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Medical devices — Recognized essential principles of safety and performance of medical devices —

Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

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Dispositifs médicaux — Principes essentiels reconnus de sécurité et de performance des dispositifs médicaux —

Partie 2: Principes essentiels généraux et principes essentiels spécifiques supplémentaires pour tous les dispositifs médicaux de DIV et directives sur le choix des normes

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

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This document builds on ISO 16142-1, which cancels and replaces ISO/TR 16142:2006.

A list of all parts in the ISO 16142 series can be found on the ISO website.

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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. Ideally, standards supporting or referenced in regulatory requirements are developed and applied in such a way as to allow product innovation by industry while assuring safety and effectiveness.

The timely development of medical device standards and their periodic revision make medical device standards effective and efficient tools for supporting regulatory systems and for achieving 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 can 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 is based on the premise that

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

— innovation can present unanticipated challenges to experience,

— rigid, mandatory, application of standards can 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, and

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

The essential principles of safety and performance of medical devices were originally developed by the Global Harmonization Task Force (GHTF), revised in 2012 to harmonize regulatory requirements for medical devices worldwide, and now archived by the International Medical Device Regulators Forum (IMDRF). Thus, an update of the original ISO/TR 16142:2006, based on those essential principles, was needed to keep the document in line with the updated essential principles.

In discussing the revision of ISO/TR 16142:2006, ISO/TC 210 decided that the information included was, at the time of writing, in a state of consensus between the stakeholders and had matured enough to elevate the document from a Technical Report (TR) to an International Standard.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— terms defined in Clause 3: italics.

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In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document,

— “may” is used to describe a permissible way to achieve compliance with a requirement or test, and

— “must” is used to describe an external constraint, but is not mandatory for compliance with this document.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

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Medical devices — Recognized essential principles of safety and performance of medical devices —

Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

1 Scope

This document, which includes the essential principles of safety and performance, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to the recognized essential principles that when met, indicate a medical device is safe and performs as intended. This document identifies and describes the six general essential principles of safety and performance (see Table B.1) that apply to all medical devices, including IVD medical devices (*in vitro* diagnostic).

This document also identifies and describes the additional essential principles of safety and performance which need to be considered during the design and manufacturing process, which are relevant to IVD medical devices.

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NOTE During the design process, the manufacturer selects which of the listed design and manufacturing principles apply to the particular medical device and documents the reasons for excluding others.

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This document is intended for use as guidance by medical device manufacturers, standards development organizations, authorities having jurisdiction, and conformity assessment bodies.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859 (all parts), *Sampling procedures for inspection by attributes*

ISO 3951 (all parts), *Sampling procedures for inspection by variables*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137 (all parts), *Sterilization of health care products — Radiation*

ISO 11138 (all parts), *Sterilization of health care products — Biological indicators*

ISO 11140 (all parts), *Sterilization of health care products — Chemical indicators*

ISO 11607 (all parts), *Packaging for terminally sterilized medical devices*

ISO 11737 (all parts), *Sterilization of medical devices — Microbiological methods*

ISO/TS 13004, *Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD*

ISO 13408 (all parts), *Aseptic processing of health care products*

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ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14161, *Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results*

ISO 14644 (all parts), *Cleanrooms and associated controlled environments*

ISO 14698 (all parts), *Cleanrooms and associated controlled environments — Biocontamination control*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15193, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures*

ISO 15194, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*

ISO 15195, *Laboratory medicine — Requirements for reference measurement laboratories*

ISO 15197, *In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15882, *Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results*

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ISO 16269 (all parts), *Statistical interpretation of data*

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ISO 17511, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

ISO 17593, *Clinical laboratory testing and in vitro medical devices — Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy*

ISO 17665 (all parts), *Sterilization of health care products — Moist heat*

ISO 18113 (all parts), *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling)*

ISO 18153, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials*

ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22442 (all parts), *Medical devices utilizing animal tissues and their derivatives*

ISO 23640, *In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents*

ISO/TR 24971, *Medical devices — Guidance on the application of ISO 14971*

ISO 25424, *Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO/IEC 15026 (all parts), *Systems and software engineering — Systems and software assurance*

