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Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires
[Revision of second edition (ISO 13485:2003)and ISO 13485:2003/Cor 1:2009]

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

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 13485 was prepared by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices.

This third edition cancels and replaces the second edition (ISO 13485:2003), which has been technically revised. Details of the changes between the second and this third edition of this Standard are described in Annex B.

This edition of ISO 13485 addresses quality assurance of product, customer requirements, and other elements of quality management systems for regulatory purposes.

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in stages of the life-cycle of a medical device including the design and development, production, storage and distribution, installation or servicing of medical devices, and the design, development, and provision of associated activities (e.g., technical support). The requirements in this standard may also be used by suppliers or other external parties providing goods and services (e.g., sterilization services, calibration services, distribution services) to medical device organizations. Such a supplier or external party may voluntarily choose to conform to the requirements of this standard or may be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this standard expects that the organization

- *identifies its role(s) under appropriate regulatory requirements,*
- *identifies the regulatory requirements that are appropriate for its activities under these roles, and*
- *incorporates these appropriate regulatory requirements within its quality management system.*

This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and appropriate regulatory requirements applicable to the quality management system, and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for products that are necessary to meet customer and appropriate regulatory requirements for safety and performance.

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

a) its organizational environment, changes in that environment, and the risks associated with that environment,
b) its varying needs,
c) its particular objectives,
d) the products it provides,
e) the processes it employs,
f) its size and organizational structure, and
g) *appropriate regulatory requirements*

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

NOTE Throughout the text of this International Standard, wherever the term 'product' occurs, it can also mean "service."

0.2 Process approach

This International Standard is based on a process approach to quality management.

An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

For an organization to function effectively, it has to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach."

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,
b) the need to consider processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) *improvement of processes based on objective measurement*.

0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001

While this is a stand-alone standard, it is based on, and follows the format of, ISO 9001:2008 for the convenience of users in the medical device sector. Annex A shows the correspondence between ISO 13485:201X and ISO 9001:2008.

Those clauses or subclauses that are quoted directly and unchanged from ISO 9001:2008 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex A.

Where the text of this International Standard is not identical to the text of ISO 9001:2008, the sentence or indent containing that text as a whole is shown in italics (in blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex A.

It is intended to revise ISO/TR 14969 to provide guidance for the application for this version of ISO 13485.

0.4 Compatibility with other management systems

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Medical devices — Quality management systems — Requirements for regulatory purposes

1 Scope

1.1 General

This International Standard specifies requirements for an organization that needs to demonstrate that its quality management system has the ability to manage the life-cycle of medical devices and associated activities consistently to meet customer and appropriate regulatory requirements. It may also be used by suppliers or external parties that provide goods and quality system related services to medical device organizations.

The main objective of this International Standard is to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations providing medical devices. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001:2008 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001:2008 unless their quality management systems conform to all the requirements of ISO 9001:2008 (see Annex A).

NOTES

1) *Throughout this standard, statutory, regulatory and legal requirements are encompassed in the term "regulatory requirements".*

2) *Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service."* The term "product" only applies to

   a) product intended for, or required by, a customer, or any intended output resulting from the product realization processes.

1.2 Application

All requirements of this International Standard are specific to organizations regardless of their type or size.

Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes. These processes, and the responsibilities of external parties that undertake such processes on behalf of the organization, need to be identified in the organization's quality management system. If the responsibilities differ due to appropriate national or regional regulatory requirements, the role of each party needs to be clearly defined in the quality management system.

If appropriate regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls.

If any requirement(s) in Clauses 6, 7 or 8 of this International Standard is (are) not applicable due to the activities undertaken by the organization or the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system.

In this International Standard the term "where appropriate" is used several times. When a requirement is qualified by this phrase, it is deemed to be "appropriate" unless the organization can justify otherwise. A requirement is considered "appropriate" if it is necessary for any of the following:

- *the product to meet specified requirements,*
- *the organization to carry out corrective action*
- *the organization to manage risks.*

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 together with the following apply. The following definitions should be regarded as generic, as definitions provided in appropriate national regulatory requirements can differ slightly and take precedence.

3.1
active implantable medical device
active medical device which is intended to be an implantable medical device

3.2
active medical device
medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy.

NOTE Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change of the energy, substance, or other element, are not considered to be active medical devices.

3.3
authorised representative
any natural or legal person who has received a documented mandate from a manufacturer to act on his behalf in respect to appropriate regulatory requirements in (a) specified jurisdiction(s).

3.4
clinical evaluation
assessment and analysis of clinical evidence pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.

3.5
complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been released from the organization's control

3.6
distributor
any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

NOTES

1) More than one distributor may be involved in the supply chain.

2) Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition. [GHTF-SG1-N055]

3.7
advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in

- *the use of a medical device,*
- *the modification of a medical device,*
- *the return of the medical device to the organization that supplied it, or*
- *the destruction of a medical device*

NOTE Issue of an advisory notice might be required to comply with national or regional regulations.

3.8
implantable medical device
medical device intended

- *to be totally or partially introduced into the human body or a natural orifice, or*
- *to replace an epithelial surface or the surface of the eye,*

by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention

3.9
importer
any natural or legal person with responsibility to first make a medical device manufactured in one jurisdiction available in another specified jurisdiction.

3.10
labelling
written, printed ,graphic or electronic information

- *affixed to a medical device or any of its containers or wrappers, or*

- *accompanying a medical device,*
- *provided for a medical device by other means*

related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

NOTE Some appropriate regional and national regulatory requirements refer to "labelling" as "information supplied by the manufacturer." This could include advertising or marketing information.

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

3.12
manufacturer
any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether or not such a medical device is designed and/or manufactured by that person or on their behalf by another person(s).

NOTES

1) *The definition of the "medical device manufacturer" differs from nation to nation and region to region. The organization needs to understand how the definition in the Standard will be interpreted in light of regulatory definitions for "medical device manufacturer" or equivalent term in the various nations and regions in which its medical devices are sold.*

2) *This 'natural or legal person' has ultimate legal responsibility for ensuring compliance with all appropriate regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.*

3) *The manufacturer's responsibilities are described in GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.*

4) *'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.*

5) *Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.*

6) *Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.*

7) *An authorised representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.*

8) *To the extent that an accessory is subject to the appropriate regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.*

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 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 Products which might be considered to be medical devices in some jurisdictions but not in others include:

- *disinfection substances,*
- *aids for persons with disabilities,*
- *devices incorporating animal and/or human tissues,*
- *devices for.in-vitro fertilization or assisted reproduction technologies. [GHTF SG1 N071 2012]*

3.14
post market surveillance
systematic process to collect and analyze experience gained from medical devices in the post-production phase.

3.15
performance evaluation
assessment and analysis of data to establish or verify the ability of an in vitro diagnostic medical device to achieve its intended use

3.16
risk
combination of the probability of occurrence of harm and the severity of that harm [ISO 14971:2007]