Technical Information Report

ANSI/AAMI/ISO TIR14969:2004

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



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

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Abstract: Provides guidance on the application of requirements contained in ISO 13485:2003, including detailed guidance related to process validation, design control, and quality planning.

Keywords: medical devices, quality management systems, design control, process control, quality records

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International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard.

NOTE—Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical

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International designation	U.S. designation	Equivalency
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

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Committee representation

Association for the Advancement of Medical Instrumentation

Quality Management and Corresponding General Aspects for Medical Devices Committee

The adoption of ISO Technical Report (TR) 14969:2004 as an AAMI Technical Information Report and revision of ANSI/AAMI/ISO 14969:1999 was initiated by the AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Application of Quality Systems to Medical Devices Working Group (U.S. Sub-TAG for ISO/TC 210/WG 1), chaired by Edward R. Kimmelman, BME, JD of Roche Diagnostics and Kimberly A. Trautman of the U.S. Food and Drug Administration, played an active part in developing the ISO Technical Report.

At the time this document was published, the **AAMI Quality Management and Corresponding General Aspects for Medical Devices Committee** had the following members:

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	Edward R. Kimmelman, BME, JD, Roche Diagnostics Corp.
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Background of AAMI adoption of ISO/TR14969:2004

As indicated in the foreword to the main body of this document (page xi), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this technical report.

International Technical Report 14969 was developed by Working Group (WG) 1 *Application of quality management to medical devices,* of ISO Technical Committee (TC) 210, *Quality management and corresponding general aspects for medical devices*, to provide guidance on the application of requirements contained in ISO 13485:2003, including detailed guidance related to process validation, design control, and quality planning.

U.S. participation in this ISO/TC 210/WG 1 is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). AAMI administers the International Secretariat for ISO/TC 210 on behalf of the United States, and U.S. experts made a considerable contribution to this technical report.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of ISO/TR 14969, the Quality Management and Corresponding General Aspects for Medical Devices Committee and the AAMI Application of Quality Systems to Medical Devices Working Group decided to adopt ISO/TR 14969:2004 verbatim as an AAMI Technical Information Report and as a revision of ANSI/AAMI/ISO 14969:1999.

This edition of ISO/TR 14969 is based on ISO 13485:2003 and provides guidance on quality assurance of product, customer requirements, and other elements of quality system management. It does not provide guidance on concepts that are not included in ISO 13485:2003, such as “continual improvement” and “customer satisfaction.”

AAMI (and ANSI) have adopted other ISO documents. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated into this technical information report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the ISO foreword on page xi, this ANSI Technical Report/AAMI Technical Information Report is identical to ISO/TR 14969:2004.

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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*."

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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.

