TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

CEN ISO/TR 14969

June 2005

ICS 11.040.01; 03.120.10

English version

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.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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

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With the publication of CEN ISO/TR 14969:2005 the following standards became obsolete and shall be withdrawn: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

TECHNICAL REPORT

ISO/TR 14969

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.