

CSA Special Publication

PLUS 13485

***The ISO 13485 essentials —
A practical handbook for
implementing the
ISO 13485 Standard
for manufacturers of
medical devices***



**CANADIAN STANDARDS
ASSOCIATION**

®Registered trade-mark of Canadian Standards Association

*Published in February 2006 by Canadian Standards
Association*

*A not-for-profit private sector organization
5060 Spectrum Way, Suite 100, Mississauga, Ontario,
Canada L4W 5N6
1-800-463-6727 • 416-747-4044*

Visit our online store at www.ShopCSA.ca

Created by
Pierre D. Landry,
Cantley, Québec

Contributors and principal editors:
Denis Pronovost,
General Manager, Accademia Qualitas,
Montréal, Québec

Betty Anne Butcher,
President, Alta Quality & Regulatory Services,
Toronto, Ontario

Nancy Bestic and George Schidowka,
Canadian Standards Association,
Mississauga, Ontario

ISBN 1-55397-912-5
© Canadian Standards Association — 2006

All rights reserved. No part of this publication may be reproduced in any form whatsoever without the prior permission of the publisher.

Contents

Preface *iv*

The Layout of this Handbook 1

PLUS 13485 — The ISO 13485 Essentials 3

Appendices

- 1** — Vocabulary Clause — ISO 9000:2000, ISO 13495:2003, and ISO 19011:2002 164
- 2** — Correspondence between ISO 13485:2003 and ISO 13485:1996 182
- 3** — Terms used in certain regulatory administrations to describe documents referenced in this Technical Report 185
- 4** — Contacts 187

Preface

The primary objective of this Handbook is to provide both novice and experienced quality practitioners with a concise, user-friendly guide to understanding and implementing the requirements of ISO 13485 as it relates to their quality management system (QMS).

The Canadian National Standard CAN/CSA-ISO 13485:03 is identical to its international counterpart, ISO 13485:03. To facilitate reading, the CAN/CSA prefix and year of issue have not been systematically included in the references to the Standard throughout this Handbook. Similarly, when ISO 9000 is used in the text, it refers to the 2000 edition. Please refer to the bibliography for the full title and designation of these Standards.

The numbering of this Handbook corresponds to the numbering of the clauses in ISO 13485, and each section contains

- a) the actual text of ISO 13485;
- b) definitions excerpted from ISO 9000, ISO 13485, and ISO 19011. The notes contained in these definitions are not always included in each section. Appendix 1 provides all definitions and accompanying notes in alphabetical order;
- c) guidance, provided by ISO/TR 14969 or by other sources;
- d) typical audit questions asked by auditors when registering the QMS to ISO 13485; and
- e) self-assessment questions to be considered by an organization while developing its QMS.

Detailed guidance on the QMS registration process and implementation path, and other valuable information is found in PLUS 9001, *The ISO 9000 Essentials*, published by CSA. The information provided in *The ISO 9000 Essentials* is not reproduced here. (Contact CSA at 1-800-463-6727 for more information.)

The Layout of this Handbook

The format and layout used in this Handbook are as follows:



Text boxes with this icon contain all the clauses of ISO 13485.

Note 1: In ISO 13485 the clauses that are identical to those in ISO 9001:2000 are presented in normal font. Where the text of ISO 13485 is not identical to ISO 9001:2000, it is shown in italics (in blue italics for the electronic version). This Handbook reproduces this format.

Note 2: ISO 13485 contains extensive informative annexes. Only Annex A, Table A.1 (Correspondence between ISO 13485:1996 and ISO 13485:2003 version), is reproduced here (Appendix 2 at the end of this Handbook). To consult Annex A, Table A.2 (Correspondence between ISO 13485:2003 and ISO 13485:1996 version), or Annex B (a 30-page table explaining the differences between ISO 13485:2003 and ISO 9001:2000), readers should refer to ISO 13485:2003, available at CSA.



Definitions

Text boxes with this icon provide definitions from ISO 9000, ISO 13485, and ISO 19011. The notes contained in these definitions are not always included in the text box. Appendix 1 supplies all definitions and their notes in alphabetical order.



Guidance

Sections preceded by boxes with this icon contain guidance excerpted from ISO/TR 14969 and other sources. ISO/TR 14969 explains its use of terminology as follows:

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

This guidance can be used to better understand the requirements of ISO 13485 and illustrate some of the variety of methods and approaches available for meeting the requirements of ISO 13485. (ISO/TR 14969, 1.1)



Sections preceded by this icon contain typical questions asked by auditors when registering the QMS to ISO 13485.



Sections preceded by this icon contain self-assessment questions to be considered by an organization while developing its QMS.

PLUS 13485 — The ISO 13485 Essentials



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 and development, production, installation and servicing of medical devices, and the design, development, and provision of related services.

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.

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

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 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.

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.



Guidance

ISO/TR 14969 provides the following introduction to quality management systems and ISO 13485:

0.1.1

This Technical Report provides guidance to assist in the development, implementation and maintenance of quality management systems that aim to meet the requirements of ISO 13485 for organizations that design and develop, produce, install and service medical devices, or that design, develop and provide related services. It provides guidance related to quality management systems for a wide variety of medical devices and related services. Such medical devices include active, non-active, implantable and non-implantable medical devices and *in vitro* diagnostic medical devices.

ISO 13485 specifies the quality management requirements for medical devices for regulatory purposes (see Annex A). ISO 13485 accommodates the previous ISO 13488 by permissible exclusion as specified in ISO 13485:2003, 1.2.

When judging the applicability of the guidance in this Technical Report, one should consider the nature of the medical device(s) to which it will apply, the risk associated with the use of these medical devices, and the applicable regulatory requirements.

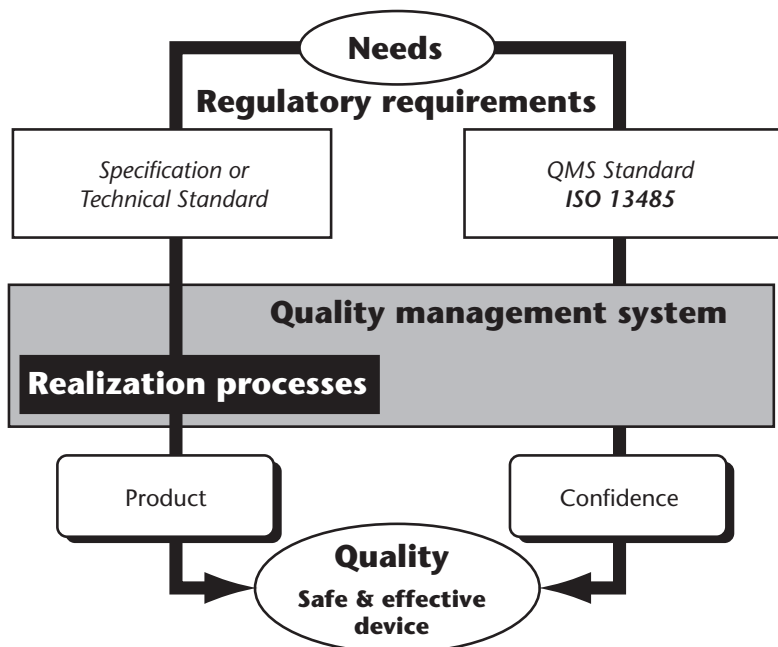
As used in this Technical Report, the term “regulatory requirement” includes any part of a law, ordinance, decree or national and/or regional regulation applicable to quality management systems for medical devices and related services.

This Technical Report provides some approaches that an organization can use to implement and maintain a quality management system which conforms with ISO 13485. Alternative approaches can be used if they also satisfy the requirements of ISO 13485. [ISO/TR 14969]

ISO/TR 14969 also notes the following:

The guidance contained in this Technical Report is not to be used for identifying specific deficiencies of quality management systems, unless such guidance is voluntarily incorporated by the organization into the documentation describing and supporting the organization’s quality management systems, or unless such guidance is specifically made part of the regulatory requirements relevant to the organization’s operation. [ISO/TR 14969, 0.1.3]

The relationships among regulatory requirements, technical standards (see Appendix 4), and requirements for the QMS are illustrated in the figure below. Conformity with these various requirements will lead to the manufacture and delivery of safe and effective quality medical devices.



Regulatory requirements — Technical Standards — QMS



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”.

