TECHNICAL **ISO/TR**

First edition
2004-10-15

Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003

Dispositifs médicaux — Systèmes de gestion de qualité — Lignes directrices pour l'application de l'ISO 13485:2003

Reference number
ISO/TR 14969:2004(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this Technical Report may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 14969 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

NOTE ISO/TC 210/WG1 is prepared to accept questions and comments related to the content of ISO 13485:2003 and/or ISO/TR 14969:2004. Please address all such questions and comments to the ISO/TC 210 secretariat at: *hwoehrle@aami.org*. These questions and comments will be considered for development of additional guidance in the application of ISO 13485:2003 either by revision of ISO/TR 14969 or the development of a “Frequently Asked Questions” document. You will not receive a response to your questions or comments, however, they will be considered for future use as noted above.

This first edition of ISO/TR 14969 cancels and replaces ISO 14969:1999, which has been technically revised.

Throughout this Technical Report, when the text of ISO 13485 is directly quoted, it appears enclosed in boxes prefaced by: “ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*”.

Introduction

0.1 General

0.1.1 This Technical Report provides guidance to assist in the development, implementation and maintenance of quality management systems that aim to meet the requirements of ISO 13485 for organizations that design and develop, produce, install and service medical devices, or that design, develop and provide related services. It provides guidance related to quality management systems for a wide variety of medical devices and related services. Such medical devices include active, non-active, implantable and non-implantable medical devices and *in vitro* diagnostic medical devices.

ISO 13485 specifies the quality management system requirements for medical devices for regulatory purposes (see Annex A). ISO 13485 accommodates the previous ISO 13488 by permissible exclusion as specified in ISO 13485:2003, 1.2.

When judging the applicability of the guidance in this Technical Report, one should consider the nature of the medical device(s) to which it will apply, the risk associated with the use of these medical devices, and the applicable regulatory requirements.

As used in this Technical Report, the term “regulatory requirement” includes any part of a law, ordinance, decree or national and/or regional regulation applicable to quality management systems for medical devices and related services.

This Technical Report provides some approaches that an organization can use to implement and maintain a quality management system which conforms with ISO 13485. Alternative approaches can be used if they also satisfy the requirements of ISO 13485.

0.1.2 The guidance given in this Technical Report is applicable to the design, development, production, installation and servicing of medical devices of all kinds. It describes concepts and methods that can be considered by organizations which are establishing and maintaining quality management systems.

An organization can voluntarily incorporate guidance from this Technical Report, wholly or in part, into its quality management system.

0.1.3 Guidance contained in this Technical Report can be useful as background information for those representing quality management system assessors, Conformity Assessment Bodies and regulatory enforcement bodies.

The guidance contained in this Technical Report is not to be used for identifying specific deficiencies of quality management systems, unless such guidance is voluntarily incorporated by the organization into the documentation describing and supporting the organization’s quality management system, or unless such guidance is specifically made part of the regulatory requirements relevant to the organization’s operation.

0.2 Process approach

ISO 13485 promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, with the objective of meeting customer and regulatory requirements, and providing medical devices that meet customer and regulatory requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity 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.

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."

An advantage of the process approach is the ongoing control which it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

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

— understanding and meeting requirements,

— considering processes in terms of added value,

— obtaining results of process performance and effectiveness, and

— improving processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in ISO 13485:2003, Clauses 4 to 8. This illustration shows that customers and regulatory authorities play a significant role in defining requirements as inputs. Monitoring of customer feedback requires the evaluation of information relating to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of ISO 13485, but does not show processes at a detailed level.

