TECHNICAL REPORT

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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

This Technical Report was approved by CEN on 3 March 2005. It has been drawn up by the Technical Committee CEN/CLC/WG QS.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36   B-1050 Brussels

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Foreword

The text of ISO/TR 14969:2004 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices". The transposition into a CEN ISO/TR 14969 has been managed by the CEN/CENELEC Co-ordinating Working Group on quality supplements for medical devices (CEN/CLC/CWG QS) the Secretariat of which is held by DIN in collaboration with the CEN Management Centre (CMC).

With the publication of CEN ISO/TR 14969:2005 the following standards became obsolete and shall be withdrawn:

*   EN 724:1994 .Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices.,

*   EN 928:1995 .In vitro diagnostic systems - Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices.

*   EN 50103:1995 .Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry."

It should be noted that the above-mentioned European standards which are not replaced by CEN ISO/TR 14969:2005, were harmonized under the European Medical Devices Directives (90/385/EEE, 93/42/EEC and (98/79/EC). CEN ISO/TR 14969:2005 is not proposed for harmonization and so does not provide a presumption of conformity with regard to these European Directives.

Contents

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.
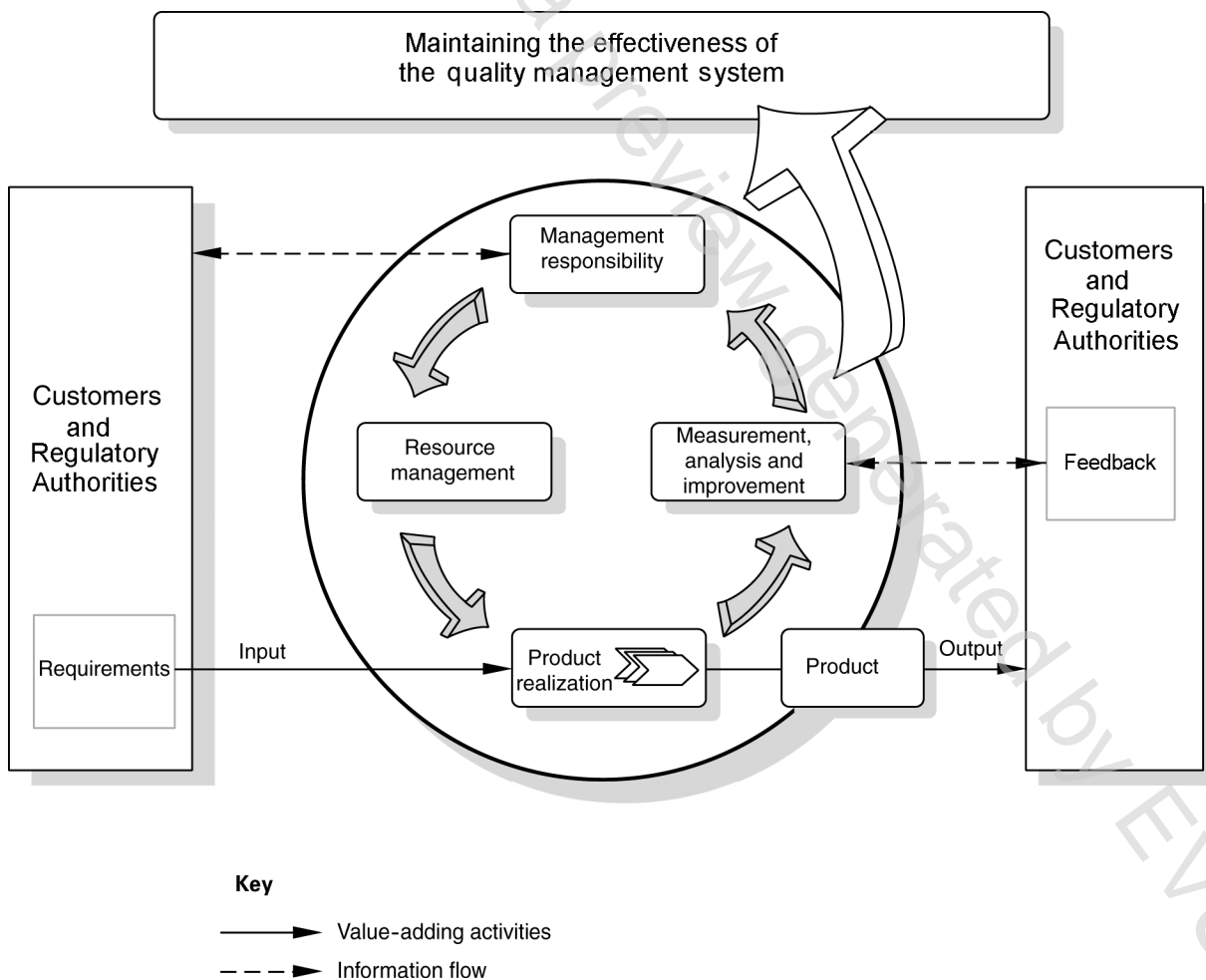