**Guidance**

ISO/TR 14969 outlines the process approach of ISO 13485 as follows:

ISO 13485 promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, with the objective of meeting customer and regulatory requirements, and providing medical devices that meet customer and regulatory requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

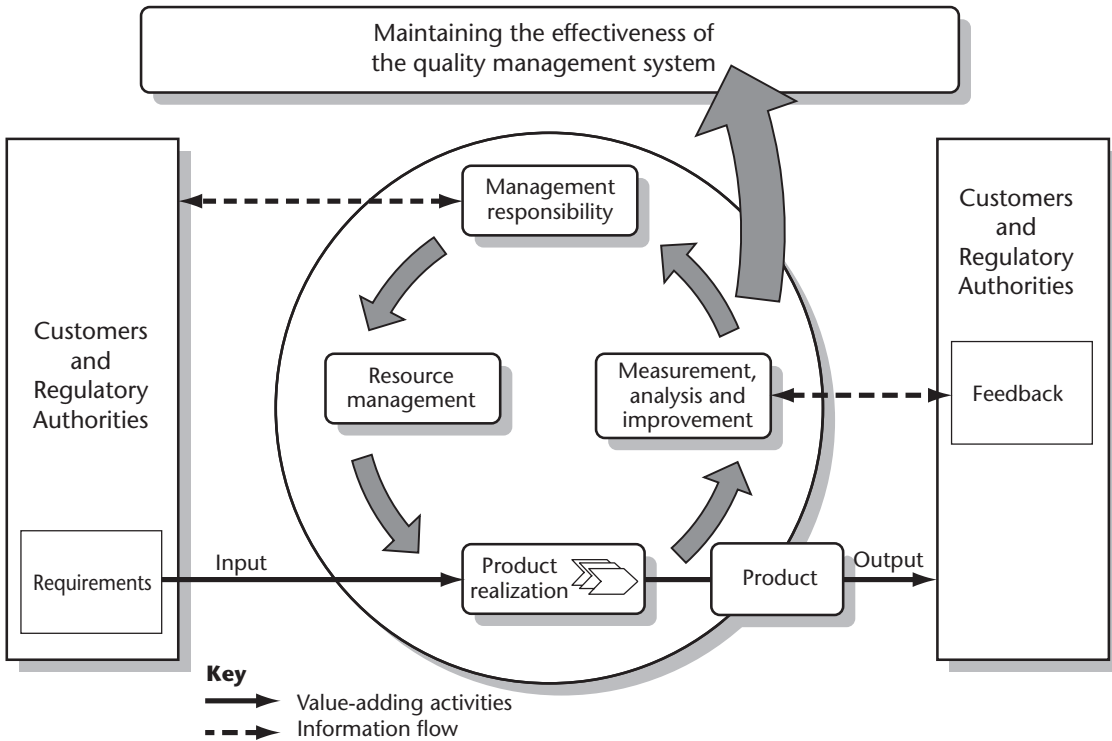
The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach.”

An advantage of the process approach is the ongoing control which it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

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

- understanding and meeting requirements,
- considering processes in terms of added value,
- obtaining results of process performance and effectiveness, and
- improving processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 [“Model of a processed-based quality management system”, reproduced below] illustrates the process linkages presented in ISO 13485:2003, Clauses 4 to 8. This illustration shows that customers and regulatory authorities play a significant role in defining requirements as inputs. Monitoring of customer feedback requires the evaluation of information relating to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of ISO 13485, but does not show processes at a detailed level. [ISO/TR 14969, 0.2]



Source: ISO/TR 14969

Model of a process-based quality management system



Definition

process

set of interrelated or interacting activities which transforms inputs into outputs [ISO 9000, 3.4.1]

ISO/TR 14969 outlines the Plan-Do-Check-Act methodology as follows:

In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies.

Do: implement the processes.

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

Act: take actions to improve process performance. [ISO/TR 14969, 0.2]



0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001

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

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

Where the text of this International Standard is not identical to the text of ISO 9001, the sentence or indent containing that text as a whole is shown in italics (in blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex B.

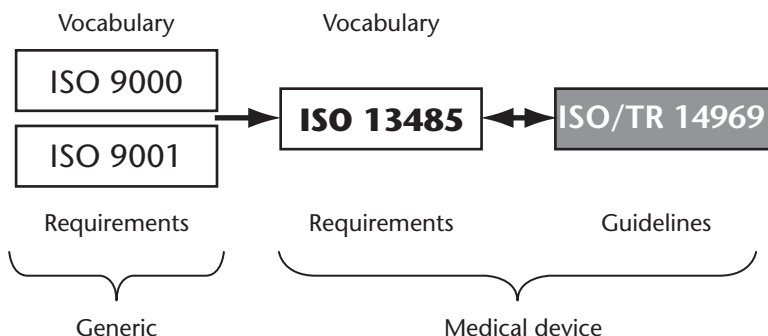
0.3.2 Relationship with ISO/TR 14969

ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.



Guidance

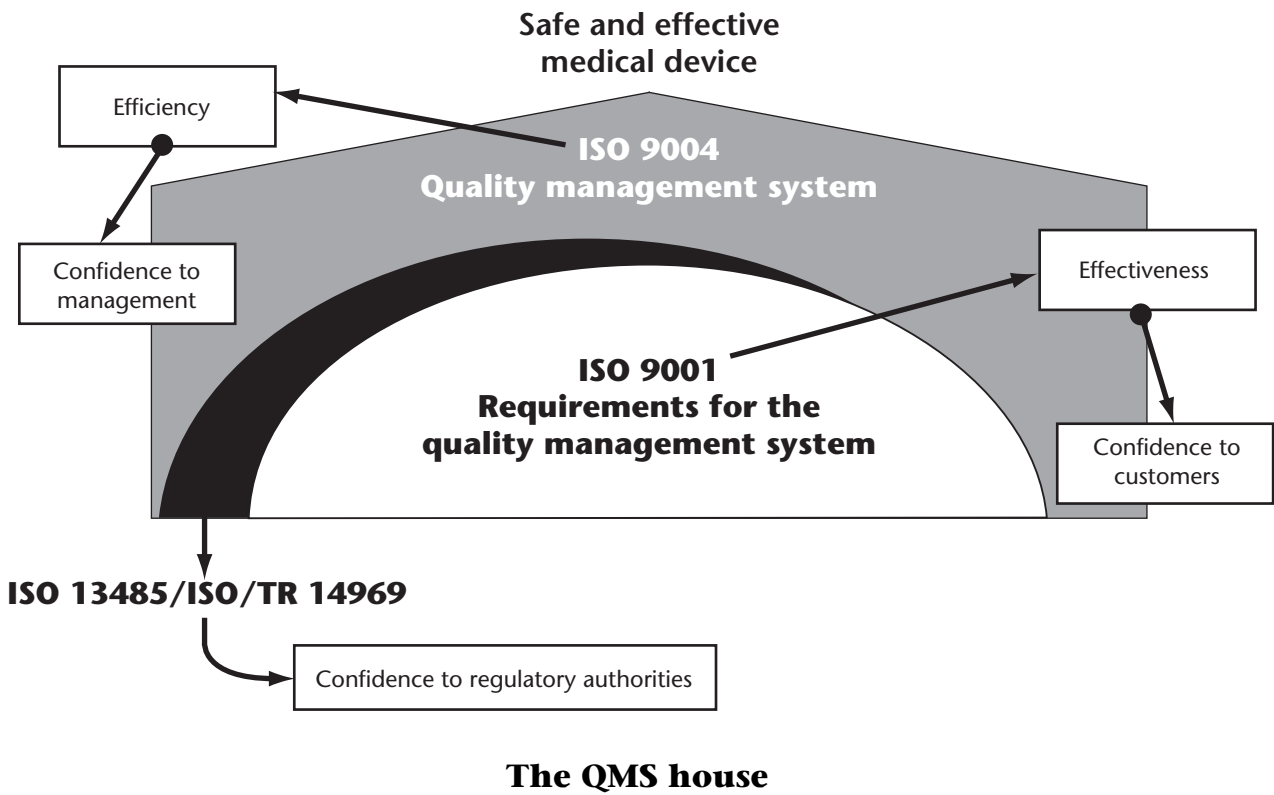
The figure below represents the relationships among ISO 13485 and other standards, guidelines, and requirements.



ISO 13485 and key standards

ISO/TR 14969 summarizes its relationship with ISO 13485 and other general standards as follows:

- The relationship between ISO 13485, this Technical Report [i.e., ISO/TR 14969] and general standards for quality management systems (ISO 9001 and ISO 9004) is summarized as follows.
- This Technical Report provides guidance on the application of ISO 13485.
 - ISO 13485 specifies requirements for quality management systems in order to achieve regulatory compliance in the medical devices industries. It follows the format, structure and process approach of ISO 9001. It differs from ISO 9001 in that it specifies additional requirements but does not include the explicit requirements for continual improvement and customer satisfaction.
 - ISO 9001 is an International Standard for quality management systems in general.
 - ISO 9004 gives guidance on a wider range of objectives of quality management systems than does this Technical Report, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is suitable as a guide for organizations whose top management wishes to move beyond the requirements of ISO 13485, in pursuit of continual performance improvement and customer satisfaction. However, it is not intended for certification or for contractual purposes. [ISO/TR 14969, 0.3]



ISO 9000 provides the normative generic vocabulary to deal with the subject of quality management systems.

ISO/TR 14969 recognizes guidance from various sources, as follows:

Guidance provided in Technical Report has taken into consideration requirements and guidance contained in documents from the following organizations:

- Global Harmonization Task Force (GHTF);
- International Organization for Standardization (ISO);
- European Committees for Standardization (CEN and CENELEC);
- national regulatory bodies.

Many of these documents are listed in the Bibliography.
[ISO/TR 14969, 0.3]



0.4 Compatibility with other management systems

This International Standard follows the format of ISO 9001 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 complies with the requirements of this International Standard.



