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Medical devices — Quality management systems — Requirements for regulatory purposes

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Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Quality management system **6**
4.1 General requirements 6
4.2 Documentation requirements 7
4.2.1 General 7
4.2.2 Quality manual 7
4.2.3 Medical device file 7
4.2.4 Control of documents 8
4.2.5 Control of records 8

5 Management responsibility **9**
5.1 Management commitment 9
5.2 Customer focus 9
5.3 Quality policy 9
5.4 Planning 9
5.4.1 Quality objectives 9
5.4.2 Quality management system planning 9
5.5 Responsibility, authority and communication 10
5.5.1 Responsibility and authority 10
5.5.2 Management representative 10
5.5.3 Internal communication 10
5.6 Management review 10
5.6.1 General 10
5.6.2 Review input 10
5.6.3 Review output 11

6 Resource management **11**
6.1 Provision of resources 11
6.2 Human resources 11
6.3 Infrastructure 12
6.4 Work environment and contamination control 12
6.4.1 Work environment 12
6.4.2 Contamination control 12

7 Product realization **12**
7.1 Planning of product realization 12
7.2 Customer-related processes 13
7.2.1 Determination of requirements related to product 13
7.2.2 Review of requirements related to product 13
7.2.3 Communication 14
7.3 Design and development 14
7.3.1 General 14
7.3.2 Design and development planning 14
7.3.3 Design and development inputs 14
7.3.4 Design and development outputs 15
7.3.5 Design and development review 15
7.3.6 Design and development verification 15
7.3.7 Design and development validation 15
7.3.8 Design and development transfer 16
7.3.9 Control of design and development changes 16
7.3.10 Design and development files 16

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7.4 Purchasing ... 17
7.4.1 Purchasing process ... 17
7.4.2 Purchasing information ... 17
7.4.3 Verification of purchased product ... 17
7.5 Production and service provision ... 18
7.5.1 Control of production and service provision ... 18
7.5.2 Cleanliness of product ... 18
7.5.3 Installation activities ... 18
7.5.4 Servicing activities ... 19
7.5.5 Particular requirements for sterile medical devices ... 19
7.5.6 Validation of processes for production and service provision ... 19
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems ... 19
7.5.8 Identification ... 20
7.5.9 Traceability ... 20
7.5.10 Customer property ... 20
7.5.11 Preservation of product ... 20
7.6 Control of monitoring and measuring equipment ... 21

8 Measurement, analysis and improvement ... 22
8.1 General ... 22
8.2 Monitoring and measurement ... 22
8.2.1 Feedback ... 22
8.2.2 Complaint handling ... 22
8.2.3 Reporting to regulatory authorities ... 23
8.2.4 Internal audit ... 23
8.2.5 Monitoring and measurement of processes ... 23
8.2.6 Monitoring and measurement of product ... 23
8.3 Control of nonconforming product ... 24
8.3.1 General ... 24
8.3.2 Actions in response to nonconforming product detected before delivery ... 24
8.3.3 Actions in response to nonconforming product detected after delivery ... 24
8.3.4 Rework ... 24
8.4 Analysis of data ... 24
8.5 Improvement ... 25
8.5.1 General ... 25
8.5.2 Corrective action ... 25
8.5.3 Preventive action ... 25

Annex A (informative) **Comparison of content between ISO 13485:2003 and ISO 13485:2016 ... 27**

Annex B (informative) **Correspondence between ISO 13485:2016 and ISO 9001:2015 ... 30**

Bibliography ... 36

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition of ISO 13485 cancels and replaces the second edition (ISO 13485:2003) and ISO/TR 14969:2004, which have been technically revised. It also incorporates the Technical Corrigendum ISO 13485:2003/Cor.1:2009. A summary of the changes incorporated into this edition compared with the previous edition is given in Annex A.

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Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this International Standard expects that the organization:

— identifies its role(s) under applicable regulatory requirements;

— identifies the regulatory requirements that apply to its activities under these roles;

— incorporates these applicable regulatory requirements within its quality management system.

The definitions in applicable regulatory requirements differ from nation to nation and region to region. The organization needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.

This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by the:

a) organizational environment, changes in that environment, and the influence that the organizational environment has on the conformity of the medical devices;

b) organization's varying needs;

c) organization's particular objectives;

d) product the organization provides;

e) processes the organization employs;

f) organization's size and organizational structure;

g) regulatory requirements applicable to the organization's activities.

It is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, uniformity of documentation or alignment of documentation to the clause structure of this International Standard.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

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0.2 Clarification of concepts

In this International Standard, the following terms or phrases are used in the context described below.

— When a requirement is qualified by the phrase "as appropriate", it is deemed to be appropriate unless the organization can justify otherwise. A requirement is considered appropriate if it is necessary for:

  — product to meet requirements;

  — compliance with applicable regulatory requirements;

  — the organization to carry out corrective action;

  — the organization to manage risks.

— When the term "risk" is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.

— When a requirement is required to be "documented", it is also required to be established, implemented and maintained.

— When the term "product" is used, it can also mean "service". Product applies to output that is intended for, or required by, a customer, or any intended output resulting from a product realization process.

— When the term "regulatory requirements" is used, it encompasses requirements contained in any law applicable to the user of this International Standard (e.g. statutes, regulations, ordinances or directives). The application of the term "regulatory requirements" is limited to requirements for the quality management system and the safety or performance of the medical device.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

0.3 Process approach

This International Standard is based on a process approach to quality management. Any activity that receives input and converts it to output can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it needs to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach."

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

a) understanding and meeting requirements;

b) considering processes in terms of added value;

c) obtaining results of process performance and effectiveness;

d) improving processes based on objective measurement.

