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Quality management systems - Medical devices - System requirements for regulatory purposes
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AAMI has circulated this draft to committee members for comment and vote. Consensus on this draft will be developed by AAMI/QM/WG 01, Application of quality systems to medical devices. Interested parties may submit public review comments, in writing, to:

AAMI
1110 N. Glebe Road
Ste 220
Arlington, VA 22201-4795
ATTN: Hillary Woehrle
Fax: 703-276-0793; Email: hwoehrle@aami.org

This is a proposed US adoption of a draft ISO document (ISO/DIS).

COMMENT DEADLINE: 7 May 2002

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- a. Section number, section heading, and page number of document;
- b. Comments/objection;
- c. Rationale for comment/objection; and,
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(AAMI/DS-2 13485)
2002-02-21
(Revision of ANSI/AAMI/ISO 13485:1996)

Committee Draft for Vote
(Proposed Draft)

AAMI/ American National Standard

NOTE - This document is still under study and subject to change.
It should not be used for reference purposes.

Quality management systems - Medical devices - System requirements for regulatory purposes

Abstract: Specifies requirements for a quality management system for medical devices where an organization needs to demonstrate its ability to provide product that consistently meets customer and applicable regulatory requirements.

Keywords: quality systems

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220, Arlington VA 22201-4795
Phone 703/525-4890 Fax 703/276-0793 Internet www.aami.org

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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 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.

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

ISO 13485 was prepared by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices.

This second edition cancels and replaces the first edition (ISO 13485:1996) which has been technically revised. It also cancels and replaces ISO 13488:1996. Those organizations which have used ISO 13488 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

This edition of ISO 13485 carries a revised title and addresses quality assurance of product, customer requirements, and other elements of quality system management.

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization for the design, production and installation and servicing for medical devices. It can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements.

It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.

The adoption of a quality management system should be a strategic decision of the organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

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.

0.2 Process approach

This International Standard is based on a process approach to quality management.

Any activity that receives inputs and converts them to outputs can be considered as a process.

For an organization to function effectively, it has to identify and manage numerous linked processes. 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".

0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001:2000

While this is a stand alone standard, it is based on ISO 9001:2000.

Those clauses or subclauses that are quoted directly and unchanged from ISO 9001:2000 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B.

If a requirements clause or subclause from ISO 9001:2000 is changed in a limited way by addition of information or by tailoring it to be consistent with medical device regulation, the original ISO 9001:2000 text that remains in the clause or subclause is shown as normal and the added text is shown in blue, italic font. The nature and reasons for the text additions or changes are noted in Annex B.

Where ISO 13485 has introduced additions to the body of text of an ISO 9001:2000 requirements clause or subclause, the original ISO 9001 text is shown in normal font and the additional text is shown in blue, italic font. The nature and reasons for the text additions are noted in Annex B.

Where ISO 13485 has deleted or amended the text of ISO 9001:2000 by the deletion or significant modification of a substantive requirement, the entire affected clause or subclause is shown in blue, italic font. The entire original ISO 9001:2000 text of the clause or subclause is reproduced in Annex B along with a description of the nature and reasons for the deletion.

0.3.2 Relationship with ISO/TS 14969

ISO/TS 14969 will be a technical specification intended to provide guidance in the implementation of ISO 13485:200X.

0.4 Compatibility with other management systems

This International Standard follows the format of ISO 9001:2000 for the convenience of users in the medical device community.

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 conforms with the requirements of this International Standard.

Quality systems — Medical devices — System requirements for regulatory purposes

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices that consistently meet customer requirements and regulatory requirements applicable to medical devices.

The primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the ISO 9001:2000 requirements 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 9001:2000 unless their quality management systems conform to the additional ISO 9001:2000 requirements (see Annex B).

1.2 Application

All requirements of this International Standard are specific to the medical device industry, regardless of the type or size of the organization.

If any requirement(s) of this International Standard cannot be applied due to the activities carried out by the organization and the nature of the medical device(s) for which the quality management system is applied, this can be considered for exclusion (see 4.2.2).

If exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements (see 4.1 and 7.1).

In addition, regulatory requirements can permit exclusions for design and development controls (see 7.3). These regulations can provide alternative arrangements that must 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 7.3).

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.

In this International Standard the term "if appropriate" is used several times. When a requirement is qualified by this phrase, it is deemed to be "appropriate" unless the organization can document a justification otherwise. A requirement is considered "appropriate" if it is necessary for:

—the product to meet specified requirements, and/or

—the organization to carry out corrective action.

2 Normative reference

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.

3 Terms and definitions

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

The terms used in this edition of ISO 13485 to describe the supply chain have been changed to reflect the vocabulary currently used:

supplier----->organization----->customer

The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

NOTE The following definitions should be regarded as generic, as definitions provided in national regulations may differ slightly and take precedence.

3.1 active implantable medical device: active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

3.2 active medical device: medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.3 advisory notice: notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in

- the use of a medical device,
- the modification of a medical device,
- the return to the organization that supplied the medical device, or
- the destruction of a medical device,

for the purpose of corrective or preventive action and in compliance with national and regional regulatory requirements

3.4 customer complaint: written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market

3.5 implantable medical device: medical device intended

- to be totally or partially introduced into the human body or a natural orifice, or
- to replace an epithelial surface or the surface of the eye,

by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention.

NOTE—This definition applies to implantable medical devices other than active implantable medical devices

3.6 labelling: *written, printed or graphic matter*

— *affixed to a medical device or any of its containers or wrappers, or,*

— *accompanying a medical device,*

related to identification, technical description, and use of the medical device, but excluding shipping documents

3.7 medical device: *instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the organization to be used for human beings for the purpose of*

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

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

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

— *control of conception,*

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

NOTE—The term “medical device” includes - in vitro diagnostic devices.

3.8 sterile medical device: *category of medical device intended to meet the requirements for sterility*

NOTE The requirements for sterility of a medical device may be subject to national or regional regulations or standards.

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 analyse 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.

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

4.2 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 requirements specified by national or regional regulations.*

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.

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

The organization shall establish and maintain a file containing documents defining for each type / model of medical device, product specifications and quality system requirements (process and quality assurance) for:

— complete manufacturing, and

— installation and servicing, if appropriate

or referring to the location(s) of this information (see 4.2.3).

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

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 (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.

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

- d) to approve documents for adequacy prior to issue,
- e) to review and update as necessary and re-approve documents,
- f) to ensure that changes and the current revision status of documents are identified,
- g) to ensure that relevant versions of applicable documents are available at points of use,
- h) to ensure that documents remain legible and readily identifiable,
- i) to ensure that documents of external origin are identified and their distribution controlled, and
- j) 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 changes to documents are reviewed and approved either by the original approving authority or another designated authority which has access to pertinent background information upon which to base their 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 specifications to which medical devices have been manufactured are available for at least the lifetime of the medical device as defined by the organization or as specified by relevant regulatory requirements.

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 2 years from the date of release for distribution from the organization.

NOTE National or regional regulations may require a period longer than 2 years.

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

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

NOTE: Statutory only refers to functionality, safety and performance of the medical device.

- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).

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.

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.

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.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.

Top management shall establish the interrelation of all personnel who manage, perform and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- a) ensuring that processes needed for the quality management system are established, implemented and maintained;
- b) reporting to top management on the performance of the quality management system and any need for improvement; and
- c) ensuring the promotion of awareness of *regulatory and* customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

- a) *maintenance of the effectiveness of the quality management system and its processes,*
- b) *improvement of product to meet regulatory, customer or defined product (see 7.2.2) requirements, and*
- c) *resource needs.*

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

- a) *to implement the quality management system and to maintain its effectiveness and*
- b) *to meet regulatory and customer requirements.*

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall

- a) determine the necessary competence for personnel performing work affecting product quality,
- b) provide training or take other actions to satisfy these needs,
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

NOTE: National or regional regulations may require the organization to establish documented procedures for identifying training needs.