Guidance

ISO/TR 14969 notes that the following should be taken into account:

Conformance to ISO 13485 quality management system requirements does not automatically constitute conformity with national or regional regulatory requirements. It is the organization's responsibility to identify and establish compliance with relevant regulatory requirements. [ISO/TR 14969, 0.4]



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 and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of this International Standard 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 requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001 (see Annex B).



Guidance

Clause 1.1 defines the scope of ISO 13485. This should not be confused with the scope of the QMS, which is a term commonly used within the context of QMS certification/registration to describe the products and product realization processes to which the QMS applies.

The scope of the QMS should be based on the nature of the organization's products and their realization processes, the result of risk assessment, commercial considerations, and contractual, statutory, and regulatory requirements. An organization is not obliged to include all the products that it provides within the scope of its QMS or to address the realization processes for products that are not included within the QMS.

However, when an organization chooses to implement a QMS with a limited scope, this should be clearly described in the organization's quality manual and any other publicly available documents (e.g., certification/registration documents and marketing material) to avoid confusing or misleading customers and end users.

Note: Annex B of ISO 13485 is not reproduced in this Handbook. This 30-page Annex details the similarities and differences between the requirements of ISO 13485 and those of ISO 9001, and states, where applicable, the reasons for such differences. Readers are advised to consult ISO 13485 for detailed information.



1.2 Application

All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of the organization.

If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls [see 4.2.2 a) and 7.3].

If any requirement(s) in Clause 7 of this International Standard is (are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system [see 4.2.2 a)].

The processes required by this International Standard, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system [see 4.1 a)].

In this International Standard the terms “if appropriate” and “where appropriate” are used several times. When a requirement is qualified by either of these phrases, it is deemed to be “appropriate” unless the organization can document a justification otherwise. A requirement is considered “appropriate” if it is necessary in order for

- the product to meet specified requirements, and/or*
- the organization to carry out corrective action.*



Guidance

The ISO Technical Committee responsible for the 9000 family of Standards, TC 176, has written the support documents on the following subjects: application, documentation requirements, terminology, the process approach to QMS, and outsourced processes. These documents are available free at www.bsi.org.uk/iso-tc176-sc2. Other guides available at this site include *Selection and use of ISO 9000* and *Quality Management Principles and Guidelines on their Application*.

ISO/TR 14969 provides guidance on the application of ISO 13485 as follows:

1.2.1 General

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

1.2.2 Exclusions

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

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

1.2.3 Non-applicability

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

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

It is important for the organization to review carefully all the requirements of ISO 13485:2003, Clause 7, in order to identify those requirements that do apply to functions performed by the organization. Once those requirements are identified, the organization is obliged to comply with ISO 13485:2003, 7.1, and to perform the planning associated with identified product realization requirements. [ISO/TR 14969]



Definition

requirement

need or expectation that is stated, generally implied or obligatory [ISO 9000, 3.1.2]



- 1) Have any requirements of Clause 7 of ISO 13485 been excluded from the scope of application of the QMS?
- 2) If there are any exclusions claimed, are these exclusions limited to the requirements of Clause 7 of ISO 13485?
- 3) Do any of the exclusions claimed affect the organization's ability or responsibility to provide product that fulfills customer requirements and applicable regulatory requirements?



- 1) Have we identified any exclusions and non-applicable areas in the QMS?
- 2) Have we ensured that any exclusions or non-applicable areas are in keeping with the requirements of ISO 13485?



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*



Guidance

In as much as the ISO 9000:2000 vocabulary is normative within the context of ISO 13485, organizations are encouraged to also adopt that vocabulary in all their activities.

Even though ISO 13485 specifies that the 2000 edition of ISO 9000 is normative, Appendix 1 contains definitions from ISO 9000, ISO 13485, and ISO 19011.



- 1) Do we use within our organization the ISO 9000:2000 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 following 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 13485:1996, 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".

Wherever requirements are specified as applying to "medical devices", the requirements apply equally to related services as supplied by the organization.

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

[There follow the definitions for the following terms, which are reprinted in this Handbook in Appendix 1: "active implantable medical device", "active medical device", "advisory notice", "customer complaint", "implantable medical device", "labelling", "medical device", and "sterile medical device".]



Definitions

customer

organization (3.3.1) or person that receives a **product** (3.4.2)
[ISO 9000, 3.3.5]

organization

group of people and facilities with an arrangement of responsibilities, authorities and relationships [ISO 9000, 3.3.1]

supplier

organization (3.3.1) or person that provides a **product** (3.4.2)
[ISO 9000, 3.3.6]



Guidance

When the 2003 edition of ISO 13485 was in production, great care was taken to use the correct English words and terms to describe the concepts and requirements. The objective was to use simple, technically accurate terms, and, to the greatest extent possible, rely on common dictionary definitions. As with most technical subjects, there are some terms that have a very specific meaning that is different from their commonly used dictionary definitions. Definitions of terms in ISO 9000 and ISO 13485 have normative status, which takes precedence over their common dictionary definitions. These normative definitions are included in Appendix 1. In all other cases, common dictionary definitions (e.g., from *The Canadian Oxford Dictionary*) are used.



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 (*see 8.5.1*).

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



Definitions

quality management system

management system (3.2.2) to direct and control an **organization** (3.3.1) with regard to **quality** (3.1.1) [ISO 9000, 3.2.3]

effectiveness

extent to which planned activities are realized and planned results achieved [ISO 9000, 3.2.14]

process

set of interrelated or interacting activities which transforms inputs into outputs [ISO 9000, 3.4.1]

**Guidance**

ISO/TR 14969 provides the following guidance:

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

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

- internal audits,
- management review,
- corrective and preventive actions, and
- independent external assessments.

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

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

- customer feedback,

and internal changes, such as changes to

- key personnel,
- facilities,
- manufacturing processes and equipment, including related software,
- software related to the quality management system, and
- product, including software.

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

- defining and promoting processes which lead to achieving regulatory compliance,
- acquiring and using process data and information on a continuing basis,
- determining and providing resources, including human and information system resources,
- directing necessary changes to the quality management system, and
- using suitable evaluation methods such as internal audits and management reviews.

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

[ISO/TR 14969]



- 1) Has the organization established, documented, implemented, and maintained a QMS?
- 2) Has the organization
 - a) identified the processes needed for the QMS and their application throughout the organization?
Note: *Processes needed should include processes for management activities, provision of resources, product realization, and measurement.*
 - b) determined the sequence and interaction of these processes?
 - c) determined criteria and methods needed to ensure that both the operation and control of these processes are effective?
 - d) ensured the availability of resources and information necessary to support the operation and monitoring of these processes?
 - e) monitored, measured, and analyzed these processes?
 - f) implemented actions necessary to achieve planned results and maintain the effectiveness of these processes?
- 3) Are these processes managed in accordance with the requirements of ISO 13485?
- 4) Does the organization outsource (subcontract) any process which has been identified as “necessary for the effective implementation of the QMS”? If yes,
 - a) does the organization ensure control over any such outsourced processes?
 - b) is the control of such outsourced processes identified within the QMS?



- 1) Who is responsible for the overview of the project of documenting, implementing, and maintaining the QMS?
- 2) Have the processes been identified, and documented as necessary?
- 3) Has the sequence and interaction of these processes been established and documented (see Clause 4.2 below on quality plans)?
- 4) Who is responsible for establishing the effectiveness of these processes?
- 5) Are resources available to monitor, measure where applicable, and analyze these processes?
- 6) Have outsourced processes been identified and considered?



4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by this International Standard,
- d) documents needed by the organization to ensure the effective planning, operation and control of its processes,
- e) records required by this International Standard (see 4.2.4), and
- f) *any other documentation specified by national or regional regulations.*

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

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

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

- a) the size of the organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

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



Definitions

document

information (3.7.1) and its supporting medium [ISO 9000, 3.7.2]

procedure

specified way to carry out an activity or a **process** (3.4.1)
[ISO 9000, 3.4.5]

quality manual

document (3.7.2) specifying the **quality management system**
(3.2.3) of an **organization** (3.3.1) [ISO 9000, 3.7.4]

quality plan

document (3.7.2) specifying which **procedures** (3.4.5) and
associated resources shall be applied by whom and when to a specific
project (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract
[ISO 9000, 3.7.5]

record

document (3.7.2) stating results achieved or providing evidence of
activities performed [ISO 9000, 3.7.6]