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0.2 Process approach

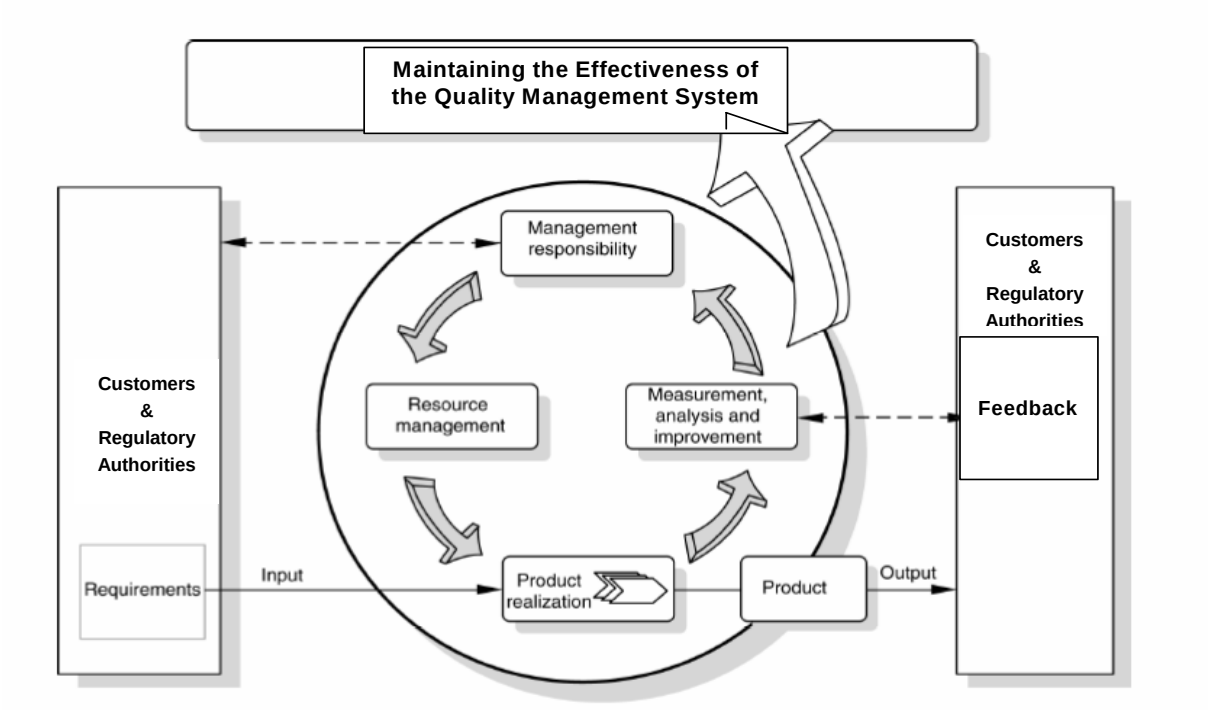


Figure 1—Model of a process-based quality management system

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. 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.

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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:

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

— 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.

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

— 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 for 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), and

— 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.

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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.

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1.2.1 General

Certain product realization requirements of ISO 13485 may 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 docment, 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.

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4 Quality management system

4.1 General requirements

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

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement, and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure, and analyze these processes, and

f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (*see 8.5.1*).

NOTE—Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization, and measurement.

4.1.1 An element of managing an organization is the implementation and maintenance of an effective quality management system that is designed to enable an organization to provide medical devices that meet customer and regulatory requirements.

The organization can maintain the effectiveness of its established quality management system through a range of activities, such as

— internal audits,

— management review,

— corrective and preventive actions, and

— independent external assessments.

4.1.2 Maintaining the effectiveness of the quality management system in its ability to meet customer and regulatory requirements will typically involve the organization responding effectively to external factors, such as

— changes in regulatory requirements, including adverse event reporting, and

— customer feedback,

and internal changes, such as changes to

— key personnel,

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— facilities,

— manufacturing processes and equipment, including related software,

— software related to the quality management system, and

— product, including software.

4.1.3 Examples of activities to maintain an effective quality management system include

— defining and promoting processes which lead to achieving regulatory compliance,

— acquiring and using process data and information on a continuing basis,

— determining and providing resources, including human and information system resources,

— directing necessary changes to the quality management system, and

— using suitable evaluation methods such as internal audits and management reviews.

For guidance on activities related to outsourced processes, see 7.4.1.

4.2 Documentation requirements

4.2.1 General

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

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation, and control of its processes,

e) records required by this International Standard (see 4.2.4), and

f) any other documentation specified by national or regional regulations.

Where this International Standard specifies that a requirement, procedure, activity, or special arrangement be "documented," it shall, in addition, be implemented and maintained.

For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality system requirements (see 4.2.3). These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

NOTE 1—The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 2—The documentation can be in any form or type of medium.

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4.2.1.1 Documented quality management system procedures are required for applicable requirements of ISO 13485 and should be consistent with the organization's quality policy. It is important to recognize that the structure and level of detail required in these procedures should be tailored to the needs of the organization, which in turn are dependent on methods used and the skills and qualifications of the organization's personnel performing the activities in question (see also 6.2.2).

Procedures or instructions can be presented in text, graphic, or audio-visual form. Frequently, a simple set of pictures can convey the requirements more accurately than a lengthy detailed description.

4.2.1.2 Documented procedures, including work instructions and flowcharts, should be stated simply, unambiguously, and understandably, and should indicate methods to be used and criteria to be satisfied. These procedures typically define activities and describe

— what is to be done and by whom,

— when, where, and how it is to be done,

— what materials, equipment, and documents are to be used,

— how an activity is to be monitored and measured, and

— what records are required.

4.2.1.3 Documentation should be evaluated with respect to the effectiveness of the quality management system against criteria, such as

— functionality,

— human interfaces,

— resources required,

— policies and objectives, and

— interfaces used by the organization's customers and suppliers.