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

- f) buildings, workspace and associated utilities,
- g) process equipment (both hardware and software), and
- h) supporting services (such as transport or communication).

The organization shall establish documented requirements for maintenance activities when such activities or lack thereof may affect product quality.

Records of such maintenance shall be kept (see 4.2.4).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements. *In particular, the following requirements shall apply:*

- a) *The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or environment could adversely affect the quality of the product.*
- b) *If appropriate, special arrangements shall be established and documented for the control of used product in order to prevent contamination of other product, the manufacturing environment or personnel.*
- c) *If environmental conditions can have an adverse effect on product quality, where appropriate, the organization shall establish documented requirements for the environmental conditions and documented procedures to monitor and control these environmental conditions (see 7.5.1.3.2).*
- d) *The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained person.*

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes, documents, and provide resources specific to the product;
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

The organization shall establish documented risk management activities throughout the product realization process, where appropriate. Records of risk management activities shall be maintained (see 4.2.4).

NOTE 3: See ISO 14971:2000

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) requirements not stated by the customer but necessary for specified or intended use, where known
- c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) product requirements are defined *and documented*,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

- a) product information,
- b) enquiries, contracts or order handling, including amendments,
- c) customer feedback, including customer complaints, *and*
- d) *advisory notices*.

7.3 Design and development

7.3.1 Design and development planning

The organization shall establish documented procedures for design and development.

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

- a) the design and development stages,
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be *documented, and* updated as appropriate, as the design and development progresses (see 4.2.3).

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy *and approved*. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

- a) meet the input requirements for design and development,
- b) provide appropriate information for purchasing, production and for service provision,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the outputs of the design and development shall be maintained (see 4.2.4).

NOTE: Records of design and development output can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

- a) to evaluate the ability of the results of design and development to meet requirements, and
- b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. *Validation shall be completed prior to the delivery or implementation of the product.* Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

NOTE: If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to have occurred until this validation is complete.

As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, if required by national or regional regulations.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

The organization shall *establish documented procedures* to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

- a) requirements for approval of product, procedures, processes, and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

To the extent required for traceability given in 7.5.3, the organization shall retain copies of relevant purchasing documents including records (see 4.2.4).

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Records of the verification shall be retained (see 4.2.4).

7.5 Production and service provision

7.5.1 Control of production and service provision

7.5.1.1 General requirements

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

- a) the availability of information that describes the characteristics of the product,
- b) the availability of *documented procedures*, work instructions, and *reference standards* as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement,
- f) the implementation of release, delivery and post-delivery activities, and
- g) *the implementation of defined labelling and packaging operations to prevent labelling errors.*

7.5.1.2 Record keeping

7.5.1.2.1 General

The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the quantity manufactured and quantity approved for distribution. The batch record shall be verified and approved.

A batch may be a single medical device.

7.5.1.2.2 Particular requirement for sterile medical devices

The organization shall retain records of the process control parameters, identified during sterilization process validation (see 7.5.2), used for each sterilization batch (see 4.2.4). Such sterilization records shall be traceable to each production batch of medical devices.

7.5.1.3 Control of product and service provision – specific requirements

7.5.1.3.1 Cleanliness of product and contamination control

The organization shall establish documented requirements for cleanliness of product if

- a) *product is cleaned by the organization prior to sterilization and/or its use, or*
- b) *product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or*
- c) *product is supplied to be used non-sterile and its cleanliness is of significance in use, or*
- d) *process agents are to be removed from product during manufacture.*

If product is cleaned in accordance with a) or b) above, 6.4 a) and 6.4 c) do not apply prior to the cleaning process.

7.5.1.3.2 Installation activities

If appropriate, the organization shall establish and maintain documented instructions and acceptance criteria for installing and verifying the installation of the medical device.

If the agreed customer requirement allows installation to be performed other than by the organization or its authorized agent, the organization shall provide documented instructions for installation and verification.

Records of installation and verification performed by the organization or its authorized agent shall be retained (see 4.2.4).

7.5.1.3.3 Servicing activities

Where servicing is a specified requirement, the organization shall establish documented procedures, work instructions and reference standards, as necessary, for performing the servicing activities and verifying that they meet the specified requirements.

Servicing activities carried out by the organization shall be recorded (see 4.2.4).

7.5.2 Validation of processes for production and service provision

7.5.2.1 General requirements

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

7.5.2.2 Record keeping

7.5.2.2.1 General

The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service operations and measuring and monitoring operations (see 8.2) that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.

The results of validation shall be recorded (see 4.2.4).

7.5.2.2.2 Particular requirements for sterile medical devices

The organization shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use.

The results of sterilization process validation(s) shall be recorded (see 4.2.4), and shall identify the process parameters of the sterilization process necessary to demonstrate control.

7.5.3 Identification and traceability

7.5.3.1 Identification

The organization shall establish documented procedures for identification.

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall establish documented procedures to ensure that medical devices returned to the organization for reprocessing to specified requirements are identified and distinguished at all times from normal production.

7.5.3.2 Traceability**7.5.3.2.1 General**

The organization shall establish documented procedures for traceability. The procedures shall define the extent of traceability and shall facilitate the control of non-conforming product (see 8.3) and the issue of advisory notices (see 8.5.1).

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE Configuration management is a means by which identification and traceability can be maintained.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices

When defining the extent of traceability, the organization shall include all components and materials used, and records of the environmental conditions when these could cause the medical device not to satisfy its specified requirements.

The organization shall require that its agents or distributors maintain records of the distribution of medical devices with regard to traceability and that such records are available for inspection.

The organization shall ensure that the name and address of the shipping package consignee is recorded (see 4.2.4).

7.5.3.3 Status Identification

The organization shall identify the product status with respect to monitoring and measurement requirements.

The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

7.5.5 Preservation of product

The organization shall *establish documented procedures for preserving* the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

The organization shall establish documented procedures for the control of product with a limited shelf- life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded (see 4.2.4).

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish *documented procedures* to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall:

- a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to enable the calibration status to be determined;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary (see 7.5.2).

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity of the product,
- b) to ensure conformity of the quality management system, and
- c) to *maintain the effectiveness* of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

NOTE National or regional regulations may require documented procedures for implementation and control of the application of statistical techniques.

8.2 Monitoring and measurement

8.2.1 Customer feedback

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

The organization shall establish a documented feedback system (see 7.2.3) to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3).

If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

8.2.4.1 General requirements

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed.

8.2.4.2 Particular requirement for active implantable devices and implantable devices

The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession. *The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. The identity of the person(s) authorizing the concession shall be recorded (see 4.2.4);*
- c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

If product needs to be reworked (one or more times), the organization shall document the rework in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).

8.4 Analysis of data

The organization shall establish documented procedures to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) *customer feedback (see 8.2.1),*
- b) conformity to product requirements (see 7.2.1),
- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

Records of the results of the analysis of data shall be maintained (see 4.2.4).

8.5 Improvement

8.5.1 General

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The organization shall establish documented procedures for the issue of advisory notices for medical devices. These procedures shall be capable of being implemented at any time.

The organization shall maintain records (see 4.2.4) of all customer complaint investigations. When the investigation determines that the activities at remote premises contributed to the customer complaint, relevant information shall be communicated between the organization and the remote premises.

If any customer complaint is not followed by corrective and/or preventive action, the reason shall be recorded.

If national or regional regulations require, the organization shall establish documented procedures to notify the regulatory authorities of those adverse events which meet the reporting criteria.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results *of any investigation and* of the action taken (see 4.2.4), and
- f) reviewing corrective action taken *and its effectiveness*.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of the results *of any investigations and* of action taken (see 4.2.4), and
- e) reviewing preventive action taken *and its effectiveness*.