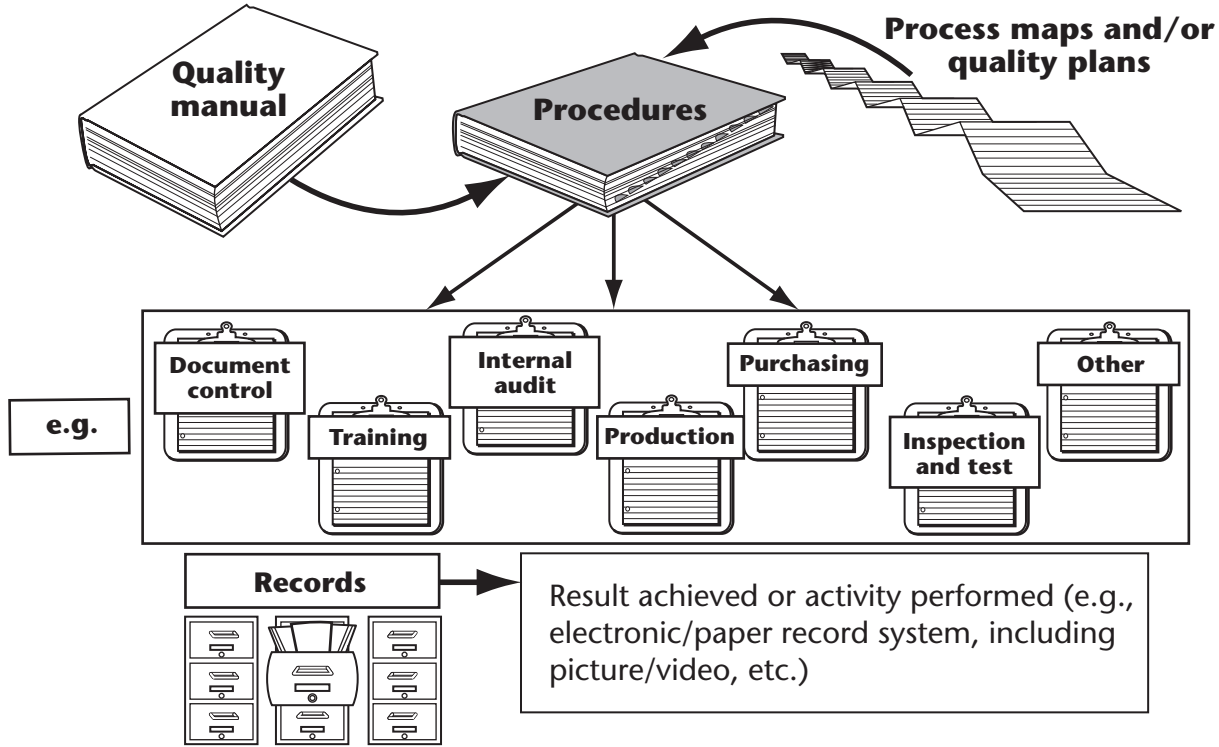
specification

document (3.7.2) stating **requirements** (3.1.2) [ISO 9000, 3.7.3]



Guidance

The figure below illustrates the relationships among the various documents typically found in a QMS. It also illustrates the difference between records and documents.



QMS documentation system

Information developed by ISO/TC 176 relating to documentation is available at www.bsi.org.uk/iso-tc176-sc2 (also see Appendix 4).

The following table lists the clauses in ISO 13485 where documented procedures are required.

Examples of required documented procedures

Clause	Documented procedures required
4.2.3	Control of documents
4.2.4	Control of records
6.4	Work environment
7.3.1	Design and development planning
7.4.1	Purchasing process
7.5.1.2.3	Servicing activities
7.5.2.1	Validation of processes for production and service provision — General requirements
7.5.2.2	Particular requirements for sterile medical devices
7.5.3.1	Identification and traceability — Identification
7.5.3.2.1	Identification and traceability — Traceability
7.5.5	Preservation of product
7.6	Control of monitoring and measuring devices
8.2.1	Monitoring and measurement — Feedback
8.2.2	Internal audit
8.3	Control of nonconforming product
8.4	Analysis of data
8.5.1	Improvement — General
8.5.2	Corrective action
8.5.3	Preventive action

ISO/TR 14969 provides the following guidance on documentation requirements:

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

the activities in question (see also 6.2.2). [Appendix 3 of this Handbook lists terms used in certain regulatory administrations to describe documents referenced in ISO/TR 14969.]

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

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

- what is to be done, and by whom,
- when, where and how it is to be done,
- what materials, equipment and documents are to be used,
- how an activity is to be monitored and measured, and
- what records are required.

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

- functionality,
- human interfaces,
- resources required,
- policies and objectives, and
- interfaces used by the organization's customers and suppliers.

4.2.1.4 The file for each type or model of medical device referred to in ISO 13485:2003, 4.2.1 is sometimes referred to by different terms (see Annex A, section B) [see Appendix 3 of this Handbook]. This file can contain, or give reference to the location of, documentation relevant to the manufacture of that product. Examples of such documentation include

- specifications for raw materials, labelling, packaging materials, sub-assemblies and medical devices,
- parts lists,
- engineering drawings,
- software programs, including source code (if available),
- work instructions, including equipment operation,
- sterilization process details, if applicable,
- quality plans,
- manufacturing/inspection/test procedures, and
- acceptance criteria.

4.2.1.5 The documentation referred to in ISO 13485:2003, 4.2.1 forms part of the quality management system and should be subject to document and record control procedures (see 4.2.3 and 4.2.4). [ISO/TR 14969]



- 1) Does the QMS documentation include
 - a) documented statements of a quality policy and quality objectives?
 - b) a quality manual?
 - c) documented procedures required by ISO 13485?
 - d) other documents needed by the organization to ensure the effective planning, operation, and control of its processes (such documents may include process maps, organization charts, internal communications, production schedules, approved supplier lists, and quality plans)?
 - e) quality records?
- 2) Are the quality records controlled according to the requirements given in Clause 4.2.4 of ISO 13485?
- 3) Has the organization established and maintained a file for each type or model of medical device either containing or identifying the documents referred to in Clause 4.2.1 of ISO 13485?



- 1) Who is responsible for ensuring that the quality manual includes the documented procedures and the interaction between the processes?
- 2) Have we documented our quality policy and quality objectives?
- 3) Have we systematically established which documents are needed to plan, operate, control, measure, and monitor processes and products effectively?
- 4) For these documents, have we defined a structure that will facilitate their maintenance?



4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

- a) *the scope of the quality management system, including details of and justification for any exclusion and/or non-application (see 1.2),*
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

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



Definitions

quality manual

document (3.7.2) specifying the **quality management system** (3.2.3) of an **organization** (3.3.1) [ISO 9000, 3.7.4]

quality plan

document (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract [ISO 9000, 3.7.5]



Guidance

The implementation of a QMS by an organization is most effective when individuals in the organization understand its intention, its function, its relevance to their own activities, and its interface with other parts of the system. The quality manual has an important role in this regard, for both internal and external parties.

Clause 4.2.2 specifies the minimum content of a quality manual. The format of the manual is a decision for each organization, and will depend on the organization's size, culture, and complexity. For example, a quality manual may be one document supported by increasingly detailed levels

of related documents. There may also be an overall system manual, one or more specific procedural manuals, work instructions, and reference documents. Together, these documents define the QMS.

A small organization may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required. Large, multinational organizations may need several manuals representing their global, national, and regional concerns, resulting in a complex hierarchy of documentation.

NOTE: Additional information relating to quality manuals is available in ISO/TR 10013:2001.

The scope of the QMS should be based on the nature of the organization's products and their realization processes, the result of risk assessment, commercial considerations, and contractual, statutory, and regulatory requirements. An organization is not obliged to include all the products that it provides within the scope of its QMS or to address the realization processes for products that are not included within the QMS.

However, when an organization chooses to implement a QMS with a limited scope, this should be clearly described in the organization's quality manual and any other publicly available documents (e.g., certification/registration documents and marketing material) to avoid confusing or misleading customers and end users.



Has the organization established and maintained a quality manual that includes

- a) the scope of the QMS, including details of and justification for any exclusions?
- b) the documented procedures established for the QMS or reference to them?
- c) a description of the interaction between the various processes of the QMS?



- 1) Do the documented procedures describe the purpose and scope of activities, identify who is responsible for activities, and provide full details of how, what, when, and where activities are performed?

- 2) Are the forms described in the QMS included or referenced in the documented procedures?



4.2.3 Control of documents

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

A documented procedure shall be established to define the controls needed

- a) *to review and approve documents for adequacy prior to issue,*
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

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

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



Definitions

document

information (3.7.1) and its supporting medium [ISO 9000, 3.7.2]

information

meaningful data [ISO 9000, 3.7.1]

procedure

specified way to carry out an activity or a **process** (3.4.1) [ISO 9000, 3.4.5]



Guidance

ISO/TR 14969 provides the following guidance on control of documentation:

- 4.2.3.1** The system established for the control of internal and external documents will, if appropriate
- assign responsibilities for preparation, approval and issue of documents,
 - ensure prompt withdrawal of obsolete copies of controlled documents,
 - define a method for recording the implementation date of a document change, and
 - allow controlled and non-controlled documents to be distinguished.

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

- 4.2.3.2** Documents may be reviewed at various times throughout the life of a document, for example, as a result of
- facilities, personnel or organizational changes,
 - audit activities,
 - acquisitions,
 - new products, technologies or software,
 - a requirement of the organization's quality management system for periodic review.

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

- document reference number,
- date of issue/date effective,
- revision status,
- review date or review frequency, as required by the quality management system,
- revision history,
- originator or author,
- person(s) approving it,
- person(s) issuing it,
- distribution,
- pagination, and
- computer file reference, if applicable.

