 Terms and definitions

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

2.1
basic standard
standard which includes fundamental concepts, principles, and requirements with regard to general aspects applicable to a wide range of products, processes, or services

NOTE Basic standards are sometimes referred to as horizontal standards.

2.2
group standard
standard which includes safety and essential performance aspects applicable to several or a family of similar products, processes, or services dealt with by two or more technical committees or subcommittees, making reference, as far as possible, to basic standards

NOTE Group standards are sometimes referred to as semihorizontal standards.

2.3
product standard
standard which includes all necessary safety and essential performance aspects of a specific or a family of product(s), process(es), or service(s) within the scope of a single technical committee or subcommittee, making reference, as far as possible, to basic standards and group standards

NOTE Product standards are sometimes referred to as vertical standards.

