INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

Reference number
ISO 13485:2003(E)

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Published in Switzerland

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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 second edition cancels and replaces the first edition (ISO 13485:1996), which has been technically revised. It also cancels and replaces ISO 13488:1996. Those organizations which have used ISO 13488 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

This edition of ISO 13485 has a revised title and addresses quality assurance of product, customer requirements, and other elements of quality system management.

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services.

It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.

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

It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.

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 varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. 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.

0.2 Process approach

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

Any activity that receives inputs and converts them to outputs can be considered as a process.

For an organization to function effectively, it has to identify and manage numerous linked processes.

Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001.

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

Where the text of this International Standard is not identical to the text of ISO 9001, 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 B.

0.3.2 Relationship with ISO/TR 14969

ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.

0.4 Compatibility with other management systems

This International Standard follows the format of ISO 9001 for the convenience of users in the medical device community.

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 a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 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 unless their quality management systems conform to all the requirements of ISO 9001 (see Annex B).

1.2 Application

All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations 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 [see 4.2.2 a) and 7.3].

If any requirement(s) in Clause 7 of this International Standard is(are) not applicable due to 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 [see 4.2.2 a)].

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 [see 4.1 a)].

In this International Standard the terms "if appropriate" and "where appropriate" are used several times. When a requirement is qualified by either of these phrases, it is deemed to be "appropriate" unless the organization can document a justification otherwise. A requirement is considered "appropriate" if it is necessary in order for

- *the product to meet specified requirements, and/or*
- *the organization to carry out corrective action.*

2 Normative references

The following referenced documents are indispensable for the application 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 9000:2000*, Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this *document*, the terms and definitions given in ISO 9000 apply, *together with the following.*

The following terms, used in this edition of *ISO 13485* to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier ----------> organization ----------> customer

The term "organization" replaces the term "supplier" used in ISO 13485:1996, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

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

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

The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.

3.1
active implantable medical device
active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

3.2
active medical device
medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.3
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.

3.4
customer 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 placed on the market

3.5
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

NOTE This definition applies to implantable medical devices other than active implantable medical devices.

3.6
labelling
written, printed or graphic matter

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

— *accompanying a medical device,*

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

NOTE Some regional and national regulations refer to "labelling" as "information supplied by the manufacturer."

3.7
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 This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15].

3.8
sterile medical device
category of medical device intended to meet the requirements for sterility

NOTE The requirements for sterility of a medical device might be subject to national or regional regulations or standards.

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system *(see 8.5.1)*.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes,

e) records required by this International Standard (see 4.2.4), and

f) any other documentation specified by national or regional regulations.

Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained.

For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

NOTE *1* The extent of the quality management system documentation can differ from one organization to another due to

a) the size of the organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE *2* The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusion and/or non-application (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to review and approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

NOTE For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.

Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

NOTE National or regional regulations might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement *(see 8.5)*, and

c) ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system,

g) recommendations for improvement, and

h) new or revised regulatory requirements.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvements needed to maintain the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement the quality management system and to maintain its effectiveness, and

b) to meet regulatory and customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

NOTE National or regional regulations might require the organization to establish documented procedures for identifying training needs.

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.

Records of such maintenance shall be maintained (see 4.2.4).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

The following requirements shall apply.

a) The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1).

b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).

c) The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)].

d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).