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

4.2.3.5 Organizations are required by ISO 13485 to define the lifetime of each of their medical devices; considerations for establishing the lifetime of the medical device are to be found in 7.1 [see Clause 7.1.3 of this Handbook].

Document retention time should take into consideration

- period of time the medical device is expected to be in the market place,
- legal considerations including liability,
- need or advisability of keeping documents indefinitely,
- retention time of related records, and
- spare parts availability.

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

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

ISO 13485 recognizes that there might be specific regional or national regulatory requirements for the retention of documents made obsolete by changes in medical devices or the quality management system. The organization should determine whether any market that it supplies has such regulatory requirements and should establish a system to ensure that such obsolete documents are retained for an appropriate period. [ISO/TR 14969]



- 1) Are the documents required by the QMS (see Clause 4.2.1 of ISO 13485) controlled?
- 2) Has the organization established a documented procedure for the control of documents?
- 3) Does this documented procedure define the controls needed to
 - a) approve documents for adequacy prior to issue?
 - b) review and update documents as necessary, and reapprove documents?
 - c) ensure that changes and the current revision of the document are identified?
 - d) ensure that relevant versions of applicable documents are available at points of use?
 - e) ensure that documents remain legible and readily identifiable?
 - f) ensure that documents of external origin are identified and their distribution controlled?
 - g) prevent the unintended use of obsolete documents and provide them with suitable identification if they are retained for any purpose?
- 4) Has the organization defined the period of time for which at least one copy of an obsolete controlled document is retained, and is this retention time equal to or greater than the defined lifetime of the device?



- 1) Is there a documented procedure for the control of documents?
- 2) Who is responsible for document control within the design group, purchasing department, production unit, servicing department, etc.?
- 3) Does the scope of the documented procedure for the control of documents cover the relevant document types (e.g., quality manual and system procedures, design documents, quality plans, process control documents, calibration procedures, audit documentation, etc.)?
- 4) Who is responsible for controlling external documents?



4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.



Definition

record

document (3.7.2) stating results achieved or providing evidence of activities performed [ISO 9000, 3.7.6]



Guidance

The following table lists clauses in ISO 13485 that require the establishment and maintenance of records.

Examples of quality records

Clause	Record required
5.6.1	Management review
6.2.2 e)	Education, training, skills, and experience
6.3	Infrastructure
7.1 d)	Evidence that the realization processes and resulting product fulfill requirements
7.1	Records arising from risk management

7.2.2	Results of the review of requirements relating to product and actions arising from the review
7.3.2	Design and development inputs
7.3.3	Design and development outputs
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions
7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design and development changes and any necessary actions
7.4.1	Results of supplier evaluations and actions arising from the evaluations
7.4.2	Traceability
7.4.3	Verification of purchased product
7.5.1.1	Batch record
7.5.1.2.2	Installation and verification
7.5.1.2.3	Servicing activities
7.5.1.3	Sterilization process parameters
7.5.2	Process validation
7.5.3	Traceability
7.5.4	Customer property
7.5.5	Preservation of product
7.6	Control of monitoring and measuring devices
8.2.2	Internal audit results
8.2.4	Product conformity with the acceptance criteria and indication of the authority responsible for inspection or testing
8.3	Control of nonconforming product
8.4	Analysis of data related to suitability and effectiveness of QMS
8.5.1	Customer complaint
8.5.2	Results of corrective action and action taken
8.5.3	Results of preventive action and action taken

ISO/TR 14969 provides the following guidance on control of records:

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

- a) those that relate to the design, and the manufacturing processes, affecting all medical devices of a particular type;
- b) those that relate to the manufacture or distribution of an individual medical device or batch of medical devices;
- c) those that demonstrate the effective operation of the overall quality management system (system records).

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

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

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

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

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

- enter data and observations as they occur;
- do not pre-date or post-date records;

- do not use another person's initial, signature or equivalent;
- complete all fields or check-offs when using a form;
- refer to raw data when transferring data, and have the transcription verified by a second person;
- verify all entries for completeness and correctness;
- number pages to ensure completeness.

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

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

- a second authorized person with logged name and identification, with time and date, can verify data entry via the keyboard, or
- systems with direct data capture can have the second check as a part of validated system functionality.

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

4.2.4.7 In addition to considering the lifetime of the device (see 7.1) in determining record retention time, legal considerations, including liability, and the need or advisability of keeping records indefinitely, should be considered. [ISO/TR 14969]



- 1) Has the organization established quality records to provide evidence of conformity to requirements and of the effective operation of the QMS?
- 2) Are the quality records legible, readily identifiable, and retrievable?
- 3) Has the organization established a documented procedure to define the control of quality records?

- 4) Does this documented procedure define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of quality records?



- 1) Which types of records are identified as necessary in our “record documentation procedure”?
- 2) Which departments are responsible for collecting and storing quality records?
- 3) What forms of media are records stored in?
- 4) How long will the records be retained?
- 5) In which locations are records stored?
- 6) What environment will be suitable?
- 7) Are records that must be destroyed after a period of time identified?



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

NOTE For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.



Definition

top management

person or group of people who directs and controls an **organization** (3.3.1) at the highest level [ISO 9000, 3.2.7]

**Guidance**

ISO/TR 14969 provides the following guidance on management commitment:

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

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

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

Consideration should be given to

- ensuring that the sequence and interaction of processes are designed to achieve the planned results effectively,
- ensuring that process inputs, activities and outputs are clearly defined and controlled,
- monitoring inputs and outputs to verify that individual processes are linked and operate effectively,
- identifying hazards and managing risks,
- conducting data analysis to facilitate necessary improvement of processes,
- identifying process owners and giving them responsibility and authority, and
- managing each process to achieve the process objectives.

[ISO/TR 14969, 5.1]



- 1) Has the organization’s top management provided evidence of its commitment to the development and implementation of the QMS, and to maintaining its effectiveness by
 - 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?
 - e) ensuring the availability of resources?



- 1) How has top management demonstrated its commitment to developing, implementing, and maintaining the effectiveness of its QMS?
- 2) Is the quality policy known to people in the organization and do staff know their objectives and the means of measuring their accomplishment?
- 3) Have resource requirements been planned and made available to meet the needs of the QMS activities?



5.2 Customer focus

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



Definitions

customer

organization (3.3.1) or person that receives a **product** (3.4.2)
[ISO 9000, 3.3.5]

customer satisfaction

customer's perception of the degree to which the customer's **requirements** (3.1.2) have been fulfilled [ISO 9000, 3.1.4]

requirement

need or expectation that is stated, generally implied or obligatory
[ISO 9000, 3.1.2]



Guidance

ISO/TR 14969 provides the following guidance on customer focus:

This subclause is intended to emphasize the responsibility of top management to make certain that customer requirements are understood

and that the necessary resources are made available to meet those requirements, regardless of who in the organization actually undertakes the interaction with the customer. The references to ISO 13485:2003, 7.2.1 and 8.2.1, are pointers to what this process will be expected to cover. [ISO/TR 14969, 5.2]



Has top management ensured that customer requirements are determined and are fulfilled with the aim of providing customer satisfaction?



- 1) How has top management focused on customer requirements?
- 2) Are the people in the organization aware of this focus?



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.



Definition

quality policy

overall intentions and direction of an **organization** (3.3.1) related to **quality** (3.1.1) as formally expressed by **top management** (3.2.7) [ISO 9000, 3.2.4]



Guidance

ISO/TR 14969 provides the following guidance on quality policy:

The quality policy establishes

- a commitment to quality and the continuing effectiveness of the quality management system to meet customer and regulatory requirements,
- the context for quality objectives, and
- the relationship of the organization's objectives to the customers' requirements.

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

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

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

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

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

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

The quality policy also needs to be reviewed from time to time to determine if it accurately reflects the current quality related goals and objectives of the organization. This review is often carried out during the management review required in 5.6. [ISO/TR 14969, 5.3]



Has top management ensured that the quality policy

- a) is appropriate to the purpose of the organization?
- b) includes a commitment to comply with requirements and a commitment to maintain the effectiveness of the QMS?
- c) provides a framework for establishing and reviewing quality objectives?
- d) is communicated and understood within the organization?
- e) is reviewed for continuing suitability?



- 1) Is the quality policy known by the personnel involved and is it appropriate?
- 2) Is there a regular review of the quality policy?



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.



Definition

quality objective

something sought, or aimed for, related to **quality** (3.1.1) [ISO 9000, 3.2.5]

**Guidance**

ISO/TR 14969 provides the following guidance on quality objectives:

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

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

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

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

- meeting the requirements (customer, regulatory and other) for medical devices and related services,
- reducing errors,
- reducing internal audit closure times,
- meeting planned schedules, and
- reducing customer complaint handling times.

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

Quality objectives provide one of the inputs into quality management system planning (see 5.4.2). [ISO/TR 14969, 5.4.1]



- 1) Has the organization's top management ensured that quality objectives are established at relevant functions and levels within the organization?
- 2) Do the established quality objectives include those needed to meet requirements for product?
- 3) Are the quality objectives measurable?
- 4) Are the quality objectives consistent with the quality policy?



- 1) How are the quality objectives established for all functions and levels?
- 2) Are the quality objectives measurable and have they been achieved?