Annex A

(informative)

Correspondence between ISO 13485:200X and ISO 13485:1996**Table A.1 – Correspondence between ISO 13485:1996 and ISO 13485:200X**

ISO 13485:1996	ISO 13485:200X
1 Scope	1
2 Normative reference	2
3 Definitions	3
4 Quality system requirements [title only]	
4.1 Management responsibility [title only]	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization [title only]	
4.1.2.1 Responsibility and authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management representative	5.5.2
4.1.3 Management review	5.6.1 + 8.5.1
4.2 Quality system [title only]	
4.2.1 General	4.1 + 4.2.2
4.2.2 Quality system procedures	4.2.1
4.2.3 Quality planning	5.4.2 + 7.1
4.3 Contract review [title only]	
4.3.1 General [title only]	
4.3.2 Review	5.2 + 7.2.1 + 7.2.2 + 7.2.3
4.3.3 Amendment to a contract	7.2.2
4.3.4 Records	7.2.2
4.4 Design control [title only]	
4.4.1 General [title only]	
4.4.2 Design and development planning	7.3.1
4.4.3 Organizational and technical interfaces	7.3.1
4.4.4 Design input	7.2.1 + 7.3.2
4.4.5 Design output	7.3.3
4.4.6 Design review	7.3.4
4.4.7 Design verification	7.3.5
4.4.8 Design validation	7.3.6
4.4.9 Design changes	7.3.7
4.5 Document and data control [title only]	
4.5.1 General	4.2.3
4.5.2 Document and data approval and issue	4.2.3
4.5.3 Document and data changes	4.2.3
4.6 Purchasing [title only]	
4.6.1 General [title only]	
4.6.2 Evaluation of subcontractors	7.4.1
4.6.3 Purchasing data	7.4.2
4.6.4 Verification of purchased product	7.4.3
4.7 Control of customer-supplied product	7.5.4
4.8 Product identification and traceability	7.5.3
4.9 Process control	6.3 + 6.4 + 7.5.1 + 7.5.2
4.10 Inspection and testing [title only]	
4.10.1 General	7.1 + 8.1
4.10.2 Receiving inspection and testing	7.4.3 + 8.2.4
4.10.3 In-process inspection and testing	8.2.4
4.10.4 Final inspection and testing	8.2.4
4.10.5 Inspection and test records	7.5.3 + 8.2.4

ISO 13485:1996	ISO 13485:200X
4.11 Control of inspection, measuring and test equipment [title only]	
4.11.1 General	7.6
4.11.2 Control procedure	7.6
4.12 Inspection and test status	7.5.3
4.13 Control of nonconforming product [title only]	
4.13.1 General	8.3
4.13.2 Review and disposition of nonconforming product	8.3
4.14 Corrective and preventive action [title only]	
4.14.1 General	8.5.2 + 8.5.3
4.14.2 Corrective action	8.5.2
4.14.3 Preventive action	8.5.3
4.15 Handling, storage, packaging, preservation & delivery [title only]	
4.15.1 General [title only]	
4.15.2 Handling	7.5.5
4.15.3 Storage	7.5.5
4.15.4 Packaging	7.5.5
4.15.5 Preservation	7.5.5
4.15.6 Delivery	7.5.1
4.16 Control of quality records	4.2.4
4.17 Internal quality audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
4.19 Servicing	7.5.1
4.20 Statistical techniques [title only]	
4.20.1 Identification of need	8.1 + 8.2.3 + 8.2.4 + 8.4
4.20.2 Procedures	8.1 + 8.2.3 + 8.2.4 + 8.4

Table A.2 – Correspondence between ISO 13485:200X and ISO 13485:1996

ISO 13485:200X	ISO 13485:1996
1 Scope	1
1.1 General	
1.2 Application	
2 Normative reference	2
3 Terms and definitions	3
4 Quality management system [title only]	
4.1 General requirements	4.2.1
4.2 Documentation requirements [title only]	
4.2.1 General	4.2.2
4.2.2 Quality manual	4.2.1
4.2.3 Control of documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of records	4.16
5 Management responsibility [title only]	
5.1 Management commitment	4.1.1
5.2 Customer focus	4.3.2
5.3 Quality policy	4.1.1
5.4 Planning [title only]	
5.4.1 Quality objectives	4.1.1
5.4.2 Quality management system planning	4.2.3
5.5 Responsibility, authority and communication [title only]	
5.5.1 Responsibility and authority	4.1.2.1
5.5.2 Management representative	4.1.2.3
5.5.3 Internal communication	
5.6 Management review [title only]	
5.6.1 General	4.1.3
5.6.2 Review input	
5.6.3 Review output	
6 Resource management [title only]	
6.1 Provision of resources	4.1.2.2
6.2 Human resources [title only]	
6.2.1 General	4.1.2.2
6.2.2 Competence, awareness and training	4.18
6.3 Infrastructure	4.9
6.4 Work environment	4.9
7 Product realization [title only]	
7.1 Planning of product realization	4.2.3 + 4.10.1
7.2 Customer-related processes [title only]	
7.2.1 Determination of requirements related to the product	4.3.2 + 4.4.4
7.2.2 Review of requirements related to the product	4.3.2 + 4.3.3 + 4.3.4
7.2.3 Customer communication	4.3.2
7.3 Design and development	
7.3.1 Design and development planning	4.4.2 + 4.4.3
7.3.2 Design and development inputs	4.4.4
7.3.3 Design and development outputs	4.4.5
7.3.4 Design and development review	4.4.6
7.3.5 Design and development verification	4.4.7
7.3.6 Design and development validation	4.4.8
7.3.7 Control of design and development changes	4.4.9
7.4 Purchasing [title only]	
7.4.1 Purchasing process	4.6.2

ISO 13485:200X	ISO 13485:1996
7.4.2 Purchasing information	4.6.3
7.4.3 Verification of purchased product	5.6.4 + 4.10.2
7.5 Product and service provision [title only]	
7.5.1 Control of production and service provision	4.9 + 4.15.6 + 4.19
7.5.2 Validation of processes for production and service provision	4.9
7.5.3 Identification and traceability	4.8 + 4.10.5 + 4.12
7.5.4 Customer property	4.7
7.5.5 Preservation of product	4.15.2 + 4.15.3 + 4.15.4 + 4.15.5
7.6 Control of monitoring and measuring devices	4.11.1 + 4.11.2
8 Measurement, analysis and improvement [title only]	
8.1 General	4.11.1 + 4.11.2
8.2 Monitoring and measurement [title only]	
8.2.1 Customer feedback	
8.2.2 Internal audit	4.17
8.2.3 Monitoring and measurement of processes	4.17 + 4.20.1 + 4.20.2
8.2.4 Monitoring and measurement of product	4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2
8.3 Control of non-conforming product	4.13.1 + 4.13.2
8.4 Analysis of data	4.20.1 + 4.20.2
8.5 Improvement [title only]	
8.5.1 General	4.1.3
8.5.2 Corrective action	4.14.1 + 4.14.2
8.5.3 Preventive action	4.14.1 + 4.14.3

Annex B
(informative)

Explanation of Differences between ISO 13485:200X and ISO 9001:2000

The contents of this Annex clarify the similarities and differences between key informative clauses and subclauses and requirements clauses and subclauses of ISO 13485:200X and ISO 9001:2000.

In this Annex:

- For those clauses or subclauses of ISO 13485:200X that are quoted directly and unchanged from ISO 9001:2000, the fact that these subclauses are presented unchanged is noted in this informative annex.
- For those clauses or subclauses from ISO 9001:2000 that are changed in ISO 13485:200X by addition of information or by tailoring it to be consistent with medical device regulation, the entire original ISO 9001:2000 text of the clause or subclause is reproduced in the left column of this informative annex. The text of the corresponding ISO 13485:200X clause or subclause and the reasons for the text changes are in the right column.
- For those clauses or subclauses where ISO 13485:200X has deleted or amended the text of ISO 9001:2000 by the deletion or significant modification of a substantive requirement, the entire original ISO 9001:2000 text of the clause or subclause is reproduced in the left column of this informative annex. The text of the corresponding ISO 13485:200X clause or subclause and the reasons for the text changes are in the right column.
- Text in the ISO 13485:200X column that appears in brackets [] describes text that is included in the body of the ISO 13485:200X, but is not reproduced in the Annex B column.