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ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO/IEEE 11073 (all parts), *Health informatics — Personal health device communication*

CLSI EP05[1)], *Evaluation of precision of quantitative measurement procedures; Approved guideline*

CLSI EP06[1)], *Evaluation of the linearity of quantitative measurement procedures: a statistical approach; Approved guideline*

CLSI EP07[1)], *Interference testing in clinical chemistry; Approved guideline*

CLSI EP12-A2[1)], *User protocol for evaluation of qualitative test performance; Approved guideline*

CLSI EP26-A[1)], *User evaluation of between-reagent lot variation; Approved guideline*

CLSI POCT12[1)], *Human point-of-care blood glucose testing in acute and chronic care facilities; Approved guideline*

AAMI HE75, *Human factors engineering — Design of medical devices*

ASTM F2027, *Standard guide for characterization and testing of raw or starting biomaterials for tissue-engineered medical products*

ASTM F2761, *Medical devices and medical systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*

EN 13532, *General requirements for in vitro diagnostic medical devices for self-testing*

EN 13612, *Performance evaluation of in vitro diagnostic medical devices*

EN 13641, *Elimination or reduction of risk of infection related to in vitro diagnostic reagents*

EN 14136, *Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures*

IEC 60068, *Environmental testing*

IEC 60812, *Analysis techniques for system reliability — Procedure for failure mode and effects analysis (FMEA)*

IEC 60825 (all parts), *Safety of laser products*

IEC 60878, *Graphical symbols for electrical equipment in medical practice*

IEC 61010-2-101, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

IEC 61326-2-6, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment*

IEC 62304, *Medical device software — Software life cycle processes*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62366-2, *Medical devices — Part 2: Guidance on the application of usability engineering to medical devices*

IEC 62471, *Photobiological safety of lamps and lamp systems*

IEC/ISO 80000 (all parts), *Quantities and units*

IEC/ISO 80001-1, *Application of risk management for IT-networks incorporating medical devices — Part 1: Roles, responsibilities and activities*

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1) Available from: Clinical and Laboratory Standards Institute, Wayne, PA US.

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IEC/TR 80001-2-1, *Application of risk management for IT-networks incorporating medical devices — Part 2-1: Step by step risk management of medical IT-networks — Practical applications and examples*

IEC/TR 80001-2-5, *Application of risk management for IT-networks incorporating medical devices — Part 2-5: Application guidance — Guidance on distributed alarm systems*

IEC/ISO 80002-1, *Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

Note For convenience, the sources of all defined terms used in this document are given in Annex E.

3.1
authority having jurisdiction
regulatory authority
governmental agency or office assigned to oversee the regulation of a regulated product within a country, jurisdiction, or assigned territory

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3.2
basic standard
standard that includes fundamental concepts or principles and specifies requirements with regard to general aspects applicable to a wide range of products, processes or services

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Note 1 to entry: Basic standards are sometimes referred to as horizontal standards and usually apply to more than one field (sector).

3.3
essential principles
essential principles of safety and performance
fundamental high-level requirements that when complied with ensure a *medical device* (3.13) is safe and performs as intended

3.4
group standard
basic standard (3.2) that specifies safety and performance requirements applicable to several or a family of similar products, processes or services

Note 1 to entry: Group standards are sometimes referred to as semi-horizontal standards and usually apply to one field (sector).

3.5
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.6
hazardous situation
circumstance in which people, property, or the environment is/are exposed to one or more *hazards* (3.5)

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

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3.7
informative
providing useful or interesting information

Note 1 to entry: Not required for compliance.

3.8
intended use
use for which a product, process or service is intended according to the specifications, instructions and information provided by the *manufacturer* (3.12)

[SOURCE: ISO 14971:2007, 2.5]

3.9
IVD kit
IVD medical device kit
set of reactive components that are packaged together and intended to be used to perform a specific IVD examination

Note 1 to entry: IVD kit components can include reagents (such as antibodies, enzymes, buffer and diluents), calibrators, controls and other articles and materials.