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.



Definition

quality planning

part of **quality management** (3.2.8) focused on setting **quality objectives** (3.2.5) and specifying necessary operational **processes** (3.4.1) and related resources to fulfil the quality objectives

NOTE Establishing **quality plans** (3.7.5) can be part of quality planning.
[ISO 9000, 3.2.9]



Guidance

ISO/TR 14969 provides the following guidance on quality management system planning:

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

In order that the quality management system can meet the requirements of ISO 13485:2003, 4.1, most of this planning will be at the initial stages of

development and implementation of the quality management system. This planning can assist the organization to fulfil its quality objectives. Since quality objectives can, and indeed should, change over time, this planning is likely to be ongoing, and can assist the quality management system to continue to be effective during and after changes.

5.4.2.2 Typical inputs into quality management system planning include

- quality policy,
- quality objectives,
- regulatory requirements,
- quality management system standards, and
- changes required (e.g. as a result of management review and/or corrective and preventive action).

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

- the quality manual and supporting documentation,
- gap analyses,
- actions plans, and
- results of action plans.

It should be noted that the term “quality plan” is more frequently used in conjunction with product realization planning (see 7.1) than in conjunction with quality management system planning. [ISO/TR 14969]



- 1) Has top management ensured that
 - a) the planning of the QMS is carried out in order to meet the requirements given in Clause 4.1 of ISO 13485?
 - b) the planning of the QMS is carried out in order to meet the quality objectives?
 - c) the integrity of the QMS is maintained when changes to the QMS are planned and implemented?



- 1) Who is responsible for the planning of the QMS?
- 2) Does the planning process include reviewing and determining the effects of any changes?



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 verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

NOTE National or regional regulations might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).



Guidance

ISO/TR 14969 provides the following guidance on responsibility and authority:

This requirement is usually achieved by means of documented position descriptions which include responsibilities and authorities, and organization charts which describe the interrelation of personnel. As this documentation forms part of the quality management system, it should be controlled (see 4.2.3). Responsibilities and authorities (including those for substitute personnel) may also be included in documented procedures. Some organizations “map” quality management system processes to show the linkages between processes and the responsibilities associated with activities to be performed.

For some activities (e.g. internal quality audits and design and development reviews), it is important that there be participation by individuals who have the required knowledge of, as well as organizational independence from, the subject being reviewed. [ISO/TR 14969, 5.5.1]



- 1) Has top management ensured that the responsibilities, authorities, and their interrelations are defined and communicated within the organization?



- 1) How have the responsibilities and authorities been communicated?
- 2) Is this information known throughout the organization?
- 3) Is the effectiveness of the QMS known throughout the organization?



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 (*see 8.5*), 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.



Guidance

ISO/TR 14969 provides the following guidance on management representatives:

Only one member of management is designated by top management as its management representative.

The functions of the management representative may be entirely related to quality management system activities or may be in conjunction with other functions and responsibilities within the organization.

If the management representative has other functions to perform, there should be no conflict of interest between the responsibilities for the other functions and those relating to the quality management system.

The management representative may delegate responsibilities for the quality management system to others in the organization. [ISO/TR 14969, 5.5.2]



- 1) Has top management appointed a member of management who, irrespective of other responsibilities, has the responsibility and authority necessary to
 - a) ensure that processes needed for the QMS are established, implemented, and maintained?
 - b) report to top management on the performance of the QMS and any need for improvement?
 - c) ensure the promotion of awareness of customer requirements throughout the organization?



- 1) Who is the management representative?



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.



Guidance

ISO/TR 14969 provides the following guidance on internal communications:

For a quality management system to work effectively, open and active communication is essential. Top management needs to establish the processes which encourage people within the organization to communicate at all levels.

Information related to the quality management system should be clear and understandable and adapted to the personnel meant to use it. Such information relates to top management's expectations regarding the quality management system performance, and information related to the

implementation and effectiveness of the quality management system [e.g. results of internal quality audits (see 8.2.2), management reviews (see 5.6), external assessments and regulatory inspections].

Examples of communication methods include

- posting information on bulletin boards,
- holding meetings, or
- circulating information via e-mail or copies of documents.

Internal communication can be facilitated by personnel having familiarity with a variety of activities or functions within the organization. This familiarity can be enhanced, for example, by placing personnel from one function into another function as a part of their personal development. [ISO/TR 14969, 5.5.3]



- 1) Has top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS?



- 1) Has top management informed people in the organization of the importance of meeting customer, statutory, and regulatory requirements?



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).



Definition

review

activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives

NOTE Review can also include the determination of **efficiency** (3.2.15).

EXAMPLE Management review, design and development review, review of customer requirements and nonconformity review. [ISO 9000, 3.8.7]



Guidance

ISO/TR 14969 provides the following guidance on management reviews:

Top management should typically review the quality management system on a regular basis; an annual review could be acceptable for an established and effective quality management system. If changes are planned or being implemented, more frequent reviews are normally needed. Circumstances can arise that might require a change to the planned intervals for management reviews.

Top management and other participants in management reviews should be able to contribute and/or take action on any outcomes, if necessary (see 6.2.2).

The method of carrying out the review should suit the organization's business practices and could consist of

- formal face-to-face meetings with an agenda, minutes and formally identified action points,
- a variant of the above by teleconference or Internet links, or
- partial reviews at various levels within an organization, reporting to the top management who review the reports.

Management review records can be in any form which suits the organization, such as notes in a daybook, formal meeting minutes or notes, which can be produced, distributed and stored on paper or electronically. The identity of those taking part in the management review should be recorded.

Records of the management review should address all points of the review together with a description of any corrective or preventive action to be taken, the responsibility for such actions, the resources which might be needed to complete such actions and target dates for completion, if known.
[ISO/TR 14969, 5.6.1]



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,
- g) recommendations for improvement, and
- h) *new or revised regulatory requirements.*



Guidance

ISO/TR 14969 provides the following guidance on review input:

5.6.2.1 To ensure that the entire quality management system is covered, a consistent approach should be followed to ensure that the review covers the following:

- the continued suitability of the quality policy and objectives with respect to current needs;
- the functional effectiveness of the QMS and its ability to meet objectives;
- analysis of process performance;
- quality problems and actions taken;
- customer feedback, including customer complaints;
- quality audit reports (both internal and external);
- areas for improvement/changes needed;
- outstanding actions from previous reviews;
- new or revised regulatory requirements.

5.6.2.2 Individual problems should be dealt with as they occur, without waiting for the next management review. The management review is intended to see if the same problems re-occur, if the action taken is appropriate, and if the customer and regulatory requirements are being met. However, the attention given to individual problems should be complemented by a review of the entirety of the quality management system in order to see if it is effective in meeting the organization's quality objectives.

Management reviews should not be devoted to repeatedly discussing relatively insignificant problems. Rather, the management review will be more useful if it carefully considers reports to obtain a clear overview and

does not just review a list of small details. Top management should analyse and decide on significant trends.

5.6.2.3 The analysis of data as required by ISO 13485:2003, 8.4, should also be included in the management review. Other inputs which could be considered include

- training needs,
- supplier problems, and
- equipment needs, working environment and maintenance.

By identifying these issues, and depending on the outcome of the review, the organization can develop and revise its quality, strategic and business plans for future activities.

5.6.2.4 For example, as improvements are achieved and problems eliminated, the organization can review the nature and level of its inspection controls; are they still essential or can some savings be made by modifying them or adopting other controls, since the cause of the problem has been addressed? If the rate of complaints is found to be increasing, a decision should be taken to explore the reasons and to set appropriate objectives.

5.6.2.5 Reviews and audits are not the same. This is clearly indicated by the requirement that the results of audits are part of the management review.

5.6.2.6 For the purposes of management review and even for the purposes of design input (see ISO 13485:2003, 7.3.2), the “regulatory requirements” referred to are any laws published or otherwise enacted by any government that establish legal prerequisite conditions in order

- to place a medical device on the market,
- to make a medical device available for use,
- to install a medical device, or
- to implement a related service.

Such regulatory requirements are only applicable to an organization if they have entered or plan to enter a particular market or region where such requirements exist. A portion of the management review should be devoted to an understanding of the organization’s regulatory compliance status as well as action plans to ensure such compliance is established and maintained. [ISO/TR 14969]



5.6.3 Review output

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

- a) *improvements needed to maintain the effectiveness of the quality management system and its processes,*
- b) improvement of product related to customer requirements, and
- c) resource needs.



Guidance

ISO/TR 14969 provides the following guidance on review output:

Review output should include a statement regarding the effectiveness of the quality management system and its processes established for the achievement of the quality policy and objectives and the extent to which those objectives have been achieved based on the established respective criteria. One possible output from a management review might be a decision to revise the planned interval for such reviews (see 5.6.1).