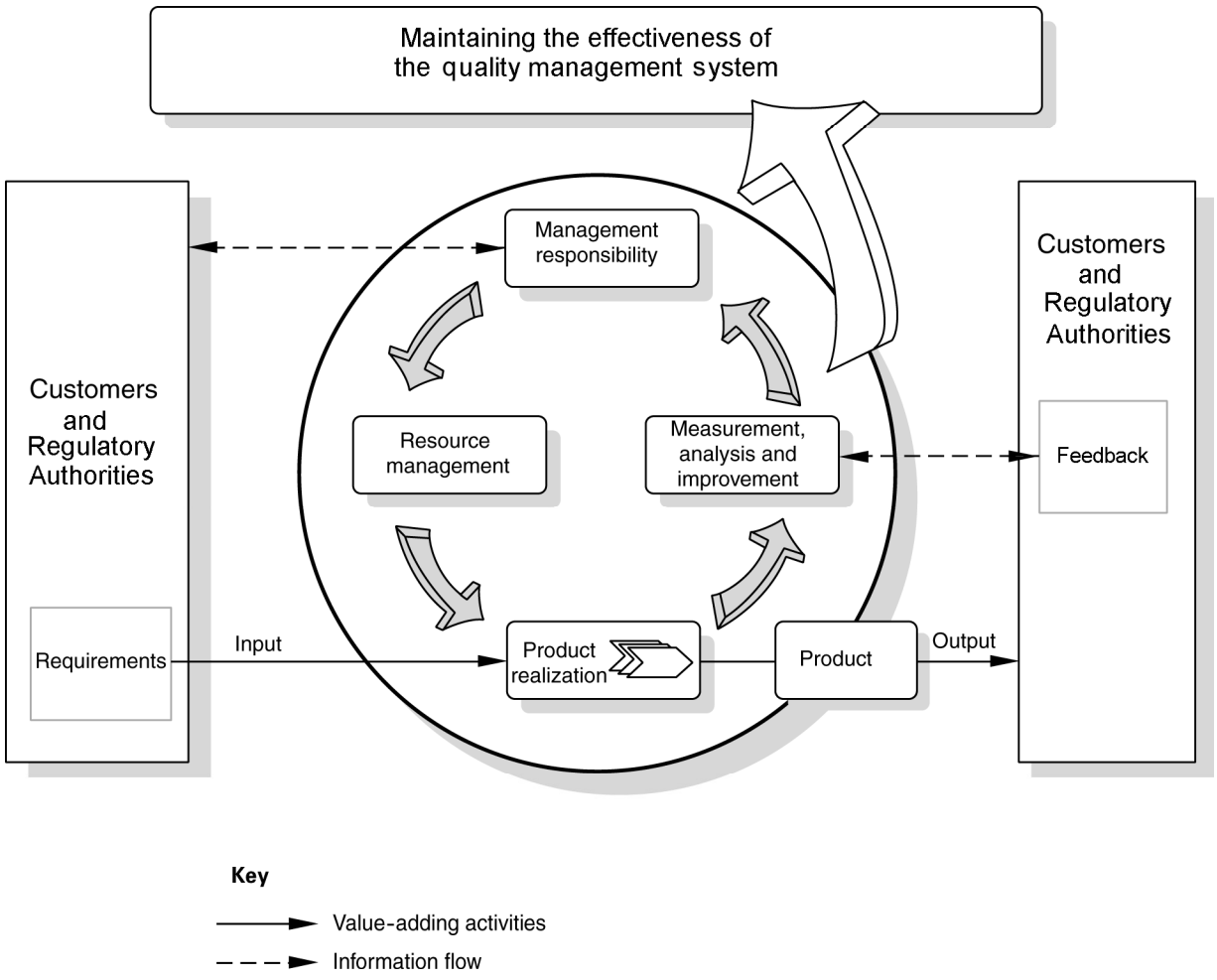

Figure 1 — Model of a process-based quality management system

In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to improve process performance.

0.3 Relationship with other standards, guidance documents and regulatory requirements

The relationship between ISO 13485, this Technical Report and the general standards for quality management systems (ISO 9001 and ISO 9004) is summarized as follows.

a) This Technical Report provides guidance on the application of ISO 13485.

b) ISO 13485 specifies requirements for quality management systems in order to achieve regulatory compliance in the medical devices industries. It follows the format, structure and process approach of ISO 9001. It differs from ISO 9001 in that it specifies additional requirements but does not include the explicit requirements for continual improvement and customer satisfaction.

c) ISO 9001 is an International Standard for quality management systems in general.

d) ISO 9004 gives guidance on a wider range of objectives of quality management systems than does this Technical Report, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is suitable as a guide for organizations whose top management wishes to move beyond the requirements of ISO 13485, in pursuit of continual performance improvement and customer satisfaction. However, it is not intended for certification or for contractual purposes.

ISO 13485 includes those generic quality management system requirements contained in ISO 9001 that are relevant to a regulated organization that designs and develops, produces, installs and/or services medical devices, or which designs and develops and provides related services. This Technical Report, however, does not set out to provide specific guidance with respect to these generic quality management system requirements which are common to both ISO 13485 and ISO 9001. Guidance on ISO 9001 can be found, for example, in the ISO brochure, *ISO 9001 for Small Businesses – What to do*, and in *ISO 9000 Introduction and Package module*.

Guidance provided in this Technical Report has taken into consideration requirements and guidance contained in documents from the following organizations:

— Global Harmonization Task Force (GHTF);

— International Organization for Standardization (ISO);

— European Committees for Standardization (CEN and CENELEC);

— national regulatory bodies.

Many of these documents are listed in the Bibliography.

0.4 Compatibility with other management systems

Conformance to ISO 13485 quality management system requirements does not automatically constitute conformity with national or regional regulatory requirements. It is the organization's responsibility to identify and establish compliance with relevant regulatory requirements.