

Contents

Page

Foreword	iv
0 Introduction	v
0.1 General	v
0.2 Process approach	v
0.3 <i>Relationship with other standards</i>	v
0.4 Compatibility with other management systems	vi
1 Scope	1
1.1 General	1
1.2 Application	1
2 Normative references	2
3 Terms and definitions	2
4 Quality management system	4
4.1 General requirements	4
4.2 Documentation requirements	4
5 Management responsibility	6
5.1 Management commitment	6
5.2 Customer focus	6
5.3 Quality policy	6
5.4 Planning	7
5.5 Responsibility, authority and communication	7
5.6 Management review	8
6 Resource management	8
6.1 Provision of resources	8
6.2 Human resources	9
6.3 Infrastructure	9
6.4 Work environment	9
7 Product realization	10
7.1 Planning of product realization	10
7.2 Customer-related processes	10
7.3 Design and development	11
7.4 Purchasing	13
7.5 Production and service provision	14
7.6 Control of monitoring and measuring devices	17
8 Measurement, analysis and improvement	17
8.1 General	17
8.2 Monitoring and measurement	18
8.3 Control of nonconforming product	19
8.4 Analysis of data	19
8.5 Improvement	20
Annex A (informative) Correspondence between ISO 13485:2003 and ISO 13485:1996	21
Annex B (informative) Explanation of differences between ISO 13485:2003 and ISO 9001:2000	25
Bibliography	57

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 9001:2000

While this is a stand-alone standard, it is based on ISO 9001:2000.

Those clauses or subclauses that are quoted directly and unchanged from ISO 9001:2000 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 9001:2000, 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 9001:2000 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 9001:2000 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 9001:2000 unless their quality management systems conform to all the requirements of ISO 9001:2000 (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.*