[SOURCE: ISO 18113-1:2009, 3.32, modified]

3.10
***in vitro* diagnostic medical device**
*** IVD medical device**
medical device (3.13) intended by the *manufacturer* (3.12) for the examination of specimens derived from the human body to provide information for diagnostic, monitoring or compatibility purposes

EXAMPLE Reagents, calibrators, specimen collection and storage devices, control materials and related instruments, apparatus or articles.

Note 1 to entry: An IVD medical device can be used alone or in combination with accessories or other medical devices.

[SOURCE: ISO 14971:2007, 2.6, modified]

3.11
life-cycle
all phases in the life of a *medical device* (3.13), from the initial conception to final decommissioning and disposal

[SOURCE: ISO 14971:2007, 2.7]

3.12
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a *medical device* (3.13), assembling a system, or adapting a *medical device* (3.13) before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

Note 2 to entry: For a definition of labelling, see ISO 13485:2016, 3.8.

[SOURCE: ISO 14971:2007, 2.8]

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3.13
medical device
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the *manufacturer* (3.12) to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Note 1 to entry: This definition has been developed by the Global Harmonization Task Force (GHTF)[5].

Note 2 to entry: Products, which could be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

— aids for disabled/handicapped people,

— devices for the treatment/diagnosis of diseases and injuries in animals,

— accessories for medical devices (see Note 3),

— disinfection substances,

— devices incorporating animal and human tissues which can meet the requirements of the above definition but are subject to different controls.

Note 3 to entry: Accessories intended specifically by manufacturers to be used together with a parent medical device to enable that medical device to achieve its *intended use* (3.9) should be subject to this document.

[SOURCE: ISO 14971:2007, 2.9, modified — The word “intended purpose” has been changed to “intended use”.]

3.14
normative
providing required information

Note 1 to entry: Required for compliance.

3.15
performance evaluation
investigation of a device intended to become an *IVD medical device* (3.10) for the purpose of establishing or verifying its performance claims

[SOURCE: ISO 18113-1:2009, 3.52]

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3.16
process standard
standard that specifies requirements for elements of a process used to develop, implement or maintain a stage of the *life-cycle* (3.11) of a product or service

Note 1 to entry: A process standard may be a *basic standard* (3.2), *group standard* (3.4) or *product standard* (3.17).

3.17
product standard
standard that specifies necessary safety and performance requirements for a specific or a family of product(s), process(es), or service(s) making reference, as far as possible, to *basic standards* (3.2) and *group standards* (3.4)

Note 1 to entry: Product standards are sometimes referred to as vertical standards.

3.18
post-production
part of the *life-cycle* (3.11) of the product after the design has been completed and the *medical device* (3.13) has been manufactured

EXAMPLE Transportation, storage, installation, product use, maintenance, repair, product changes, decommissioning and disposal.

[SOURCE: ISO 14971:2007, 2.11]

3.19
residual risk
risk (3.20) remaining after *risk control* (3.21) measures have been taken

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Note 1 to entry: Adapted from ISO/IEC Guide 51:2014, 3.9.

Note 2 to entry: ISO/IEC Guide 51:2014, 3.9 uses the term "protective measures" rather than "risk control measures." However, in the context of this document, "protective measures" are only one option for controlling risk as described in 6.2.

[SOURCE: ISO 14971:2007, 2.15]

3.20
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

3.21
risk control
process in which decisions are made and measures implemented by which *risks* (3.20) are reduced to, or maintained within, specified levels

[SOURCE: ISO 14971:2007, 2.19]

3.22
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.20)

[SOURCE: ISO 14971:2007, 2.22]

3.23
state of the art
developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

[SOURCE: ISO/IEC Guide 2:2004, 1.4]

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4 Essential principles of safety and performance of IVD medical devices

IVD medical device standards developers are encouraged to consider the essential principles as design input for the development of new and revised IVD medical device standards. Additional information is found in Annex D.