Figure 1 — Model of a process-based quality management system

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.

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

1   Scope

1.1   General

This Technical Report provides guidance for the application of the requirements for quality management systems contained in ISO 13485. It does not add to, or otherwise change, the requirements of ISO 13485. This Technical Report does not include requirements to be used as the basis of regulatory inspection or certification assessment activities.

NOTE   The terms "should", "can" and "might" within this Technical Report are used as follows. "Should" is used to indicate that, amongst several possibilities to meet a requirement in ISO 13485, one is recommended as being particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required. "Can" and "might" are used to indicate possibilities or options. These terms do not indicate requirements.

This guidance can be used to better understand the requirements of ISO 13485 and to illustrate some of the variety of methods and approaches available for meeting the requirements of ISO 13485.

1.2   Application

> **ISO 13485:2003, Medical devices — Quality management systems — Requirements for regulatory purposes**
>
> **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.*

1.2.1 General

Certain product realization requirements of ISO 13485 can legitimately be omitted in one of two ways: they can be "excluded", or they might be "not applicable". It is important to note, however, that any exclusion or non-applicability should be detailed and justified in the organization's quality manual.

1.2.2 Exclusions

Some regulatory requirements permit organizations to place some medical devices on the market without having to demonstrate conformance with design and development controls (see ISO 13485:2003, 7.3). Organizations should determine the exclusion of 7.3 on a product-by-product, market-by-market basis.

Even if the organization is permitted by regulations to exclude the requirements of 7.3, it still has obligations to meet product realization requirements of ISO 13485:2003, 7.2, 7.4 and 7.5 and 7.6.

1.2.3 Non-applicability

ISO 13485 provides for the organization to omit from its quality management system those product realization requirements that are not applicable due to the nature of the medical device.

For example, an organization providing single-use, sterile medical devices does not need to include within its quality management system elements related to installation and servicing. Similarly, an organization providing non-sterile medical devices does not need to include the elements related to sterilization.

It is important for the organization to review carefully all the requirements of ISO 13485:2003, Clause 7, in order to identify those requirements that do apply to functions performed by the organization. Once those requirements are identified, the organization is obliged to comply with ISO 13485:2003, 7.1, and to perform the planning associated with identified product realization requirements.

EXAMPLE   An organization intends

— to place its own label on a medical device designed and developed, produced, and serviced by suppliers outside its quality management system, and to market this medical device,

— to communicate with customers who have purchased the medical device, and

— to have systems in place for receiving customer complaints.

Even though the organization does not perform design and development activities itself, it cannot consider 7.3 to be non-applicable. It still has obligations to meet the requirements of 7.3, unless relevant regulations permit an exclusion. Once the organization identifies those requirements, it is obliged under 7.1 to plan for the quality management system processes needed to meet those requirements.

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*

ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and ISO 13485 apply.

NOTE   The terms provided in Annex A should be regarded as generic, as definitions provided in national regulatory requirements can differ.