
**Medical devices — Quality
management systems —
Requirements for regulatory purposes**

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



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Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Quality management system	6
4.1 General requirements.....	6
4.2 Documentation requirements.....	7
4.2.1 General.....	7
4.2.2 Quality manual.....	7
4.2.3 Medical device file.....	7
4.2.4 Control of documents.....	8
4.2.5 Control of records.....	8
5 Management responsibility	9
5.1 Management commitment.....	9
5.2 Customer focus.....	9
5.3 Quality policy.....	9
5.4 Planning.....	9
5.4.1 Quality objectives.....	9
5.4.2 Quality management system planning.....	9
5.5 Responsibility, authority and communication.....	10
5.5.1 Responsibility and authority.....	10
5.5.2 Management representative.....	10
5.5.3 Internal communication.....	10
5.6 Management review.....	10
5.6.1 General.....	10
5.6.2 Review input.....	10
5.6.3 Review output.....	11
6 Resource management	11
6.1 Provision of resources.....	11
6.2 Human resources.....	11
6.3 Infrastructure.....	12
6.4 Work environment and contamination control.....	12
6.4.1 Work environment.....	12
6.4.2 Contamination control.....	12
7 Product realization	12
7.1 Planning of product realization.....	12
7.2 Customer-related processes.....	13
7.2.1 Determination of requirements related to product.....	13
7.2.2 Review of requirements related to product.....	13
7.2.3 Communication.....	14
7.3 Design and development.....	14
7.3.1 General.....	14
7.3.2 Design and development planning.....	14
7.3.3 Design and development inputs.....	14
7.3.4 Design and development outputs.....	15
7.3.5 Design and development review.....	15
7.3.6 Design and development verification.....	15
7.3.7 Design and development validation.....	15
7.3.8 Design and development transfer.....	16
7.3.9 Control of design and development changes.....	16
7.3.10 Design and development files.....	16

7.4	Purchasing.....	17
7.4.1	Purchasing process.....	17
7.4.2	Purchasing information.....	17
7.4.3	Verification of purchased product.....	17
7.5	Production and service provision.....	18
7.5.1	Control of production and service provision.....	18
7.5.2	Cleanliness of product.....	18
7.5.3	Installation activities.....	18
7.5.4	Servicing activities.....	19
7.5.5	Particular requirements for sterile medical devices.....	19
7.5.6	Validation of processes for production and service provision.....	19
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems.....	19
7.5.8	Identification.....	20
7.5.9	Traceability.....	20
7.5.10	Customer property.....	20
7.5.11	Preservation of product.....	20
7.6	Control of monitoring and measuring equipment.....	21
8	Measurement, analysis and improvement.....	22
8.1	General.....	22
8.2	Monitoring and measurement.....	22
8.2.1	Feedback.....	22
8.2.2	Complaint handling.....	22
8.2.3	Reporting to regulatory authorities.....	23
8.2.4	Internal audit.....	23
8.2.5	Monitoring and measurement of processes.....	23
8.2.6	Monitoring and measurement of product.....	23
8.3	Control of nonconforming product.....	24
8.3.1	General.....	24
8.3.2	Actions in response to nonconforming product detected before delivery.....	24
8.3.3	Actions in response to nonconforming product detected after delivery.....	24
8.3.4	Rework.....	24
8.4	Analysis of data.....	24
8.5	Improvement.....	25
8.5.1	General.....	25
8.5.2	Corrective action.....	25
8.5.3	Preventive action.....	25
	Annex A (informative) Comparison of content between ISO 13485:2003 and ISO 13485:2016.....	27
	Annex B (informative) Correspondence between ISO 13485:2016 and ISO 9001:2015.....	30
	Bibliography.....	36

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 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.

The committee responsible for this document is Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition of ISO 13485 cancels and replaces the second edition (ISO 13485:2003) and ISO/TR 14969:2004, which have been technically revised. It also incorporates the Technical Corrigendum ISO 13485:2003/Cor.1:2009. A summary of the changes incorporated into this edition compared with the previous edition is given in [Annex A](#).

Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can 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 International Standard expects that the organization:

- identifies its role(s) under applicable regulatory requirements;
- identifies the regulatory requirements that apply to its activities under these roles;
- incorporates these applicable regulatory requirements within its quality management system.

The definitions in applicable regulatory requirements differ from nation to nation and region to region. The organization needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.

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 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 product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

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

- a) organizational environment, changes in that environment, and the influence that the organizational environment has on the conformity of the medical devices;
- b) organization's varying needs;
- c) organization's particular objectives;
- d) product the organization provides;
- e) processes the organization employs;
- f) organization's size and organizational structure;
- g) regulatory requirements applicable to the organization's activities.

It is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, uniformity of documentation or alignment of documentation to the clause structure of this International Standard.

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 Clarification of concepts

In this International Standard, the following terms or phrases are used in the context described below.

- When a requirement is qualified by the phrase “as appropriate”, it is deemed to be appropriate unless the organization can justify otherwise. A requirement is considered appropriate if it is necessary for:
 - product to meet requirements;
 - compliance with applicable regulatory requirements;
 - the organization to carry out corrective action;
 - the organization to manage risks.
- When the term “risk” is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.
- When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.
- When the term “product” is used, it can also mean “service”. Product applies to output that is intended for, or required by, a customer, or any intended output resulting from a product realization process.
- When the term “regulatory requirements” is used, it encompasses requirements contained in any law applicable to the user of this International Standard (e.g. statutes, regulations, ordinances or directives). The application of the term “regulatory requirements” is limited to requirements for the quality management system and the safety or performance of the medical device.

In this International Standard, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

0.3 Process approach

This International Standard is based on a process approach to quality management. Any activity that receives input and converts it to output can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it needs 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) considering processes in terms of added value;
- c) obtaining results of process performance and effectiveness;
- d) improving processes based on objective measurement.

0.4 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001:2008, which has been superseded by ISO 9001:2015. For the convenience of users, [Annex B](#) shows the correspondence between this International Standard and ISO 9001:2015.

This International Standard is intended to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device. This International Standard includes some particular requirements for organizations involved in the life-cycle of 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 system meets all the requirements of ISO 9001.

0.5 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

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 and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. 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 that are applicable to the organization, but 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.

If applicable 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 approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this International Standard reflect any exclusion of design and development controls.

If any requirement in [Clauses 6, 7 or 8](#) of this International Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in [4.2.2](#).

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 9000:2015¹⁾, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

1) Supersedes ISO 9000:2005.