Top management should reach decisions as a result of the review and provide the necessary resources for implementation. [ISO/TR 14969, 5.6.3]



- 1) Has top management reviewed the organization's QMS at planned intervals to ensure its continuing suitability, adequacy, and effectiveness?
- 2) Does the review include assessing
 - a) opportunities for improvement?
 - b) the need for changes to the QMS?
 - c) the need for changes to the quality policy?
 - d) the need for changes to quality objectives?
- 3) Does the input to management review include information related to
 - 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) planned changes that could affect the QMS?
 - g) recommendations for improvement?
 - h) new or revised regulatory requirements?
- 4) Does the output from the management review include any decisions and actions related to
- a) maintenance of the effectiveness of the QMS and its processes?
 - b) ensuring that product meets customer requirements?
 - c) resource needs?



- 1) Who is responsible for conducting the management review?
- 2) Who are the regular participants?
- 3) Are the reviews scheduled?
- 4) How are the reviews documented?
- 5) What information and records are reviewed?
- 6) How are the suitability, adequacy, and effectiveness of the QMS evaluated?



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.*



Guidance

ISO/TR 14969 provides the following guidance on the provision of resources:

The provision and maintenance of adequate resources is a prerequisite to the effective initiation, maintenance and management of a quality management system and its processes. The nature and quantity of such resources will be determined by the processes involved.

Consideration should be given by the organization's management to the identification and provision of adequate resources needed to implement its quality policy and to achieve its objectives, as well as to satisfy customer requirements, inclusive of applicable regulatory requirements.

Resources can be people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources. Responsibility for the provision of resources resides with the organization regardless of whether associated processes are performed by the organization itself or are outsourced. [ISO/TR 14969, 6.1]



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 might require the organization to establish documented procedures for identifying training needs.



Definitions

competence

demonstrated personal attributes and demonstrated ability to apply knowledge and skills [ISO 19011, 3.14]

competence

demonstrated ability to apply knowledge and skills

NOTE The concept of competence is defined in a generic sense in this International Standard. The word usage can be more specific in other ISO documents. [ISO 9000/FDAM1, 3.1.6]



Guidance

ISO/TR 14969 provides the following guidance on human resources:

The organization should consider the experience, qualifications, capabilities and abilities of personnel, especially in those areas that can affect the safety and effectiveness of the medical devices being manufactured and provided to customers. The level of training required prior to performing a process is usually determined by the level of competence required for the personnel intended to perform that process.

Work allocation and assignment of personnel (6.2.1), management review (5.6), corrective action (8.5.2), preventive action (8.5.3) and internal quality audit (8.2.2) are all likely to identify areas which could indicate a need for improving the competence of personnel and the means for such improvement, be it replacement of personnel, further education or training.

Personnel working within the quality management system require a certain level of competence or training (internal or external) before they can perform tasks properly or safely. It might be necessary for people to be further qualified or formally certified for some tasks (e.g. chemical or microbiological analysis, radiation activities, laser operation, welding or soldering).

Organizations typically provide general education and training for full-time, part-time and contract personnel, tailored to the person's assignment. Such training and education should cover

- the nature of the business,
- the health, safety and environmental regulations,
- the quality policy and other internal policies,
- the function of the employee, and
- the procedures and instructions of relevance to them.

Training may be carried out in stages, and usually includes follow-up or refresher training, as needed and planned. Persons and functions who are assigned responsibility via the documented procedures of the quality management system should receive training on those procedures.

Organizations should evaluate the effectiveness of training or other actions taken in order to ensure competency. Evaluation can consist of polling the trained employee to assess whether he or she feels they have learned the required information, evaluating the work performance of the trained individual, and reviewing the trainer assessment of training effectiveness.

Organizations should maintain records which show what competencies an employee possesses. Records should also be kept of the training an employee has received and any results of that training. The records which show that the training course has been successfully completed and that competence has been achieved may be as simple or complex as necessary. At their simplest, the records may consist of 'sign-off' to confirm that personnel are now able to use certain equipment, carry out specific processes or follow certain procedures. The records should include a clear statement that a person is now deemed to be competent to do the task for which they were trained. The effectiveness of any further education and training should be reevaluated, after a period, to confirm that the competence achieved is continuing.

Training should be carried out by personnel with appropriate skills, qualifications and experience. Records are typically kept to document the qualifications of the personnel used as trainers. [ISO/TR 14969, 6.2.2]



- 1) Are the personnel who are performing work that affects product quality competent (i.e., do they have the appropriate education, training, skills, and experience)?
- 2) Has the organization
 - a) determined the necessary competence for personnel performing work affecting quality?
 - b) provided training or taken other actions to ensure such competence?
 - c) evaluated the effectiveness of the training provided or the other actions taken?
 - d) ensured that its personnel are aware of the relevance and importance of their activities, and the way in which they contribute to the achievement of quality objectives?
 - e) maintained appropriate records of education, training, skills, and experience?



- 1) Have the persons responsible for providing resources been identified?
- 2) Have the requirements for education, training, skills, and experience been identified?
- 3) Do people performing work affecting quality meet the above requirements?
- 4) Who is responsible for training?
- 5) Who is responsible for reviewing training results and determining the effectiveness of training?
- 6) Have the requirements for the trainers been identified?
- 7) Who is responsible for making people aware of the effect of their work on the achievement of quality?
- 8) How and where are the records stored?



6.3 Infrastructure

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

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport or communication).

The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.

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



Definition

infrastructure

<organization> system of facilities, equipment and services needed for the operation of an **organization** (3.3.1) [ISO 9000, 3.3.3]

**Guidance**

ISO/TR 14969 provides the following guidance on infrastructures:

Manufacturing equipment should be designed, constructed, correctly installed and located to facilitate proper operation, maintenance, adjustment and cleaning.

The organization should ensure that, if applicable, any inherent limitations or allowable tolerances of production, measurement and test equipment are documented and are readily available to the operators.

Documented procedures should be available for the maintenance, cleaning and checking of all equipment used in production, and for the control of the work environment. The determination of the necessary adjustments and maintenance intervals should be established.

The maintenance schedule should normally be posted on or near the equipment, or should be readily available. Maintenance should be carried out on schedule.

The organization should ensure that the buildings utilized are of suitable design and contain adequate space to facilitate cleaning, maintenance and other necessary operations. The premises should be laid out in such a way, and with sufficient allocation of space, to facilitate orderly handling and to prevent mixing between incoming material, in-process batches, material scrapped, re-worked, modified or repaired, any other nonconforming material, finished devices, manufacturing equipment, inspection aids, documents and drawings. [ISO/TR 14969, 6.3]



- 1) Has the organization established documented procedures for maintenance activities if such activities or lack thereof can affect product quality?



- 1) Has a maintenance schedule been developed for manufacturing equipment?
- 2) Has the frequency of maintenance activities been identified?
- 3) Who is responsible for carrying out the maintenance activities?



6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

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 work environment could adversely affect the quality of the product (see 7.5.1.2.1).*
- b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).*
- c) The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)].*
- d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).*



Definition

work environment

set of conditions under which work is performed

NOTE Conditions include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition) [ISO 9000, 3.3.4]

**Guidance**

ISO/TR 14969 provides the following guidance on work environments:

6.4.1 General

Product quality can be influenced by the production work environment. The most significant factors within the work environment that can affect product quality are

- the process equipment,
- the work environment established, and
- the personnel within that work environment.

6.4.2 Environmental control in product realization

6.4.2.1 The need for control of the work environment and the extent to which that control is exercised depend upon the type of the product being produced. To control the work environment means to direct, regulate, coordinate and monitor activities and variables that affect the conditions such that the quality of the work environment is known. Qualified and quantified limits for the desired quality of the work environment should be established and may be used to describe the extent to which control capabilities are implemented. The extent of the control required will influence the type of facility construction, equipment, resources and documentation needed to establish, monitor and maintain the work environment. An environmental control system should be validated if the resulting output cannot be verified (see 7.5.2 and 7.5.2.1), and should be regularly inspected to verify that the system is functioning properly. Such systems and inspections should be documented.

NOTE Additional information regarding cleanrooms and associated environments is available in the various parts of ISO 14644.

6.4.2.2 Examples of situations in which the work environment can have an effect on product quality include medical devices which

- are to be supplied labelled sterile (this also includes medical devices labelled “pyrogen free”),
- are to be supplied non-sterile and are intended to be sterilized before use,
- have a limited shelf life,
- have special handling or storage requirements,
- are susceptible to electrostatic discharge (ESD) due to electronic microcircuits or imbedded software, and
- are affected in their use by microbiological and/or particulate cleanliness or other environmental conditions.

6.4.2.3 During the manufacture of sterile product or product intended to be sterilized before use, or product for which viable or non-viable particulate contamination (including pyrogens) has significance in their manufacture or use, special consideration should be paid to microbial and particulate contamination levels. The organization should ensure that if the work environment could have an adverse effect on the fitness of product in use, this environment is controlled to limit contamination of product and to provide proper conditions for all operations performed. Such product should be produced and packaged in a qualified, controlled environment with established specifications. An exception to the need for a controlled environment during the entirety of manufacturing processes would be if contamination can be reduced to a known, consistent, controlled level by validated product cleaning, and maintained at this level by controlled packaging. However, even when a validated cleaning procedure is relied upon, a controlled environment might need to be established to contain the validated cleaning and packaging process.

