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Technical Information Report

ANSI/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

AAMI Association for the Advancement of Medical Instrumentation

An ANSI Technical Report prepared by AAMI ANSI/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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Association for the Advancement of Medical Instrumentation

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Abstract: This technical information report considers and identifies certain significant standards and guides useful in the assessment of product conformity with recognized essential principles of safety and performance of medical devices. It is intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes.

Keywords: medical devices, basic safety standard, essential principles, conformity assessment

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AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Dept., 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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ANSI Technical Report

This AAMI TIR has been approved 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 ANSI Technical Reports. 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, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

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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 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI VP20:1994	Major technical variations
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	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 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:200x [1)]	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 TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	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

[1)] FDIS approved; being prepared for publication

International designation	U.S. designation	Equivalency
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO TS 15843:2000	AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Committee on Quality Management and Corresponding General Aspects for Medical Devices

The adoption of ISO Technical Report 16142 (type 3), first edition, 1999, as an ANSI/AAMI technical information report was initiated by the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices, which also serves as a U.S. Technical Advisory Group (TAG) to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the 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 role in developing the ISO technical report.

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

Chair: Robert C. Flink
Members: Robert C. Flink, Medtronic, Inc.
Edward R. Kimmelman, BME, JD, Boehringer Manneheim Corporation
Harvey Rudolph, PhD, U.S. Food and Drug Administration
Kimberly A. Trautman, U.S. Food and Drug Administration
Alternate: Charles B. Sidebottom, Medtronic, Inc.

At the time this document was balloted, the **AAMI General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group** had the following members:

Chair: Robert C. Flink
Members: Melvyn R. Altman, PhD, U.S. Food and Drug Administration
Robert G. Britain, NEMA
Cynthia Burns, Becton Dickinson
John Carline, Survivalink Corporation
Debra L. Conner, Pharmaceutical Delivery Systems
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Robert Fuson, Zimmer, Inc.
Zisimos Giatis, Inovision Radiation Measurements
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David Himes, Quinton Instrument Company
Ariel Kopelioff, St. Jude Medical
Gordon Leichter, Getinge/Castle, Inc.
David M. Link, Expertech Associates
Dawn Lopez, WL Gore & Associates, Inc.
Gretel Lumley, Zymed, Inc.
Stanley Mastrangelo, Abbott Laboratories
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Willaim Murphy, Alaris Medical Systems, Inc.
Robert H. O'Holla, Johnson & Johnson
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George Peters, Datascope Corp.
William H. Robinson, C.R. Bard, Inc.
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Edward E. Newton, RAC, Sulzer Carbomedics

Gregory W. O'Connell, U.S. Food and Drug Administration
Rebecca Rickey, Sterigenics International
Teresa Skog, 3M Healthcare
Mark N. Smith, Getinge/Castle, Inc.
Richard C. Thorne, Pharmaceutical Delivery Systems

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/TR 16142:1999

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.

ISO/TR 16142 (Technical Report, type 3) was developed by ISO Technical Committee 210, *Quality management and corresponding general aspects for medical devices*, to identify certain significant standards and guides useful in the assessment of product conformity with recognized essential principles of safety and performance of medical devices, intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes.

U.S. participation in ISO/TC 210 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 United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international documents as much as possible. Upon review of ISO/TR 16142, the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices and the AAMI General Aspects Stemming from the Application of Quality Principles to Medical Devices Working Group decided to adopt ISO/TR 16142 verbatim as an AAMI technical information report.

Continuous maintenance: This document will be reviewed on a continuous maintenance basis to ensure that any ISO updates made to the list of horizontal standards in table A.1 are made publicly available in the U.S. If and when an update is made, it will be listed in *AAMI News* and will be posted on the AAMI Web site [www.aami.org]. The Glossary of Equivalent Standards on page vi provides the latest editions of the documents referred to in table A.1 and it is up to the user to ensure the latest edition of a standard is being utilized.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page xi, this ANSI/AAMI technical information report is identical to ISO/TR 16142:1999.

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 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committee 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.*

Introduction

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

Continuous innovation is key to the advancement of medical device technology, contributing to more effective health care. 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 device 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. This 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 advanced 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 system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health;

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

— such provisions include field experience, risk analysis and management, phased reviews, and documentation and recordkeeping, 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 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 Technical Report, 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 all kinds of 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 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 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.