ISO 9001:2000	ISO 13485:200X
<p>0 Introduction</p> <p>0.1 General</p> <p>The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization’s quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p>The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.</p> <p>This International Standard can be used by internal and external parties, including certification bodies, to assess the organization’s ability to meet customer regulatory</p>	<p>0 Introduction</p> <p>0.1 General</p> <p>This International Standard specifies requirements for a quality management system that can be used by an organization for the design, production and installation and servicing for medical devices. It can also be used by internal and external parties, including certification bodies, to assess the organization’s ability to meet customer and regulatory requirements.</p> <p>It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.</p> <p>The adoption of a quality management system should be a strategic decision of the organization. The design and implementation of an organization’s quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International</p>

ISO 9001:2000	ISO 13485:200X
<p>the organization's ability to meet customer, regulatory and the organization's own requirements.</p> <p>The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.</p>	<p>Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p>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 described in clause 3.</p> <p>Reason for differences: Except for the contents of paragraph 4 of subclause 0.1 in ISO 13485, any changes to the text in subclause 0.1 of ISO 9001 text is intended only to tailor this text for application to the medical device sector.</p>
<p>0.2 Process approach</p> <p>This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.</p> <p>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.</p> <p>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".</p> <p>An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.</p> <p>When used within a quality management system, such an approach emphasizes the importance of</p> <ul style="list-style-type: none"> a) understanding and meeting requirements, b) the need to consider processes in terms of added value, c) obtaining results of process performance and effectiveness, and d) continual improvement of processes based on objective measurement. <p>The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration</p>	<p>0.2 Process approach</p> <p>This International Standard is based on a process approach to quality management.</p> <p>Any activity that receives inputs and converts them to outputs can be considered as a process.</p> <p>For an organization to function effectively, it has to identify and manage numerous linked processes. Often the output from one process directly forms the input to the next.</p> <p>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".</p> <p>Reason for differences: Much of the guidance contained in subclause 0.2 in ISO 9001 is being considered for inclusion in ISO14969, the Technical Specification that is intended to provide guidance in the implementation of the requirements of ISO 13485. This information is included in this subclause of ISO 9001 because no such guidance document as ISO/TS 14969 exists. Because ISO 14969 will be developed, the guidance text is not included in this subclause in ISO 13485.</p>

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shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE: 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 to deliver results in accordance with customer requirements and the organization’s policies.

Do: implement to processes

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

Act: take actions to continually improve process performance.

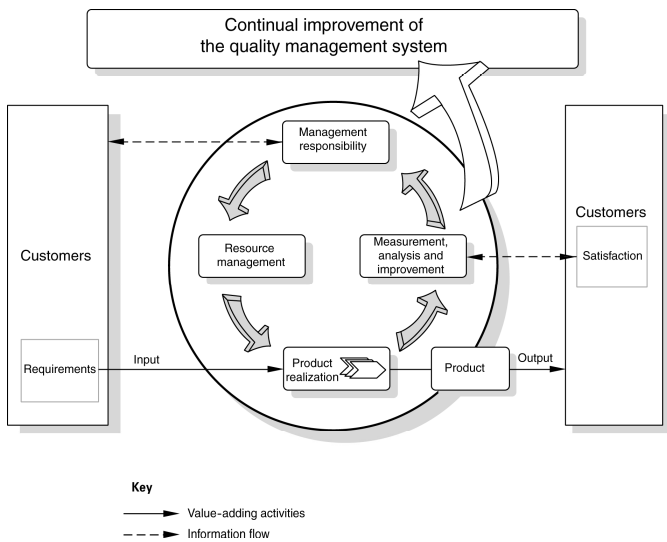


Figure 1 – Model of a process-based quality management system

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<p>0.3 Relationship with ISO 9004</p> <p>The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.</p> <p>ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.</p> <p>ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.</p>	<p>0.3 Relationship with other standards</p> <p>0.3.1 Relationship with ISO 9001:2000</p> <p>While this is a stand alone standard, it is based on ISO 9001:2000.</p> <p>Those clauses or subclauses that are quoted directly and unchanged from ISO 9001:2000 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B.</p> <p>If a requirements clause or subclause from ISO 9001:2000 is changed in a limited way by addition of information or by tailoring it to be consistent with medical device regulation, the original ISO 9001:2000 text that remains in the clause or subclause is shown as normal and the added text is shown in blue, normal font. The nature and reasons for the text additions or changes are noted in Annex B.</p> <p>Where ISO 13485 has introduced additions to the body of text of an ISO 9001:2000 requirements clause or subclause, the original ISO 9001 text is shown in normal font and the additional text is shown in blue, normal font. The nature and reasons for the text additions are noted in Annex B.</p> <p>Where ISO 13485 has deleted or amended the text of ISO 9001:2000 by the deletion or significant modification of a substantive requirement, the entire affected clause or subclause is shown in blue, normal font. The entire original ISO 9001:2000 text of the clause or subclause is reproduced in Annex B along with a description of the nature and reasons for the deletion.</p> <p>0.3.2 Relationship with ISO/TS 14969</p> <p>ISO/TS 14969 will be a technical specification intended to provide guidance in the implementation of ISO 13485:200X.</p> <p>Reason for differences: There is no significant relationship between ISO 13485 and ISO 9004. The key relationships that benefit from explanation in this introductory subclause are the ones between ISO 13485 and ISO 9001:2000 and ISO/TS 14969.</p>
<p>0.4 Compatibility with other management systems</p> <p>This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the</p>	<p>0.4 Compatibility with other management systems</p> <p>This International Standard follows the format of ISO 9001:2000 for the convenience of users in the medical</p>

<p style="text-align: center;">ISO 9001:2000</p>	<p style="text-align: center;">ISO 13485:200X</p>
<p>two standards for the benefit of the user community.</p> <p>This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk 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.</p>	<p>device community.</p> <p>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 conforms with the requirements of this International Standard.</p> <p>Reason for differences: The first paragraph of subclause 0.4 in ISO 13485 emphasizes the alignment of ISO 13485 with ISO 9001.</p> <p>Risk management is a key requirement in many activities and requirements associated with quality management systems for medical device organizations</p>
<p>Quality management system – Requirements</p> <p>1 Scope</p> <p>1.1 General</p> <p>This International Standard specifies requirements for a quality management system where an organization</p> <p>a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and</p> <p>b)</p> <p>NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.</p>	<p>Quality management system – Requirements</p> <p>1 Scope</p> <p>1.1 General</p> <p><i>This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices that consistently meet customer requirements and regulatory requirements applicable to medical devices.</i></p> <p><i>The primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the ISO 9001:2000 requirements 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 9001:2000 unless their quality management systems conform to the additional ISO 9001:2000 requirements (see Annex B).</i></p> <p>Reason for differences: The paraphrasing of this subclause uses and explains terms that are appropriate for the medical device sector. In addition, the terms “customer satisfaction” and “continual improvement” are eliminated as they are not relevant in a standard whose objective is to facilitate the harmonization of medical device regulations for quality management system around the world.</p>

