TECHNICAL REPORT

ISO/TR 16142

First edition
1999-12-15

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

Dispositifs médicaux — Lignes directrices pour le choix de normes à l'appui des principes fondamentaux reconnus de sécurité et performance des dispositifs médicaux

Reference number
ISO/TR 16142:1999(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

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 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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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*.

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 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 make 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. 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 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, 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 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 sometime 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 sometime referred to as semi-horizontal 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 sometime referred to as vertical standards.

3 Essential principles of safety and performance of medical devices

Essential principles of safety and performance (hereinafter 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 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 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.

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	*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 14155	*Clinical investigations of medical devices*
		See also specific device standards.

Table A.1 *(continued)*

Essential principles of safety and performance of medical devices	References	Standards and guides potentially applicable
A.2 The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of 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*
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.