3 Essential principles of safety and performance of medical devices

Essential principles of safety and performance (after this, called “essential principles”) provide general requirements for design and production of all medical devices, ensuring their safety and performance. The concept of essential principles was developed by the Global Harmonization Task Force (GHTF; see annex B). The concept is intended to encourage convergence in the evolution of regulatory systems for medical devices.

To ensure that, where relevant, the essential principles are met, a manufacturer may use consensus standards addressing the essential principles. Such standards provide a greater level of detail than can be expressed in the essential principles. Equally, legislators may find the essential principles and their related standards useful in the context of regulatory systems for medical devices.

4 Use of standards and guides in support of regulatory requirements

4.1 Reference to standards

Basic standards have been and are being developed to address the essential principles which are applicable to all kinds or a wide range of medical devices. Basic standards provide the technical details needed to satisfy compliance with the essential principles. In general, international consensus standards should be adopted by member bodies without alteration. Their use is to be encouraged as this minimizes the proliferation of standards.

In some countries, regulatory authorities accept the use of consensus standards as one means of demonstrating compliance with relevant essential principles of safety and performance of medical devices.

When a consensus standard is either (a) not utilized, (b) is not available, or (c) is not applied in full, this is acceptable if an equivalent level of compliance with the essential principles of safety and performance can be achieved and demonstrated through other means.

In the absence of international consensus standards, it may be appropriate for regulatory authorities to accept the use of regional, national consensus standards or industry standards.

Standards suitable to address the essential principles should be based on:

— a close relationship of the scope of the standard to one or more of the essential principles;

— the clarity and completeness of the technical requirements contained in the standard;

— the existence of methods for determining compliance with each of the technical requirements in the standard;

— the definition of clear criteria for determining that the technical requirements are met.

4.2 Conformity assessment

In assessing the conformity of a medical device with the essential principles, a manufacturer of a particular medical device may utilize parts of several standards and combine them in a way which is considered to be appropriate for the device in question.

The use of parts and/or combinations of standards should be acceptable for conformity assessment purposes. Specific product standards are necessary where basic and/or group standards are inadequate.

5 Essential principles and references to relevant standards or guides

Before placing a medical device on the market, a manufacturer has to establish that the applicable essential principles of safety and performance have been met in a satisfactory way.

There may be a number of ways for a manufacturer to demonstrate compliance to essential principles.

In annex A, a number of significant standards are indicated which may be suitable for demonstrating compliance with certain features of the related essential principles as listed in Table A.1.

When selecting standards from annex A, it is important to consider the type of the device and process concerned, as some standards listed relate to particular families of devices, or processes (e.g., IEC 60601 relates to medical electrical equipment; ISO 11140 series relates to sterilization of health care products).

It is recognized that the requirements in a single standard may not meet all the features of a given essential principle as related to a given device. Other standards may be available, or under development, that can assist in demonstrating that device meets all the relevant essential principles.

The standards referenced in annex A may be used as a starting point, and any reference material intended to be used should be checked against a maintained source for the latest effective revision.

It is not possible in this Technical Report to identify all standards which may be used to meet particular essential principles.

6 How to find relevant standards

The following Internet addresses[1)] are available to aid in locating standards:

ISO http://www.iso.ch/

IEC http://www.iec.ch/

National member bodies of ISO and IEC may have national standards equivalent to those listed in annex A, although the numbers may not be the same.

[1)] In addition, standards information is available from http://www.aami.org and http://www.ansi.org.

Annex A

Tables relating essential principles to standards

The list of standards in Table A.1 is to be used as a starting point and any reference material intended to be used should be checked against a maintained source for the latest effective revision.

Standards that are referenced for a major category of essential principles are potentially applicable to most if not all of the specific principle in the category. Where standards are limited to one or a few specific principles, references are made specific to the associated principle.

Other types of documents may be useful, in particular for standards writers.

Some of these documents are:

— ISO Guide 51, *Guidelines for the inclusion of safety aspects in standards.*

— ISO Guide 63, *Guidance on the development of International Standards in the field of health care technology.*

— ISO Guide 64, *Guide for the inclusion of environmental aspects in product standards.*

— IEC 60513, *Fundamental aspects of safety standards for medical electrical equipment.*

In this annex, a number of significant standards are indicated which may be suitable for demonstrating compliance with certain features of the related essential principles. Other standards may be available, or under development, that can assist in demonstrating that a device meets all the relevant essential principles.