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	<p>Paragraph 2 is intended to explain the standalone nature of ISO 13485, to clarify that the intent of ISO 13485 is to facilitate the harmonization of regulatory quality management system requirements around the world, to point out that this intent requires the addition of some requirements not found in ISO 9001 and the deletion of some requirements that are found in ISO 9001, and to clarify the fact that adherence to ISO 13485 cannot result in the claim of adherence to ISO 9001.</p>
<p>1.2 Application</p> <p>All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.</p> <p>Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.</p> <p>Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.</p>	<p>1.2 Application</p> <p><i>All requirements of this International Standard are specific to the medical device industry, regardless of the type or size of the organization.</i></p> <p><i>If any requirement(s) of this International Standard cannot be applied due to the activities carried out by the organization and the nature of the medical device(s) for which the quality management system is applied, this can be considered for exclusion (see 4.2.2).</i></p> <p><i>If exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements (see 4.1 and 7.1).</i></p> <p><i>In addition, regulatory requirements can permit exclusions for design and development controls (see 7.3). These regulations can provide alternative arrangements that must 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 7.3).</i></p> <p><i>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.</i></p> <p><i>In this International Standard the term "if appropriate" is used several times. When a requirement is qualified by this phrase, it is deemed to be "appropriate" unless the organization can document a justification otherwise. A requirement is considered "appropriate" if it is necessary for:</i></p> <ul style="list-style-type: none"> <i>—the product to meet specified requirements, and/or</i> <i>—the organization to carry out corrective action.</i> <p>Reason for differences: The text clarifies that the requirements of</p>

<p style="text-align: center;">ISO 9001:2000</p>	<p style="text-align: center;">ISO 13485:200X</p>
	<p>ISO 13485 are specific to the medical device sector. In addition, it amplifies the relationship between exclusions for design and development that may have regulatory impact in certain locations in the world.</p>
<p>2 Normative reference</p> <p>The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.</p> <p>ISO 9000:2000, <i>Quality management systems — Fundamentals and vocabulary.</i></p>	<p>2 Normative reference</p> <p><i>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.</i></p> <p><i>ISO 9000:2000, Quality management systems — Fundamentals and vocabulary.</i></p> <p>Reason for differences: The ISO 13485 text reflects a revision required by the 2001 edition of the ISO/IEC Directives.</p>
<p>3 Terms and definitions</p> <p>For the purposes of this International Standard, the terms and definitions given in ISO 9000:2000 apply.</p> <p>The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:</p> <p style="text-align: center;">supplier----->organization----- >customer</p> <p>The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".</p> <p>Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".</p>	<p>3 Terms and definitions</p> <p><i>For the purposes of this document, the terms and definitions given in ISO 9000 apply, together with the following.</i></p> <p><i>The terms used in this edition of ISO 13485 to describe the supply chain have been changed to reflect the vocabulary currently used:</i></p> <p style="text-align: center;">supplier----->organization----- >customer</p> <p>The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".</p> <p>Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".</p> <p><i>NOTE The following definitions should be regarded as generic, as definitions provided in national regulations may differ slightly and take precedence.</i></p> <p>[Definitions 3.1 through 3.8 are specific to the medical device sector]</p> <p>Reason for differences: The resulting text is tailored for use in the medical device sector and also includes a caveat related to the fact that local regulation may have a definition that supercedes that</p>

ISO 9001:2000	ISO 13485:200X
	contained or referenced in ISO 13485.
<p>4 Quality management system</p> <p>4.1 General requirements</p> <p>The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.</p> <p>The organization shall</p> <ul style="list-style-type: none"> 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 continual improvement of these processes. <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>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.</p> <p>NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.</p>	<p>4 Quality management system</p> <p>4.1 General requirements</p> <p>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.</p> <p>[The remaining paragraphs of this subclause are identical with those of ISO 9001:2000]</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world. Current regulation are targeted at the effectiveness of the quality management system to consistently produce safe and effective products.</p>

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<p>4.2 Documentation requirements</p> <p>4.2.1 General</p> <p>The quality management system documentation shall include</p> <ul style="list-style-type: none"> 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, and e) records required by this International Standard (see 4.2.4). <p>NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <ul style="list-style-type: none"> a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. <p>NOTE 3 The documentation can be in any form or type of medium.</p>	<p>4.2 Documentation requirements</p> <p>4.2.1 General</p> <p>[Subclause 4.2.1 a) through e) is identical with that in ISO 9001:2000.]</p> <p>f) <i>any other documentation requirements specified by national or regional regulations.</i></p> <p>[NOTE 1 is identical with NOTE 2 of ISO 9001:2000]</p> <p><i>Where this International Standard specifies that a requirement, procedure, activity, or special arrangement be “documented”, it shall, in addition, be implemented and maintained.</i></p> <p><i>The organization shall establish and maintain a file containing documents defining for each type / model of medical device, product specifications and quality system requirements (process and quality assurance) for:</i></p> <ul style="list-style-type: none"> — <i>complete manufacturing, and</i> — <i>installation and servicing, if appropriate</i> <p><i>or referring to the location(s) of this information (see 4.2.3).</i></p> <p>NOTE 2 The documentation can be in any form or type of medium.</p> <p>Reason for differences: The text in subclause 4.2.1 of ISO 13485 paraphrases and includes all of the requirements contained in the corresponding subclause of ISO 9001, with the addition of a general statement related to regulations that may contain documentation requirements and a specific requirement for a file containing specified documents for each type/model of medical device. In addition, the text includes the documentation requirements to activities and special arrangements. The resulting text is consistent with the objectives of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>4.2.2 Quality manual</p> <p>The organization shall establish and maintain a quality manual that includes</p> <ul style="list-style-type: none"> a) the scope of the quality management system, including details of and justification for any exclusion (see 1.2) b) the documented procedures established for the quality management system, or reference to them, 	<p>4.2.2 Quality manual</p> <p>[Paragraph 1 is identical with that of ISO 9001:2000]</p> <p><i>The quality manual shall outline the structure of the documentation used in the quality management system.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>

ISO 9001:2000	ISO 13485:200X
<p>and</p> <p>c) a description of the interaction between the processes of the quality management system.</p>	
<p>4.2.3 Control of documents</p> <p>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.</p> <p>A documented procedure shall be established to define the controls needed</p> <p>a) to approve documents for adequacy prior to issue,</p> <p>b) to review and update as necessary and re-approve documents,</p> <p>c) to ensure that changes and the current revision status of documents are identified,</p> <p>d) to ensure that relevant versions of applicable documents are available at points of use,</p> <p>e) to ensure that documents remain legible and readily identifiable,</p> <p>f) to ensure that documents of external origin are identified and their distribution controlled, and</p> <p>g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</p>	<p>4.2.3 Control of documents</p> <p>[Paragraphs 1 and 2 are identical with those of ISO 9001:2000]</p> <p><i>The organization shall ensure changes to documents are reviewed and approved either by the original approving authority or another designated authority which has access to pertinent background information upon which to base their decisions.</i></p> <p><i>The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that specifications to which medical devices have been manufactured are available for at least the lifetime of the medical device as defined by the organization or as specified by relevant regulatory requirements.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>4.2.4 Control of records</p> <p>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.</p>	<p>4.2.4 Control of records</p> <p>[Paragraph 1 is identical with that of ISO 9001:2000.]</p> <p><i>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 2 years from the date of release for distribution from the organization.</i></p> <p><i>NOTE National or regional regulations may require a period longer than 2 years.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>

<p style="text-align: center;">ISO 9001:2000</p>	<p style="text-align: center;">ISO 13485:200X</p>
<p>5 Management responsibility</p> <p>5.1 Management commitment</p> <p>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by</p> <ul style="list-style-type: none"> a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. 	<p>5 Management responsibility</p> <p>5.1 Management commitment</p> <p><i>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by</i></p> <ul style="list-style-type: none"> a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, <p><i>NOTE: Statutory only refers to functionality, safety and performance of the medical device.</i></p> <ul style="list-style-type: none"> b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world. Current regulation are targeted at the effectiveness of the quality management system to consistently produce safe and effective products.</p>
<p>5.2 Customer focus</p> <p>Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).</p>	<p>5.2 Customer focus</p> <p><i>Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).</i></p> <p>Reason for differences: The rewording of the text is consistent with the position that customer satisfaction is not relevant to the objective of regulation of medical devices and may, in fact, have a detrimental effect on the ability of an organization to produce safe and effective medical devices. As a result, this rewording is consistent with the objective of this standard to facilitate the harmonization of quality management system regulation around the world.</p>
<p>5.3 Quality policy</p> <p>Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, 	<p>5.3 Quality policy</p> <p>Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and <i>to maintain</i> the effectiveness of the quality management system,