4.2.1.4 The file for each type or model of medical device referred to in ISO 13485:2003, 4.2.1 is sometimes referred to by different terms (see Annex A, section B). This file can contain, or give reference to the location of, documentation relevant to the manufacture of that product. Examples of such documentation can include

— specifications for raw materials, labeling, packaging materials, sub-assemblies, and medical devices,

— parts lists,

— engineering drawings,

— software programs, including source code (if available),

— work instructions, including equipment operation,

— sterilization process details, if applicable,

— quality plans,

— manufacturing/inspection/test procedures, and

— acceptance criteria.

4.2.1.5 The documentation referred to in ISO 13485:2003, 4.2.1 forms part of the quality management system and should be subject to document and record control procedures (see 4.2.3, 4.2.4).

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4.2.2 Quality manual

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

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusion and/or non-application (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

There is no specific guidance for this subclause of ISO 13485.

NOTE—Additional information relating to quality manuals is available in ISO/TR 10013.

4.2.3 Control of documents

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

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to review and approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or by another designated function that has access to pertinent background information upon which to base its decisions.

The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements.

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4.2.3.1 The system established for the control of internal and external documents will, if appropriate

— assign responsibilities for preparation, approval, and issue of documents,

— ensure prompt withdrawal of obsolete copies of controlled documents,

— define a method for recording the implementation date of a document change, and

— allow controlled and non-controlled documents to be distinguished.

The quality management system may also identify recipients of controlled copies of documents.

4.2.3.2 Documents may be reviewed at various times throughout the life of a document, for example, as a result of

— facilities, personnel, or organizational changes,

— audit activities,

— acquisitions,

— new products, technologies, or software,

— a requirement of the organization's quality management system for periodic review.

4.2.3.3 Document control procedures can be assisted by the adoption of a consistent structure for the documents within the quality management system. These procedures should clearly indicate what document control information should be included in each document. Consideration should be given to the inclusion of

— title and scope,

— document reference number,

— date of issue/date effective,

— revision status,

— review date or review frequency, as required by the quality management system,

— revision history,

— originator or author,

— person(s) approving it,

— person(s) issuing it,

— distribution,

— pagination, and

— computer file reference, if applicable.

4.2.3.4 The topic of electronic documents is complex and evolving. National or regional regulations and guidance documents might address requirements for the organization to establish documented procedures specifically for control of electronic records. This may include, but is not limited to, access, storage, reproducibility, readability, audit trails, electronic signatures, if appropriate.

4.2.3.5 Organizations are required by ISO 13485 to define the lifetime of each of their medical devices; considerations for establishing the lifetime of the medical device are to be found in subclause 7.1.

Document retention time should take into consideration

— period of time the medical device is expected to be in the market place,

— legal considerations including liability,

— need or advisability of keeping documents indefinitely,

— retention time of related records, and

— spare parts availability.

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4.2.3.6 The organization should retain at least one copy of obsolete controlled documents for at least the minimum period of time required by regulation. Obsolete documents should also be retained for as long as is necessary to understand the content of records which are related to the document (see 4.2.4).

ISO 13485 requires the organization "to apply suitable identification" to obsolete documents; such identification can be applied physically (as with a stamp) or electronically (as in a computerized database).

ISO 13485 recognizes that there might be specific regional or national regulatory requirements for the retention of documents made obsolete by changes in medical devices or the quality management system. The organization should determine whether any market that it supplies has such regulatory requirements and should establish a system to ensure that such obsolete documents are retained for an appropriate period.

4.2.4 Control of records

> **ISO 13485:2003, *Medical devices—Quality management systems—Requirements for regulatory purposes***
>
> **4.2.4 Control of records**
>
> Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable, and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.
>
> *The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.*

4.2.4.1 Records can be considered as falling into one of three categories, as follows:

a) those that relate to the design, and the manufacturing processes, affecting all medical devices of a particular type,

b) those that relate to the manufacture or distribution of an individual medical device or batch of medical devices,

c) those that demonstrate the effective operation of the overall quality management system (system records).

It is clear that records in categories a) and b) are related directly to particular medical devices. Those in category a) should be kept for a time at least equivalent to the lifetime of the medical device after manufacture of the last product made to that design. Those records in category b) should be kept for a time at least equivalent to the lifetime of that particular batch of medical devices.