Table A.1—Relating essential principles to standards

Essential principles of safety and performance of medical devices		References	Standards and guides potentially applicable
I	GENERAL PRINCIPLES		
A.1	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against benefits to the patient and are compatible with a high level of protection of health and safety.	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969 ISO 14155	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 Clinical investigations of medical devices See also specific device standards.
A.2	The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking into account the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: – identify hazards and the associated risks arising from the intended use and foreseeable misuse; – eliminate or reduce risks as far as possible (inherently safe design and construction); – where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated; – inform users of the residual risks due to any shortcomings of the protection methods adopted.	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488

Essential principles of safety and performance of medical devices		References	Standards and guides potentially applicable
A.3	Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device applicable in each jurisdiction.	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 See also specific device standards.
A.4	The characteristics and performances referred to in clauses A.1, A.2, and A.3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969 ISO 14155	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 Clinical investigations of medical devices See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.5 The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking into account the instructions and information provided by the manufacturer.	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 See also specific device standards.
A.6 The benefits must be determined to outweigh any undesirable side effects for the performances intended.	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
II REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION		
A.7 Chemical, physical, and biological properties	ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis
	ISO 13485	Quality systems—Medical devices—Particular requirements for the application of ISO 9001
	ISO 13488	Quality systems—Medical devices—Particular requirements for the application of ISO 9002
	ISO 14969	Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488
	ISO 10993 series	Biological evaluation of medical devices
		See also specific device standards.
A.7.1 The devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section I on the "General Requirements". Particular attention should be paid to: – the choice of materials used, particularly as regards toxicity and, where appropriate flammability; – the compatibility between the materials used and biological tissues, cells and body fluids, taking account of to the intended purpose of the device; – the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.	ISO 14969	Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488
	ISO 10993 series	Biological evaluation of medical devices
		See also specific device standards
A.7.2 The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking into account the intended purpose of the product. Particular attention should be paid to the tissues exposed and the duration and frequency of the exposure.	ISO 14969	Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488
	ISO 10993 series	Biological evaluation of medical devices
	ISO 11607	Packaging for terminally sterilized medical devices
		See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.7.3 The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products, they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing those products and that their performance is maintained in accordance with the intended use.	ISO 14971-1 ISO 10993 series ISO 11607	Medical devices—Risk management—Part 1: Application of risk analysis Biological evaluation of medical devices Packaging for terminally sterilized medical devices See also specific device standards.
A.7.4 Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking into account the intended purpose of the device.	ISO 10993 series ISO 11607	Biological evaluation of medical devices Packaging for terminally sterilized medical devices See also specific device standards.
A.7.5 The devices should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances that can leach from the device.	ISO 14971-1 ISO 10993 series ISO 11607	Medical devices—Risk management—Part 1: Application of risk analysis Biological evaluation of medical devices Packaging for terminally sterilized medical devices Sterilization packaging See also specific device standards.
A.7.6 The devices should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress or egress of substances into or from the devices taking into account the device and the nature of the environment in which it is intended to be used.	ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.8 Infection and microbial contamination	ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis
	ISO 13485	Quality systems—Medical devices—Particular requirements for the application of ISO 9001
	ISO 13488	Quality systems—Medical devices—Particular requirements for the application of ISO 9002
	ISO 14969	Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488
	ISO 11135	Medical devices—Validation and routine control of ethylene oxide sterilization
	ISO 11137	Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization
	ISO 11134	Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization
	ISO 11138 series	Sterilization of health care products—Biological indicators
	ISO 11140 series	Sterilization of health care products—Chemical indicators
	ISO 11607	Packaging for terminally sterilized medical devices
	ISO 11737 series	Sterilization of medical devices—Microbiological methods
	ISO 13408 series	Aseptic processing of health care products
	ISO/TR 13409	Sterilization of health care products—Radiation sterilization—Substantiation of 25 kGy as a sterilization dose for small or infrequent production batches
	ISO 13683	Sterilization of health care products—Requirements for validation and routine control of moist heat sterilization in health care facilities
	ISO 14160	Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid chemical sterilants