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<p>c) provides a framework for establishing and reviewing quality objectives,</p> <p>d) is communicated and understood within the organization, and</p> <p>e) is reviewed for continuing suitability.</p>	<p>c) provides a framework for establishing and reviewing quality objectives,</p> <p>d) is communicated and understood within the organization, and</p> <p>e) is reviewed for continuing suitability.</p> <p>Reason for differences: The text of subclause 5.3 of ISO 13485 eliminates in list item b) the commitment to continually improve the effectiveness of the quality management system and substitutes the commitment to maintain the effectiveness of the quality management system. This substitution is consistent with the objective of current regulation and is intended to facilitate the harmonization of quality management system regulation around the world.</p>
	<p>5.4 Planning</p> <p>[The text of subclause 5.4 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p>Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.</p>	<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p>Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.</p> <p><i>Top management shall establish the interrelation of all personnel who manage, perform and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>5.5.2 Management representative</p> <p>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:</p> <p>a) ensuring that processes needed for the quality management system are established, implemented and maintained;</p> <p>b) reporting to top management on the performance of the quality management system and any need for improvement; and</p> <p>c) ensuring the promotion of awareness of customer</p>	<p>5.5.2 Management representative</p> <p>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:</p> <p>a) ensuring that processes needed for the quality management system are established, implemented and maintained;</p> <p>b) reporting to top management on the performance of the quality management system and any need for improvement; and</p> <p>c) ensuring the promotion of awareness <i>of regulatory</i></p>

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<p>requirements throughout the organization.</p> <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p>	<p><i>and</i> customer requirements throughout the organization.</p> <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
	<p>5.5.3 Internal communication</p> <p>[The text of subclause 5.5.3 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
<p>5.6 Management review</p>	<p>5.6.1 General</p> <p>[The text of subclause 5.6.1 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
	<p>5.6.2 Review input</p> <p>[The text of subclause 5.6.2 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
<p>5.6.3 Review output</p> <p>The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> a) improvement of the effectiveness of the quality management system and its processes b) improvement of product related to customer requirements, and c) resource needs. 	<p>5.6.3 Review output</p> <p><i>The output from the management review shall include any decisions and actions related to</i></p> <ul style="list-style-type: none"> a) <i>maintenance of the effectiveness of the quality management system and its processes,</i> b) <i>improvement of product related to customer requirements, and</i> c) <i>resource needs.</i> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>6 Resource management</p> <p>6.1 Provision of resources</p> <p>The organization shall determine and provide the resources needed</p> <ul style="list-style-type: none"> a) to implement and maintain the quality management 	<p>6 Resource management</p> <p>6.1 Provision of resources</p> <p><i>The organization shall determine and provide the resources needed</i></p> <ul style="list-style-type: none"> a) <i>to implement the quality management system and</i>

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<p>system and continually improve its effectiveness, and</p> <p>b) to enhance customer satisfaction by meeting customer requirements.</p>	<p><i>to maintain its effectiveness and</i></p> <p>b) <i>to meet regulatory and customer requirements.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>6.2 Human resources</p>	<p>6.2.1 General</p> <p>[The text of subclause 6.2.1 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
<p>6.2.2 Competence, awareness and training</p> <p>The organization shall</p> <p>a) determine the necessary competence for personnel performing work affecting product quality,</p> <p>b) provide training or take other actions to satisfy these needs,</p> <p>c) evaluate the effectiveness of the actions taken,</p> <p>d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and</p> <p>e) maintain appropriate records of education, training, skills and experience, training, skills and experience (see 4.2.4).</p>	<p>6.2.2 Competence, awareness and training</p> <p>[Paragraph 1 is identical to that of ISO 9001:2000]</p> <p><i>NOTE: National or regional regulations may require the organization to establish documented procedures for identifying training needs.</i></p> <p>Reason for differences: The addition of the NOTE makes the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>6.3 Infrastructure</p> <p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</p> <p>a) buildings, workspace and associated utilities,</p> <p>b) process equipment (both hardware and software), and</p> <p>c) supporting services (such as transport or communication).</p>	<p>6.3 Infrastructure</p> <p>[Paragraph 1 is identical to that in ISO 9001:2000]</p> <p><i>The organization shall establish documented requirements for maintenance activities when such activities or lack thereof may affect product quality.</i></p> <p><i>Records of such maintenance shall be kept (see 4.2.4).</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>6.4 Work environment</p> <p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p>	<p>6.4 Work environment</p> <p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements. <i>In particular, the following requirements shall apply:</i></p>

ISO 9001:2000	ISO 13485:200X
	<p>a) <i>The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or environment could adversely affect the quality of the product.</i></p> <p>b) <i>If appropriate, special arrangements shall be established and documented for the control of used product in order to prevent contamination of other product, the manufacturing environment or personnel.</i></p> <p>c) <i>If environmental conditions can have an adverse effect on product quality, where appropriate, the organization shall establish documented requirements for the environmental conditions and documented procedures to monitor and control these environmental conditions (see 7.5.1.3.2).</i></p> <p>d) <i>The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained person.</i></p> <p>Reason for differences: The additional requirements for documentation of work environment requirements and the training or supervision of personnel required to work temporarily under special environmental conditions makes the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7 Product realization</p> <p>7.1 Planning of product realization</p> <p>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <p>a) quality objectives and requirements for the product;</p> <p>b) the need to establish processes, documents, and provide resources specific to the product;</p> <p>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;</p> <p>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).</p>	<p>7 Product realization</p> <p>7.1 Planning of product realization</p> <p>[Paragraphs 1 and 2 and NOTES 1 and 2 are identical with those in ISO 9001:2000]</p> <p><i>The organization shall establish documented risk management activities throughout the product realization process, where appropriate. Records of risk management activities shall be maintained (see 4.2.4).</i></p> <p><i>NOTE 3: See ISO 14971:2000</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world. Risk management is a key activity that determines the nature and amount of activity in many of the areas addressed by the medical device organization's quality management system.</p>

ISO 9001:2000	ISO 13485:200X
<p>The output of this planning shall be in a form suitable for the organization's method of operations.</p> <p>NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.</p> <p>NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.</p>	
<p>7.2 Customer-related processes</p>	<p>7.2.1 Determination of requirements related to the product</p> <p>[The text of subclause 7.2.1 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
<p>7.2.2 Review of requirements related to the product</p> <p>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <ul style="list-style-type: none"> a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).</p> <p>Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.</p> <p>NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.</p>	<p>7.2.2 Review of requirements related to the product</p> <p>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <ul style="list-style-type: none"> a) product requirements are defined <i>and documented</i>, <p>[The balance of paragraph 1; paragraphs 2, 3 and 4; and the NOTE are identical with those in ISO 9001:2000]</p> <p>Reason for differences: The addition of the requirement in sub item a) that product requirements be documented makes the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>