4.2.4.2 Some system records may also have a retention period related to the lifetime of a medical device; for example, calibration and training of individuals. For some other system records, it is less straightforward to relate them to the lifetime of a medical device; for example, management review, internal audit, infrastructure, evaluation of some suppliers, and analysis of data. In these cases, the organization is required by ISO 13485 to identify an appropriate retention period. In defining this retention period, the organization should take into account the nature of the medical device, the risks associated with its use, the records involved, and relevant regulatory requirements.

4.2.4.3 Records should be stored safely, protected from unauthorized access, and protected from alteration. These records should be properly identified, collected, indexed, and filed, and should be readily accessible as and if needed. They may be stored or copied in any suitable form (e.g., hard copy or electronic media). If records are retained on electronic media, consideration of the retention times and accessibility of the records should take into account the degradation of the electronic data and the availability of devices and software needed to access the records. Such copies of records should contain all the relevant information captured in the original records.

4.2.4.4 Handwritten entries should be made by indelible medium. Persons making authorized entries on records or verifying such entries should do so in clear legible writing, and should confirm the entry by adding their initials, signature, or equivalent, and the date.

Good recording practices can include the following considerations, as appropriate:

— enter data and observations as they occur,

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— do not pre-date or post-date records,

— do not use another person's initial, signature, or equivalent,

— complete all fields or check-offs when using a form,

— refer to raw data when transferring data, and have the transcription verified by a second person,

— verify all entries for completeness and correctness, and

— number pages to ensure completeness.

4.2.4.5 If an error is made or detected on a record, it should be corrected in such a manner that the original entry is not lost and the correction is initialed and dated. If appropriate, the reason for the correction should be recorded. Where electronic records systems are used in place of paper based ones, these systems should, wherever possible, incorporate time-stamped, immutable, system generated audit trails, for tracking changes. Such audit trails may include the identity of the authorized user, creations, deletions, modifications/corrections, time and date, links, and embedded comments.

4.2.4.6 The organizations may have alternative provisions for critical data entry of electronic records, for example:

— a second authorized person with logged name and identification, with time and date, can verify data entry via the keyboard, or

— systems with direct data capture can have the second check as a part of validated system functionality.

A system should be implemented that assures the integrity of electronic records and protects against unauthorized entries. The topic of electronic records is complex and evolving. National or regional regulations and guidance documents might address requirements for the organization to establish documented procedures specifically for control of electronic records. This might include, but not be limited to, access, storage, reproducibility, readability, audit trails, and electronic signatures, if appropriate.

4.2.4.7 In addition to considering the lifetime of the device (see 7.1) in determining record retention time, legal considerations, including liability, and the need or advisability of keeping records indefinitely, should be considered.

5 Management responsibility

5.1 Management commitment

> **ISO 13485:2003, *Medical devices—Quality management systems—Requirements for regulatory purposes***
>
> **5 Management responsibility**
>
> **5.1 Management commitment**
>
> *Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by*
>
> — communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
>
> — establishing the quality policy,
>
> — ensuring that quality objectives are established,
>
> — conducting management reviews, and
>
> — ensuring the availability of resources.
>
> *NOTE—For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.*

It is important to note the emphasis on "top management" throughout this clause. This is intended to ensure that the quality management system is effective as a result of commitment on the part of management at the highest levels of the organization.

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Top management's commitment is best demonstrated by its actions.

Remembering that the quality management system is a set of interrelated processes, top management should ensure that processes operate as an effective network.

Consideration should be given to

— ensuring that the sequence and interaction of processes are designed to achieve the planned results effectively,

— ensuring that process inputs, activities, and outputs are clearly defined and controlled,

— monitoring inputs and outputs to verify that individual processes are linked and operate effectively,

— identifying hazards and managing risks,

— conducting data analysis to facilitate necessary improvement of processes,

— identifying process owners and giving them responsibility and authority, and

— managing each process to achieve the process objectives.

5.2 Customer focus

> **ISO 13485:2003, *Medical devices—Quality management systems—Requirements for regulatory purposes***
>
> **5.2 Customer focus**
>
> *Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).*

This subclause is intended to emphasize the responsibility of top management to make certain that customer requirements are understood and the necessary resources are made available to meet those requirements, regardless of who in the organization actually undertakes the interaction with the customer. The references to ISO 13485:2003, 7.2.1 and 8.2.1, are pointers to what this process will be expected to cover.