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.8 Infection and microbial contamination *(continued)*	ISO 14161 ISO/TR 15843 ISO/TR 15844	Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results Sterilization of health care products—Radiation sterilization—Product families, sampling plans verification dose experiments and sterilization dose audits Sterilization of health care products—Radiation sterilization—Selection of sterilization dose for a single production batch See also specific device standards.
A.8.1 The devices and their manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and, where applicable, other persons. The design should allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	See also clause A.8. ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis See also specific device standards.
A.8.1.1 Tissues of non-human origin as far as considered a medical device should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the competent/regulatory authority should retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	See also clause A.8. ISO 14160	Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid chemical sterilants See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.8.1.2 In some jurisdictions, products incorporating human tissues, cells and substances may be considered medical devices. In this case, selection, processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	See also clause A.8.	See also specific device standards.
A.8.2 Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	ISO 14971-1 See also clause A.8.	Medical devices—Risk management—Part 1: Application of risk analysis See also specific device standards.
A.8.3 Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	See also clause A.8.	See also specific device standards.
A.8.4 Devices intended to be sterilized should be manufactured in appropriately controlled (e.g., environmental) conditions.	See also clause A.8. ISO 14644 series	Cleanrooms and associated controlled environments See also specific device standards.
A.8.5 Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking into account the method of sterilization indicated by the manufacturer.	ISO 14971-1 See also clause A.8.	Medical devices—Risk management—Part 1: Application of risk analysis See also specific device standards.
A.8.6 The packaging and/or label of the device should distinguish between identical or similar products sold in both sterile and non-sterile conditions.		See note on labeling in A.13.1. See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.9 Construction and environmental properties	ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis
	ISO 13485	Quality systems—Medical devices—Particular requirements for the application of ISO 9001
	ISO 13488	Quality systems—Medical devices—Particular requirements for the application of ISO 9002
	ISO 14969	Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488
	IEC 60601 series	Medical electrical equipment See also specific device standards.
A.9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, should be safe and should not impair the specified performance of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.	IEC 60601 series	Medical electrical equipment
	ISO 594 series	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. See also specific device standards.
A.9.2 Devices should be designed and manufactured in such a way as to remove or minimize as far as is practicable: – the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional, and where appropriate the ergonomic features; – risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration; – risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; – risks arising where maintenance or calibration is not possible (as with implants) from aging of the materials used or loss of accuracy of any measuring or control mechanism.	ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis
	IEC 60601 series	Medical electrical equipment See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.9.3 Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	ISO 14971-1 IEC 60601 series	Medical devices—Risk management—Part 1: Application of risk analysis Medical electrical equipment See also specific device standards.
A.10 Devices with a measuring function	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969 IEC 60601 series	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 Medical electrical equipment See also specific device standards.
A.10.1 Devices with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy, precision, and stability within appropriate limits of accuracy and taking into account the intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.	ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis See also specific device standards.
A.10.2 The measurement, monitoring, and display scale should be designed in line with ergonomic principles, taking into account the intended purpose of the device.	ISO 14971-1	Medical devices—Risk management—Part 1: Application of risk analysis See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.10.3 The measurements made by devices with a measuring function should be expressed in legal units as required by the legislation governing such expression of each jurisdiction in which the device is to be sold.	ISO 2955	Information processing -- Representation of SI and other units in systems with limited character sets See also note in clause A.13.1. See also specific device standards.
A.11 Protection against radiation	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969 IEC 60601 series	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 Medical electrical equipment See also specific device standards.
A.11.1 General A.11.1.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation should be reduced as far as possible, compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	See also clause A.11.	See also specific device standards.
A.11.2 Intended radiation A.11.2.1 Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	See also clause A.11.	See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	See also clause A.11.	See also specific device standards.
A.11.3 Unintended radiation A.11.3.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray, or scattered radiation is reduced as far as possible.	See also clause A.11.	See also specific device standards.
A.11.4 Instructions for use A.11.4.1 The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	See also clause A.11.	See also specific device standards.
A.11.5 Ionizing radiation A.11.5.1. Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.	See also clause A.11.	See also specific device standards.
A.11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose while minimizing radiation exposure of the patient and user.	See also clause A.11.	See also specific device standards.
A.11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.	See also clause A.11.	See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.12 Requirements for medical devices connected to or equipped with an energy source	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969 ISO 14155 IEC 60601 series	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 Clinical investigations of medical devices Medical electrical equipment See also specific device standards.
A.12.1 Devices incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition in the system, appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	See also clause A.12.	See also specific device standards.
A.12.2 Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.	See also clause A.12.	See also specific device standards.
A.12.3 Devices where the safety of the patient depends on an external power supply should include an alarm system to signal any power failure.	See also clause A.12.	See also specific device standards.
A.12.4 Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	See also clause A.12.	See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.12.5 Devices should be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	See also clause A.12.	
A.12.6 Protection against electrical risks Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided that the devices are installed correctly.	See also clause A.12.	See also specific device standards.
A.12.7 Protection against mechanical and thermal risks A.12.7.1 The devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability, and moving parts.	See also clause A.12.	See also specific device standards.
A.12.7.2 The devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generation by the devices, taking into account technical progress and the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	See also clause A.12.	See also specific device standards.
A.12.7.3 The devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking into account technical progress and the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	See also clause A.12.	See also specific device standards.
A.12.7.4 Terminals and connectors to the electricity, gas, or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.	See also clause A.12.	See also specific device standards.
A.12.7.5 Accessible parts of devices (excluding any parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.	See also clause A.12.	See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.12.8 Protection against the risks posed to the patient by energy supplies or substances A.12.8.1 Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the amount can be set and maintained accurately enough to guarantee the safety of the patient and the user.	See also clause A.12.	See also specific device standards.
A.12.8.2 Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	See also clause A.12.	See also specific device standards.
A.12.8.3 The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.	See also clause A.12.	See also specific device standards.
A.13 Information supplied by the manufacturer	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.13.1 Each device should be accompanied by the information needed to identify the manufacturer, to use it safely and to ensure the intended performance, taking into account the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use, and should be easily understandable. NOTE—Detailed information on labeling requirements is the subject of a separate document	ISO 7000 IEC 60417 IEC 60878 ISO/TR 15223	Graphical symbols for use on equipment—Index and synopsis Graphical symbols for use on equipment Graphical symbols for electrical equipment in medical practice Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied See also specific device standards.
A.14 Clinical evaluation	ISO 14971-1 ISO 13485 ISO 13488 ISO 14969 ISO 14155	Medical devices—Risk management—Part 1: Application of risk analysis Quality systems—Medical devices—Particular requirements for the application of ISO 9001 Quality systems—Medical devices—Particular requirements for the application of ISO 9002 Quality systems—Medical devices—Guidance on the application of ISO 13485 and ISO 13488 Clinical investigation of medical devices See also specific device standards.