IVD medical device performance can include technical functions in addition to clinical effectiveness. Performance is easier to objectively measure and quantify than clinical effectiveness. Performance may be described as how well or accurately an IVD medical device carries out its use(s) as intended by its manufacturer. For some IVD medical devices, medical benefit or clinical effectiveness can only be determined by conducting clinical performance studies carried out in human subjects.

The manufacturer of an IVD medical device is expected to design and manufacture a product that is safe and clinically effective throughout its life-cycle. This document describes fundamental design and manufacturing criteria, referred to as essential principles of safety and performance, to ensure this outcome. This document is structured to provide general essential principles that apply to all medical devices including IVD medical devices. This document also includes additional essential principles of safety and performance which are relevant to IVD medical devices that need to be considered during the design and manufacturing process.

Essential principles of safety and performance provide broad, high-level, criteria for design, production and post-production (including post-market surveillance) throughout the life-cycle of all IVD medical devices, ensuring their safety and performance. The concept of essential principles was developed by Study Group 1 of the Global Harmonization Task Force[5]. The concept is intended to encourage convergence in the evolution of regulatory systems for IVD medical devices.

NOTE Some authorities having jurisdiction have more requirements and some have less. Therefore, manufacturers need to understand the requirements of the authorities having jurisdiction in the markets they intend to serve.

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Where relevant, to ensure all of the essential principles are met, a manufacturer may use consensus standards that contain detailed requirements demonstrating conformance with the essential principles. Such consensus standards provide a greater level of detail and specificity than can be expressed in the essential principles. Equally, authorities having jurisdiction may find the essential principles and their related standards useful in the fulfilment of premarket and post-market requirements throughout the life-cycle of IVD medical devices.

Every IVD medical device has a use as intended by its manufacturer. An IVD medical device is clinically effective when it provides accurate and reliable information for diagnostic, monitoring or compatibility purposes in a safe manner as intended by its manufacturer relative to

— the medical condition of the patient, or

— the state of the patient

where the medical benefits of the use of the IVD medical device outweighs the risk of the use to the patient.

5 Use of standards and guides in support of the essential principles

5.1 General approach to using standards

The essential principles of safety and performance are the general, high-level criteria that when met indicate that an IVD medical device is safe and effective. Regulatory requirements expect that an IVD medical device be safe and effective during its life-cycle and so conformity with the essential principles of safety and performance must be achieved throughout the life-cycle of the IVD medical device.

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For the IVD medical device manufacturer, this usually means that their IVD medical device complies with the essential principles and must be

a) designed to be safe and effective,

b) manufactured to maintain the design characteristics,

c) used in a way that maintains the design characteristics, and

d) in the post-production phase, reviewed to evaluate the production and post-production information for relevancy to safety and performance, in which case, a design change might be needed to make the IVD medical device compliant again with the essential principles.

It is important to note that it is not possible to ensure an acceptable level of safety and performance in the life-cycle by simply being compliant with one or more standards at one time. A process for continuous compliance is required and the expectation is that this is achieved through the use of a quality management system and a risk management process (this is addressed in the general essential principles, 1 to 6, although the word risk management is not used there).

5.2 Types of standards useful to demonstrate compliance

Basic standards, group standards, product standards and process standards are the four types of consensus standards, any of which can be normative. Figure 1 illustrates the relationships between these types of standards. Because basic standards are so broad that they cross multiple sectors as noted in the examples below, it is rare, if ever, that basic standards are used in the medical device sector.

EXAMPLE 1 Management system standard (ISO 9001).

EXAMPLE 2 Environmental management system standard (ISO 14001).

EXAMPLE 3 Risk management standard (ISO 31000).

EXAMPLE 4 Conformity assessment standard (ISO/IEC 17000).

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The majority of medical device consensus standards fall within the group standard and product standard types. While process standards are widely used in the medical device sector, they are subtypes of group standards and product standards.

Group standards are generally horizontal in nature within the medical device sector and are developed to address the essential principles that are applicable to a wide range of medical devices. Examples of group standards include safety standards or standards specifying requirements for a process, such as biological evaluation, general requirements for basic safety and essential performance for medical electrical equipment, sterilization and usability.

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