TECHNICAL REPORT

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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 des normes correspondant aux principes essentiels reconnus de sécurité et de performance des dispositifs médicaux

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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.

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.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

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 D). 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 Basic standards

Basic standards are developed to address the essential principles that 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. The development and use of basic standards is encouraged as this minimizes the proliferation of standards and prevents the development of divergent or conflicting requirements or expectations. Basic standards support the development of consistent expectations between regulatory authorities and manufacturers. In general, member bodies should adopt international consensus standards without alteration.

Basic standards can be broadly categorized into:

— management systems standards, e.g. quality management systems, risk management, and

— essential safety standards or standards specifying requirements for a process, e.g. biological safety, general requirements for safety and essential performance for medical electrical equipment, sterilization, and usability.

4.2 Recognition of standards

In some countries, regulatory authorities recognize the use of voluntary consensus standards as one means of demonstrating compliance with relevant essential principles of safety and performance of medical devices. When a recognized consensus standard is either

a) not utilized,

b) not available, or

c) 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 or 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.

4.3 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 that 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 do not cover all the necessary essential principles of safety and performance.

4.4 Reference to basic standards

It can be appropriate for a standard to make a reference to a basic standard in order to ensure consistent application of requirements. Such references should be made with caution so as not to limit any options allowed by regulatory requirements and conformity assessment procedures, especially in the situations in which product standards need to make normative reference to basic standards for management systems (see 4.1). There is general agreement that controlling certain processes is the best way, or the only way, of ensuring that the products emerging from the processes meet regulatory requirements. Classic instances are for sterile products and for software; therefore standards for sterile products and products utilizing software are examples where it can be appropriate to call up basic standards. However, caution is appropriate before requiring application of Management System Standards through normative reference in a product standard.

Manufacturers using standards to support conformity with regulatory requirements have the option of using all or part of a standard (see 4.3).

Basic standards may be evoked by other standards in a number of ways. Examples are:

— specifying requirements for systems or properties supported by informative reference to a basic standard,

— including normative reference to identified requirements, clauses or subclauses of a basic standard,

— specifying requirements using verbatim text taken from a basic standard and citing the source document informatively, or

— including normative reference to a basic standard.

Examples of these approaches are given in Annex B.

It can also be appropriate to make normative reference from one product standard to another, following the above guidelines.

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).

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 a 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 that 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.org

— 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
(informative)

Table relating essential principles to standards

The list of standards in Table A.1 is to be used as a starting point. 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, *Safety aspects — Guidelines for their inclusion in standards*

— ISO Guide 63, *Guide to the development and inclusion of safety aspects in International Standards for medical devices*

— 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 — Correspondence between the essential principles of safety and performance of medical devices and standards

Essential principles of safety and performance of medical devices			References[a]
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 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts)
	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 ISO 13485 ISO/TR 14969
	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 ISO 13485 ISO/TR 14969
	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 ISO 13485 ISO/TR 14969 ISO 14155 (all parts)
	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 ISO 13485 ISO/TR 14969
	A.6	The benefits must be determined to outweigh any undesirable side effects for the performances intended.	ISO 14971 ISO 13485 ISO/TR 14969

Table A.1 (*continued*)

Essential principles of safety and performance of medical devices			References[a]
II	REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION		
	A.7	Chemical, physical, and biological properties	ISO 14971 ISO 13485 ISO/TR 14969 ISO 10993 (all parts)
	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 the intended purpose of the device; — the choice of materials used should reflect, where appropriate, matters such as hardness, wear and fatigue strength.	ISO/TR 14969 ISO 10993 (all parts)
	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/TR 14969 ISO 10993 (all parts) ISO 11607 (all parts)
	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 their performance is maintained in accordance with the intended use.	ISO 14971 ISO 10993 (all parts) ISO 11607 (all parts)
	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.	See also Pharmacopoeia and publications of authorities responsible for medicinal products/drugs.
	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 ISO 10993 (all parts) ISO 11607 (all parts) IEC 60601 (all parts)
	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 ISO 10993 (all parts)

Table A.1 (*continued*)

Essential principles of safety and performance of medical devices			References[a]
	A.8	Infection and microbial contamination	ISO 14971 ISO 13485 ISO/TR 14969 ISO 11135 (all parts) ISO 11137 (all parts) ISO 11607 (all parts) ISO 11737 (all parts) ISO 13408 (all parts) ISO 14160 ISO 14937 ISO 17665 (all parts)
	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 A.8
	A.8.1.1	Tissues of non-human origin as far as 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.	ISO 22442 (all parts) See also A.8
	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 A.8
	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.	See A.8
	A.8.3	Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	See A.8
	A.8.4	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	ISO 14644 (all parts) See also A.8
	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.	See A.8
	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 labelling in A.13.1.