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0.4 Relationship with ISO 9001

While this is a stand-alone standard, it is based on ISO 9001:2008, which has been superseded by ISO 9001:2015. For the convenience of users, Annex B shows the correspondence between this International Standard and ISO 9001:2015.

This International Standard is intended to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device. This International Standard includes some particular requirements for organizations involved in the life-cycle of medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management system meets all the requirements of ISO 9001.

0.5 Compatibility with other management systems

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

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Medical devices — Quality management systems — Requirements for regulatory purposes

1 Scope

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of this International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by this International Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to this International Standard reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of this International Standard is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015[1)], *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

1) Supersedes ISO 9000:2005.

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3.1
advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the:

— use of a medical device,

— modification of a medical device,

— return of the medical device to the organization that supplied it, or

— destruction of a medical device

Note 1 to entry: Issuance of an advisory notice can be required to comply with applicable regulatory requirements.

3.2
authorized representative
natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation

[SOURCE: GHTF/SG1/N055:2009, 5.2]

3.3
clinical evaluation
assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

[SOURCE: GHTF/SG5/N4:2010, Clause 4]

3.4
complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices

Note 1 to entry: This definition of "complaint" differs from the definition given in ISO 9000:2015.

3.5
distributor
natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user

Note 1 to entry: More than one distributor may be involved in the supply chain.

Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.

[SOURCE: GHTF/SG1/N055:2009, 5.3]

3.6
implantable medical device
medical device which can only be removed by medical or surgical intervention and which is intended to:

— be totally or partially introduced into the human body or a natural orifice, or

— replace an epithelial surface or the surface of the eye, and

— remain after the procedure for at least 30 days

Note 1 to entry: This definition of implantable medical device includes active implantable medical device

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3.7
importer
natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed

[SOURCE: GHTF/SG1/N055:2009, 5.4]

3.8
labelling
label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

[SOURCE: GHTF/SG1/N70:2011, Clause 4]

3.9
life-cycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

[SOURCE: ISO 14971:2007, 2.7]

3.10
manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture", as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: GHTF/SG1/N055:2009, 5.1]

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3.11
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: GHTF/SG1/N071:2012, 5.1]

3.12
medical device family
group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function

3.13
performance evaluation
assessment and analysis of data to establish or verify the ability of an *in vitro* diagnostic medical device to achieve its intended use

3.14
post-market surveillance
systematic process to collect and analyse experience gained from medical devices that have been placed on the market

3.15
product
result of a process

Note 1 to entry: There are four generic product categories, as follows:

— services (e.g. transport);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine mechanical part);

— processed materials (e.g. lubricant).

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Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example, the offered product "automobile" consists of hardware (e.g. tyres), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

Note 2 to entry: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures.

Hardware is generally tangible and its amount is a countable characteristic. Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.

Note 3 to entry: This definition of "product" differs from the definition given in ISO 9000:2015.

[SOURCE: ISO 9000:2005[2)], 3.4.2, modified]

3.16
purchased product
product provided by a party outside the organization's quality management system

Note 1 to entry: The provision of product does not necessarily infer a commercial or financial arrangement.

3.17
risk
combination of the probability of occurrence of harm and the severity of that harm

Note 1 to entry: This definition of "risk" differs from the definition given in ISO 9000:2015.

[SOURCE: ISO 14971:2007, 2.16]

3.18
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

[SOURCE: ISO 14971:2007, 2.22]

3.19
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use

[SOURCE: ISO 11607-1:2006, 3.22]

2) Superseded by ISO 9000:2015.

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3.20
sterile medical device
medical device intended to meet the requirements for sterility

Note 1 to entry: The requirements for sterility of a medical device can be subject to applicable regulatory requirements or standards.

4 Quality management system

4.1 General requirements

4.1.1 The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements.

The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.

NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.

4.1.2 The organization shall:

a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;

b) apply a risk based approach to the control of the appropriate processes needed for the quality management system;

c) determine the sequence and interaction of these processes.

4.1.3 For each quality management system process, the organization shall:

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

b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes;

d) monitor, measure as appropriate, and analyse these processes;

e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).

4.1.4 The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:

a) evaluated for their impact on the quality management system;

b) evaluated for their impact on the medical devices produced under this quality management system;

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c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.

4.1.5 When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.

4.1.6 The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

Records of such activities shall be maintained (see 4.2.5).

4.2 Documentation requirements

4.2.1 General

The quality management system documentation (see 4.2.4) shall include:

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

b) a quality manual;

c) documented procedures and records required by this International Standard;

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

e) other documentation specified by applicable regulatory requirements.

4.2.2 Quality manual

The organization shall document a quality manual that includes:

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

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

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.

4.2.3 Medical device file

For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;

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b) specifications for product;

c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;

d) procedures for measuring and monitoring;

e) as appropriate, requirements for installation;

f) as appropriate, procedures for servicing.

4.2.4 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 4.2.5.

A documented procedure shall define the controls needed to:

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

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

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

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

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled;

g) prevent deterioration or loss of documents;

h) prevent the unintended use of obsolete documents and apply suitable identification to them.

The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or 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 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 4.2.5), or as specified by applicable regulatory requirements.

4.2.5 Control of records

Records shall be maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization shall document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

The organization shall define and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records shall remain legible, readily identifiable and retrievable. Changes to a record shall remain identifiable.

The organization shall retain the records for at least the lifetime of the medical device as defined by the organization, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the organization.

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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 maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;

b) establishing the quality policy;

c) ensuring that quality objectives are established;

d) conducting management reviews;

e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.

5.3 Quality policy

Top management shall ensure that the quality policy:

a) is applicable 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;

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

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;

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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