5.3 Quality policy

> **ISO 13485:2003, *Medical devices—Quality management systems—Requirements for regulatory purposes***
>
> **5.3 Quality policy**
>
> Top management shall ensure that the quality policy
>
> a) is appropriate to the purpose of the organization,
>
> *b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system,*
>
> c) provides a framework for establishing and reviewing quality objectives,
>
> d) is communicated and understood within the organization, and
>
> e) is reviewed for continuing suitability.

The quality policy establishes

— a commitment to quality and the continuing effectiveness of the quality management system to meet customer and regulatory requirements,

— the context for quality objectives, and

— the relationship of the organization's objectives to the customers' requirements.

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It is important that the organization's quality policy be considered when preparing the overall organization policies related to its business operations (e.g., marketing, sales, finance) in order to ensure that all organization policies are consistent and supportive of each other.

The quality policy should communicate the organization's commitment to quality and its overall vision of what quality means to the organization's business and customers.

ISO 13485:2003, 4.2.1 requires the organization to state this quality policy in writing.

In order to demonstrate that the organization is committed to implementing its quality policy, it will need to identify clear, overall quality goals for the business that are directly relevant to the organization and its customers.

Top management's commitment to the quality policy should be visible, active, and effectively communicated. For example, a publicly displayed copy of the quality policy signed by top management is one method to show that commitment to both employees and customers. Another method is to present and discuss the quality policy at organization meetings throughout the year. Top management's commitment is best communicated through its decisions and actions.

All employees need to understand the quality policy and how it affects them. Top management should ensure that the organization decides on the methods which will be used to achieve this understanding.

The quality policy also needs to be reviewed from time to time to determine if it accurately reflects the current quality-related goals and objectives of the organization. This review is often carried out during the management review required in 5.6.

5.4 Planning

5.4.1 Quality objectives

> **ISO 13485:2003, *Medical devices—Quality management systems—Requirements for regulatory purposes***
>
> **5.4 Planning**
>
> **5.4.1 Quality objectives**
>
> Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1 a)), are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

In order to put the organization's quality policy into effect, top management needs to establish clearly defined quality objectives for which the organization can aim. The activities undertaken to reach these objectives do not need to be carried out personally by top management, but the responsibility is still theirs.

In setting quality objectives and any associated targets, time frames for achieving the targets are usually established.

ISO 13485 calls for quality objectives not only for the quality management system but also for medical devices and related services (see 7.1 a)).

Quality objectives should be realistic and related to achievable and measurable outcomes, such as

— meeting the requirements (customer, regulatory, and other) for medical devices and related services,

— reducing errors,

— reducing internal audit closure times,

— meeting planned schedules, and

— reducing customer complaint handling times.

Groups within the organization typically establish group objectives which follow from the overall organization objectives and relate to the specific activities of the group.

Quality objectives provide one of the inputs into quality management system planning (see 5.4.2).

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5.4.2 Quality management system planning

> **ISO 13485:2003, *Medical devices—Quality management systems—Requirements for regulatory purposes***
>
> **5.4.2 Quality management system planning**
>
> Top management shall ensure that
>
> a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
>
> b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.4.2.1 This subclause deals with planning related to the quality management system in general, in contrast to planning required in other subclauses related to individual elements of the quality management system.

In order that the quality management system can meet the requirements of ISO 13485:2003, 4.1, most of this planning will be at the initial stages of development and implementation of the quality management system. This planning can assist the organization to fulfill its quality objectives. Since quality objectives can, and indeed should, change over time, this planning is likely to be ongoing, and can assist the quality management system to continue to be effective during and after changes.

5.4.2.2 Typical inputs into quality management system planning include

— quality policy,

— quality objectives,

— regulatory requirements,

— quality management system standards, and

— changes required (e.g., as a result of management review and/or corrective and preventive action).

5.4.2.3 Typical outputs from quality management system planning that demonstrate meeting the requirements of ISO 13485:2003, 4.1 and the quality objectives include

— the quality manual and supporting documentation,

— gap analyses,

— actions plans, and

— results of action plans.

It should be noted that the term “quality plan” is more frequently used in conjunction with product realization planning (see 7.1) than in conjunction with quality management system planning.

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