Table A.1 (*continued*)

Essential principles of safety and performance of medical devices			References[a]
	A.9	Construction and environmental properties	ISO 14971 ISO 13485 ISO/TR 14969 IEC 60601 (all parts)
	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 (all parts) ISO 594 (all parts) ISO/IEEE 11073 (all parts)
	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 IEC 60601 (all parts) ISO/IEEE 11073 (all parts)
	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 IEC 60601 (all parts)
	A.10	Devices with a measuring function	ISO 14971 ISO 13485 ISO/TR 14969 IEC 60601 (all parts)
	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 ISO/IEEE 11073 (all parts)
	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
	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.	See also note in Clause A.13.1

Table A.1 (*continued*)

Essential principles of safety and performance of medical devices			References[a]
	A.11	Protection against radiation	ISO 14971 ISO 13485 ISO/TR 14969 IEC 60601 (all parts)
	A.11.1	General 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 A.11
	A.11.2	Intended radiation	See also A.11
	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 A.11
	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 A.11
	A.11.3	Unintended radiation 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 A.11
	A.11.4	Instructions for use 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 A.11
	A.11.5	Ionizing radiation	See also A.11
	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 A.11
	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 A.11
	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 A.11

Table A.1 (*continued*)

Essential principles of safety and performance of medical devices			References[a]
	A.12	Requirements for medical devices connected to or equipped with an energy source.	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
	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.	IEC 60601-1-4 See also A.12
	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 A.12
	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 A.12
	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 A.12
	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 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 A.12
	A.12.7	Protection against mechanical and thermal risks	See A.12
	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 A.12
	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 A.12
	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 A.12
	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 A.12
	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 A.12

Table A.1 (*continued*)

Essential principles of safety and performance of medical devices			References[a]
	A.12.8	Protection against the risks posed to the patient by energy supplies or substances	See A.12
	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 A.12
	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 A.12
	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 A.12
	A.13	Information supplied by the manufacturer.	ISO 14971 ISO 13485 ISO/TR 14969
	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 labelling requirements is the subject of a separate document.	ISO 7000 IEC 60417 IEC/TR 60878 ISO 15223
	A.14	Clinical evaluation	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts)
	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 the 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 (all parts)

[a] See also specific product standards.

Annex B
(informative)

Examples of reference to basic standards

B.1 Example of normative reference to a basic standard

EXAMPLE A system shall be specified and implemented to ensure that the condition of product presented for sterilization, including its bioburden, is controlled so that the effectiveness of the sterilization process is not compromised. The effectiveness of the system shall be demonstrated and shall include determination of bioburden in accordance with ISO 11737-1.

NOTE This example is taken from ISO 11137-1.

B.2 Example of normative reference to identified requirements, clauses or subclauses

EXAMPLE A risk analysis or part of a risk analysis that focuses on usability shall be performed in accordance with ISO 14971:2000, Clause 4.

NOTE This example is adapted from IEC 60601-1-6.

B.3 Example of specifying requirement(s) supported by informative reference to basic standards

EXAMPLE The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4 and Note 3).

NOTE 1 See ISO 14971 for guidance related to risk management.

NOTE 2 The example shown above, including NOTE 1, is taken from ISO 13485:2003.

Annex C
(informative)

Website listings of other standards suitable for the medical device sector and for assessment purposes

The following website addresses list other standards suitable for the medical device sector and for assessment purposes:

— http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html

— http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

— http://www.tga.gov.au/docs/html/devstdord.htm

— http://www.hc-sc.gc.ca

— http://www.jisc.go.jp/index.html or http://www.jsa.or.jp/default_english.asp

Annex D
(informative)

Information on the Global Harmonization Task Force

The objective of the GHTF[29] 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 the regulatory means considered to be the most suitable.

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

The GHTF 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. There is a Memorandum of Understanding between the GHTF and ISO/TC 210 recognizing that the development of international standards supports the harmonization of global regulations.

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

The GHTF accomplishes its 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.

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