ISO 9001:2000	ISO 13485:200X
<p>7.2.3 Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <ul style="list-style-type: none"> a) product information, b) enquiries, contracts or order handling, including amendments, c) customer feedback, including customer complaints. 	<p>7.2.3 Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <ul style="list-style-type: none"> a) product information, b) enquiries, contracts or order handling, including amendments, c) customer feedback, including customer complaints, <i>and</i> d) <i>advisory notices</i>. <p>Reason for differences: The addition of sub item d) advisory notices makes the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p>The organization shall plan and control the design and development of product.</p> <p>During the design and development planning, the organization shall determine</p> <ul style="list-style-type: none"> a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p> <p>Planning output shall be updated as appropriate, as the design and development progresses (see 4.2.3).</p>	<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p><i>The organization shall establish documented procedures for design and development.</i></p> <p>[Paragraphs 2, 3 and 4 are identical with paragraphs 1, 2 and 3 of ISO 9001:2000]</p> <p>Planning output shall be <i>documented, and</i> updated as appropriate, as the design and development progresses (see 4.2.3).</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world. In general, ISO 13485 retains the same level of documented procedure requirements contained in ISO 9001:1994, the standard with which many local regulations are consistent.</p>
<p>7.3.2 Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include</p>	<p>7.3.2 Design and development inputs</p> <p>[Paragraph 1 is identical to that in ISO 9001:2000.]</p> <p>These inputs shall be reviewed for adequacy <i>and approved</i>. Requirements shall be complete,</p>

ISO 9001:2000	ISO 13485:200X
<p>a) functional and performance requirements,</p> <p>b) applicable statutory and regulatory requirements,</p> <p>c) where applicable, information derived from previous similar designs, and</p> <p>d) other requirements essential for design and development.</p> <p>These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</p>	<p>unambiguous and not in conflict with each other.</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7.3.3 Design and development outputs</p> <p>The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p> <p>a) meet the input requirements for design and development,</p> <p>b) provide appropriate information for purchasing, production and for service provision,</p> <p>c) contain or reference product acceptance criteria, and</p> <p>d) specify the characteristics of the product that are essential for its safe and proper use.</p>	<p>7.3.3 Design and development outputs</p> <p>[Paragraphs 1 and 2 are identical to those in ISO 9001:2000.]</p> <p><i>Records of the outputs of the design and development shall be maintained (see 4.2.4).</i></p> <p><i>NOTE: Records of design and development output can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.</i></p> <p>Reason for differences: The addition of a requirement for recording of design outputs and a NOTE describing the various acceptable forms of design output records make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
	<p>7.3.4 Design and development review</p> <p>[The text of subclause 7.3.4 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
	<p>7.3.5 Design and development verification</p> <p>[The text of subclause 7.3.5 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
<p>7.3.6 Design and development validation</p> <p>Design and development validation shall be performed in accordance with planned arrangements (7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of</p>	<p>7.3.6 Design and development validation</p> <p>Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. <i>Validation shall be completed prior to the delivery or implementation of the product.</i> Records of the results of validation and any</p>

<p style="text-align: center;">ISO 9001:2000</p>	<p style="text-align: center;">ISO 13485:200X</p>
<p>validation and any necessary actions shall be maintained (see 4.2.4)</p>	<p>necessary actions shall be maintained (see 4.2.4).</p> <p><i>NOTE: If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to have occurred until this validation is complete.</i></p> <p><i>As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, if required by national or regional regulations.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
	<p>7.3.7 Control of design and development changes</p> <p>[The text of subclause 7.3.7 in ISO 13485 is identical with that in the corresponding subclause of ISO 9001.]</p>
<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.</p> <p>The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</p>	<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>The organization <i>shall establish documented procedures</i> to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.</p> <p>[Paragraph 2 is identical with that in ISO 9001:2000]</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p> <ul style="list-style-type: none"> a) requirements for approval of product, procedures, processes, and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. <p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	<p>7.4.2 Purchasing information</p> <p>[Paragraphs 1 and 2 are identical with those in ISO 9001:2000.]</p> <p><i>To the extent required for traceability given in 7.5.3, the organization shall retain copies of relevant purchasing documents including records (see 4.2.4).</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>

ISO 9001:2000	ISO 13485:200X
<p>7.4.3 Verification of purchased product</p> <p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p> <p>Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.</p>	<p>7.4.3 Verification of purchased product</p> <p>[Paragraphs 1 and 2 are identical with those in ISO 9001:2000.]</p> <p><i>Records of the verification shall be retained (see 4.2.4).</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7.5 Production and service provision</p> <p>7.5.1 Control of production and service provision</p> <p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ul style="list-style-type: none"> a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities. 	<p>7.5 Production and service provision</p> <p>7.5.1 Control of production and service provision</p> <p>7.5.1.1 General requirements</p> <p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ul style="list-style-type: none"> a) the availability of information that describes the characteristics of the product, b) the availability of <i>documented procedures</i>, work instructions, <i>and reference standards</i> as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, f) the implementation of release, delivery and post-delivery activities, <i>and</i> g) <i>the implementation of defined labelling and packaging operations to prevent labelling errors.</i> <p>7.5.1.2 Record keeping</p> <p>7.5.1.2.1 General</p> <p><i>The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the quantity manufactured and quantity approved for distribution. The batch record shall be verified and approved.</i></p>

<p style="text-align: center;">ISO 9001:2000</p>	<p style="text-align: center;">ISO 13485:200X</p>
	<p><i>A batch may be a single medical device.</i></p> <p>7.5.1.1 Particular requirements for sterile medical devices</p> <p><i>The organization shall retain records of the process control parameters, identified during sterilization process validation (see 7.5.2), used for each sterilization batch (see 4.2.4). Such sterilization records shall be traceable to each production batch of medical devices.</i></p> <p>[Subclause 7.5.1.3 contains specific requirements relevant to medical devices]</p> <p>Reason for differences: The subclauses, not included in ISO 9001, that contain requirements that are normally found in medical device regulation around the world make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7.5.2 Validation of processes for production and service provision</p> <p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement . This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</p> <p>Validation shall demonstrate the ability of these processes to achieve planned results.</p> <p>The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. 	<p>7.5.2.1 Validation of processes for production and service provision</p> <p>7.5.2.2 General requirements</p> <p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</p> <p>Validation shall demonstrate the ability of these processes to achieve planned results.</p> <p>The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. <p>7.5.2.2 Record keeping</p> <p>7.5.2.2.1 General</p> <p><i>The organization shall establish documented procedures for the validation of the application of</i></p>

ISO 9001:2000	ISO 13485:200X
	<p><i>computer software (and changes to such software and/or its application) for production and service operations and measuring and monitoring operations (see 8.2) that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.</i></p> <p><i>The results of validation shall be recorded (see 4.2.4).</i></p> <p>7.5.2.2.2 Particular requirements for sterile medical devices</p> <p><i>The organization shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use.</i></p> <p><i>The results of sterilization process validation(s) shall be recorded (see 4.2.4), and shall identify the process parameters of the sterilization process necessary to demonstrate control.</i></p> <p>Reason for differences: The addition of the requirement for documented procedures for the validation of the application of process software for production and measurement and recording of the results of such validation work and particular requirements for the validation of sterile medical devices and the identification of process parameters that demonstrate control of the sterilization processes make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7.5.3 Identification and traceability</p> <p>Where appropriate, the organization shall identify the product by suitable means throughout product realization.</p> <p>The organization shall identify the product status with respect to monitoring and measurement requirements.</p> <p>Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).</p> <p>NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.</p>	<p>7.5.3 Identification and traceability</p> <p>7.5.3.1 Identification</p> <p><i>The organization shall establish documented procedures for identification.</i></p> <p><i>Where appropriate, the organization shall identify the product by suitable means throughout product realization.</i></p> <p><i>The organization shall establish documented procedures to ensure that medical devices returned to the organization for reprocessing to specified requirements are identified and distinguished at all times from normal production.</i></p> <p>7.5.3.2 Traceability</p> <p>7.5.3.2.1 General</p> <p><i>The organization shall establish documented procedures for traceability. The procedures shall define</i></p>