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.14.1 Where conformity with these essential principles should be based on clinical evaluation data, such data should be established in accordance with the relevant requirements applicable in each jurisdiction. Clinical investigations on human subjects should be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in spirit of the Helsinki Declaration. This includes all steps in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent. NOTE—Specific guidance on clinical evaluation may be developed in the future.	ISO 14155	Clinical investigation of medical devices See also specific device standards.

Annex B

Information on the Global Harmonization Task Force

The objective of the GHTF is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered to be most suitable.

Participation in GHTF is from regulators and industry representatives from countries and regions having experience with medical device regulations.

The objective is achieved by identifying and developing areas of international cooperation in order to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices.

The results are also available to inform interested countries that may be engaged in the development of such regulations.

The GHTF accomplishes these objective by:

— examining medical devices regulatory systems in use in major trading countries and regions;

— identifying similarities and divergences between individual systems;

— identifying features of those systems which have a common basis but differences in application;

— creating proposals for the technical and regulatory harmonization which would approach or achieve the above objectives;

— communicating output from the above procedures to all concerned.

In drafting the essential principles, many common features have been identified within existing and draft regulations of GHTF members. Some of these features are presented in different ways in various regulations.

The development of these essential principles has been identified as providing a major contribution towards convergence in the evolution of regulatory systems for medical devices.

Further information about GHTF and access to its latest documents, are available through http://www.ghtf.org.

Bibliography

[1] *Global Harmonization Task Force—Study Group 1—Essential principles of safety and performance of medical devices.*

NOTE—The standards cited in annex A are not listed here.