ISO 9001:2000	ISO 13485:200X
	<p><i>the extent of traceability and shall facilitate the control of non-conforming product (see 8.3) and the issue of advisory notices (see 8.5.1).</i></p> <p><i>Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).</i></p> <p><i>NOTE Configuration management is a means by which identification and traceability can be maintained.</i></p> <p>7.5.3.2 Particular requirements for active implantable medical devices and implantable medical devices</p> <p><i>When defining the extent of traceability, the organization shall include all components and materials used, and records of the environmental conditions when these could cause the medical device not to satisfy its specified requirements.</i></p> <p><i>The organization shall require that its agents or distributors maintain records of the distribution of medical devices with regard to traceability and that such records are available for inspection.</i></p> <p><i>The organization shall ensure that the name and address of the shipping package consignee is recorded (see 4.2.4).</i></p> <p>7.5.3.3 Status identification</p> <p><i>The organization shall identify the product status with respect to monitoring and measurement requirements.</i></p> <p><i>The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
	<p>7.5.4 Customer property</p> <p>[The text of subclause 7.5.4 in ISO 13485 is identical to that of the corresponding subclause in ISO 9001.]</p>
<p>7.5.5 Preservation of property</p> <p>The organization shall preserve the conformity of product during internal processing and delivery to the</p>	<p>7.5.5 Preservation of property</p> <p>The organization shall <i>establish documented procedures for preserving</i> the conformity of product</p>

ISO 9001:2000	ISO 13485:200X
<p>intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p>	<p>during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p> <p><i>The organization shall establish documented procedures for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded (see 4.2.4).</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>7.6 Control of monitoring and measuring devices</p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).</p> <p>The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.</p> <p>Where necessary to ensure valid results, measuring equipment shall:</p> <ul style="list-style-type: none"> f) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; g) be adjusted or re-adjusted as necessary; h) be identified to enable the calibration status to be determined; i) be safeguarded from adjustments that would invalidate the measurement result; j) be protected from damage and deterioration during handling, maintenance and storage. <p>In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the</p>	<p>7.6 Control of monitoring and measuring devices</p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).</p> <p>The organization shall establish <i>documented procedures</i> to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.</p> <p>[Paragraphs 3, 4 and 5; and the NOTE are identical with those in ISO 9001:2000]</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>

<p style="text-align: center;">ISO 9001:2000</p>	<p style="text-align: center;">ISO 13485:200X</p>
<p>equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).</p> <p>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary (see 7.5.2).</p> <p>NOTE See ISO 10012-1 and ISO 10012-2 for guidance.</p>	
<p>8 Measurement, analysis and improvement</p> <p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <p>a) to demonstrate conformity of the product,</p> <p>b) to ensure conformity of the quality management system, and</p> <p>c) to continually improve the effectiveness of the quality management system.</p> <p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p>	<p>8 Measurement, analysis and improvement</p> <p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <p>a) to demonstrate conformity of the product,</p> <p>b) to ensure conformity of the quality management system, and</p> <p>c) to <i>maintain the effectiveness</i> of the quality management system.</p> <p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p> <p><i>NOTE National or regional regulations may require documented procedures for implementation and control of the application of statistical techniques.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world. The objective of medical device regulation is the maintenance of the effectiveness of the quality management system to consistent produce medical devices that are safe and effective, not the continual improvement of the quality management system.</p>
<p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer satisfaction</p> <p>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.</p>	<p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer feedback</p> <p><i>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.</i></p>

ISO 9001:2000	ISO 13485:200X
	<p><i>The organization shall establish a documented feedback system (see 7.2.3) to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3).</i></p> <p><i>If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).</i></p> <p>Reason for differences: Both “customer satisfaction” and “customer perception” are too subjective for implementation as requirements in a regulation. The resulting text is consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
	<p>8.2.2 Internal audit</p> <p>[The text of subclause 8.2.2 of ISO 13485 is identical with that of the corresponding subclause of ISO 9001]</p>
	<p>8.2.3 Monitoring and measurement of processes</p> <p>[The text of subclause 8.2.3 of ISO 13485 is identical with that of the corresponding subclause of ISO 9001]</p>
<p>8.2.4 Monitoring and measurement of product</p> <p>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).</p> <p>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).</p> <p>Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.</p>	<p>8.2.4 Monitoring and measurement of product</p> <p>8.2.4.1 General requirements</p> <p>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) <i>and documented procedures (see 7.5.1).</i></p> <p>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).</p> <p><i>Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed.</i></p> <p>8.2.4.2 Particular requirement for active implantable devices and implantable devices</p> <p><i>The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>

<p style="text-align: center;">ISO 9001:2000</p>	<p style="text-align: center;">ISO 13485:200X</p>
<p>8.3 Control of nonconforming product</p> <p>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.</p> <p>The organization shall deal with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. <p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p> <p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</p> <p>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.</p>	<p>8.3 Control of nonconforming product</p> <p>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.</p> <p>The organization shall deal with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession, <i>organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met; the identity of the person(s) authorizing the concession shall be recorded (see 4.2.4);</i> c) by taking action to preclude its original intended use or application. <p>[Paragraphs 3, 4 and 5 are identical with those in ISO 9001:2000.]</p> <p><i>If product needs to be reworked (one or more times), the organization shall document the rework in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>8.4 Analysis of data</p> <p>The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.</p> <p>The analysis of data shall provide information relating to</p> <ul style="list-style-type: none"> a) customer satisfaction (see 8.2.1), 	<p>8.4 Analysis of data</p> <p><i>The organization shall establish documented procedures to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.</i></p> <p>The analysis of data shall provide information relating to</p> <ul style="list-style-type: none"> a) <i>customer feedback (see 8.2.1),</i>

ISO 9001:2000	ISO 13485:200X
<p>b) conformity to product requirements (see 7.2.1),</p> <p>c) characteristics and trends of processes and products including opportunities for preventive action, and</p> <p>d) suppliers.</p>	<p>b) conformity to product requirements (see 7.2.1),</p> <p>c) characteristics and trends of processes and products including opportunities for preventive action, and</p> <p>d) suppliers.</p> <p><i>Records of the results of the analysis of data shall be maintained (see 4.2.4).</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>8.5 Improvement</p> <p>8.5.1 Continual improvement</p> <p>The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</p>	<p>8.5 Improvement</p> <p>8.5.1 General</p> <p><i>The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</i></p> <p><i>The organization shall establish documented procedures for the issue of advisory notices for medical devices. These procedures shall be capable of being implemented at any time.</i></p> <p><i>The organization shall maintain records (see 4.2.4) of all customer complaint investigations. When the investigation determines that the activities at remote premises contributed to the customer complaint, relevant information shall be communicated between the organization and the remote premises.</i></p> <p><i>If any customer complaint is not followed by corrective and/or preventive action, the reason shall be recorded.</i></p> <p><i>If national or regional regulations require, the organization shall establish documented procedures to notify the regulatory authorities of those adverse events which meet the reporting criteria.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world. Continual improvement of the quality management system is not a current objective of regulation.</p>

ISO 9001:2000	ISO 13485:200X
<p>8.5.2 Corrective action</p> <p>The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p> <p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken. 	<p>8.5.2 Corrective action</p> <p>[Paragraphs 1 and 2a) through 2d) are identical with those in ISO 9001:2000.]</p> <ul style="list-style-type: none"> e) records of the results of <i>any investigation and</i> of the action taken (see 4.2.4), and f) reviewing corrective action taken <i>and its effectiveness</i>. <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>
<p>8.5.3 Preventive action</p> <p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p> <p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of the results of action taken (see 4.2.4), and e) reviewing preventive action taken. 	<p>8.5.3 Preventive action</p> <p>[Paragraphs 1 and 2a) through 2c) are identical with those in ISO 9001:2000]</p> <ul style="list-style-type: none"> d) records of the results of <i>any investigations and</i> of action taken (see 4.2.4), and e) reviewing preventive action taken <i>and its effectiveness</i>. <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulation around the world.</p>

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