6.4.2.4 There are various parameters, indicators and controls associated with the work environment. Some examples of these are

- temperature,
- humidity,
- airflow,
- air filtration,
- air ionization,
- pressure differentials,
- lighting (both spectral content and intensity),
- sound,
- vibration,
- cleanliness of work surfaces and process,
- water quality, and
- number of people in the work environment.

6.4.2.5 Each of the parameters, indicators and controls should be considered for evaluation to determine if lack of control could increase the risk posed by product when put into use; i.e. the need and extent of environmental control should be traceable through records of risk management activities for product. If the environmental conditions are of significance in its manufacturing processes, the organization should establish requirements for the work environment to which product is exposed. For some product it might also be necessary to ensure traceability to environmental exposure, such as records of continuous monitoring of environmental parameters even during times when product is not undergoing manufacturing processes (e.g. evenings or weekends).

6.4.3 Personnel

6.4.3.1 Any personnel, including those entering the area on a temporary or transient basis, who can come in contact with product or work environment, should be suitably clothed, clean and in good health if these factors could adversely affect the product. This is because individuals spread both microorganisms and particles, which constitute contamination risks.

Examples of persons who might enter the work environment are

- manufacturing personnel, their supervisors and managers,
- material handlers,
- manufacturing engineers,
- design and development engineers,
- quality control, quality assurance, quality engineering personnel,
- suppliers of any material or service (including cleaning services),
- persons responsible for process equipment maintenance,
- customers,
- auditors, and
- visitors.

It is also important to remember that contact with product or work environment includes those times when product is not actually being produced, such as evenings, weekends and holidays.

6.4.3.2 Persons who have a medical condition that can adversely affect the product should be excluded from those operations, or prevented from entry into such areas until they have recovered. Personnel should be instructed and encouraged to report such conditions to their supervisor. This is of particular importance in the manufacture of medical devices which are to be supplied

- sterile,
- for sterilization before use, or
- for purposes in which microbiological cleanliness is of significance.

6.4.3.3 Special training and/or supervision should be provided to persons required to perform work under special environmental conditions (e.g. in a room where the temperature or humidity is controlled to such high or low levels that prolonged exposure might be hazardous, or a room or area where exhaust fans keep hazardous fumes at an acceptable level) or within a controlled environment. Any personnel, including temporary personnel such as those involved in manufacturing, maintenance, cleaning or repair, who have not been trained for performing specific tasks in a controlled environment, should not be allowed to enter unless supervised by an appropriately trained person.

6.4.4 Contaminated or potentially contaminated product

Examples of aspects to consider for special arrangements designed to prevent cross-contamination of product, work environment or personnel, are

- identification of the product, and
- handling, cleaning, and decontamination procedures for product, work surfaces, or personnel which have been or might have been contaminated. [ISO/TR 14969]



- 1) Has the organization planned and established the work environment needed to achieve conformity to product requirements?
- 2) Has the organization
 - a) established documented requirements for health, cleanliness, and clothing of personnel if contact between personnel and the product or work environment could adversely affect the quality of the products?
 - b) established documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions if work environment conditions could have an adverse effect on product quality?
 - c) ensured that all personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained person?
 - d) established and documented special arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel?



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.

The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4).

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.

NOTE 3 See ISO 14971 for guidance related to risk management.



Definitions

quality plan

document (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract [ISO 9000, 3.7.5]

process

set of interrelated or interacting activities which transforms inputs into outputs [ISO 9000, 3.4.1]

verification

confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled [ISO 9000, 3.8.4]

validation

confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled [ISO 9000, 3.8.5]

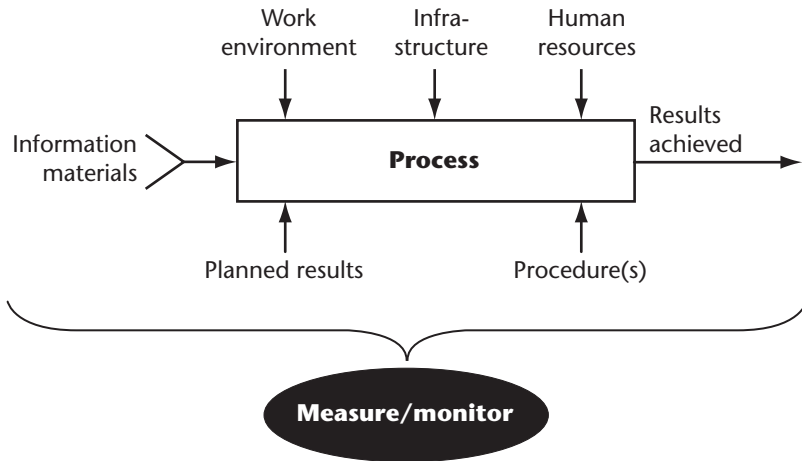


Guidance

Like Clause 5.4.2, which requires the planning of the QMS, Clause 7.1 requires the planning of all the processes related to the realization of the product. The elements of such processes are shown in the figure below.

The planning of each process may include the following activities:

- a) specifying the inputs required;
- b) determining the desired output for the process;
- c) establishing the sequence of activities (documented, as needed) necessary to obtain the desired output;
- d) allocating appropriate resources in terms of personnel, infrastructure, and work environment; and
- e) identifying the necessary measurement and monitoring of the process parameters.



Elements of a process

ISO/TR 14969 provides the following guidance on the planning of product realization:

7.1.1 General

7.1.1.1 “Product realization” is the term used in ISO 13485 to describe the processes starting with planning and proceeding through

- determination of customer requirements and customer communication (ISO 13485:2003, 7.2),
- design and development (ISO 13485:2003, 7.3),
- purchasing (ISO 13485:2003, 7.4),
- production and servicing (ISO 13485:2003, 7.5),
- control of monitoring and measuring devices (of ISO 13485:2003, 7.6), and including the delivery of the medical device.

Product realization also includes certain post-delivery activities such as customer service, spare parts supply and technical support.

7.1.1.2 Organizations whose quality management systems exclude design and development control (ISO 13485:2003, 7.3) are still required to comply with the product verification and validation requirements as specified in ISO 13485:2003, 7.1, dealing with product realization. In such organizations, the controls included in 7.3 should be considered for all changes made to the product. Such changes will require objective evidence (e.g. product verifications and validations, inspection and test specifications, revised procedures) of the results of the activities described in ISO 13485:2003, 7.3.

Note 1 in ISO 13485:2003, 7.1, is consistent with the definition of “quality plan” in ISO 9000 as being related to the planning for product realization.

NOTE Additional information regarding quality plans is available in ISO 10005.

7.1.1.3 In planning for product realization, the organization should consider the scope of its quality management system (see 1.2). If the organization has used a regulatory approach which allows exclusion of design and development control from the scope of quality management system, the design information related to necessary verification and validation may be part of, or referenced within, the records of planning product realization. This information may be contained or referenced in a file (see Annex A, section A) [see Appendix 3 of this Handbook].

7.1.1.4 ISO 13485:2003, 7.1, lists several needs or requirements relating to product realization which are to be considered “as appropriate.” However, ISO 13485:2003, 1.2, also states that when a requirement is qualified by this phrase, it is considered to be appropriate *unless* the organization can document justification otherwise. A requirement should always be considered “appropriate” if it is necessary for the product to meet specified requirements, or for the organization to carry out corrective action.

A requirement need not be stated in order to be appropriate to an organization; applicable regulatory requirements in the markets for which an organization’s medical devices are destined are also considered requirements.

7.1.1.5 Some examples of such requirements which are typically associated with medical devices include

- quality objectives and product requirements,
- established processes, documents and required resources specific to the product,
- required verification, validation, monitoring, measurement, inspection and test activities specific to the product, and
- records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

7.1.1.6 The organization’s procedures should ensure the objectivity of the inspection and test results, if inspection and testing is carried out by production personnel.

The resultant records referred to in ISO 13485:2003, 4.2.4, 7.1 d), 7.1 (Note 1) and 7.3.3 are sometimes referred to by different terms (see Annex A, section C) [see Appendix 3 of this Handbook].

7.1.2 Risk management

ISO 13485:2003, 7.1, requires the establishment of documented requirements for risk management activities throughout the product realization, and that records of the same be maintained. The key elements of

such risk management include risk assessment (made up of risk analysis and risk evaluation) and risk control. Special attention should be paid to the word “throughout.” The intent of ISO 13485 in using this term is that all processes within ISO 13485:2003, Clause 7, should be considered as to how they provide input to, or benefit from the results of, risk management activities.

To make risk management activities complete, information from the post-production phase (e.g. feedback, see 8.2.1, or customer complaints, see 8.5.1) should be considered and included in a risk management file.

The results of risk management activities influence the organization’s product realization processes by, for example

- helping to determine the nature and extent of purchasing controls,
- influencing supplier approval activities,
- providing important design inputs,
- serving as criteria for evaluating design outputs,
- establishing the need for design change, and
- helping to determine production and process control requirements, and monitoring and measurement devices controls, as well as acceptance activities.

It is also important to note that the output of risk management activities can influence decisions and activities outside of the area of product realization, ISO 13485:2003, Clause 7. For example, management review decisions, personnel training, infrastructure, monitoring and measurement, handling of nonconforming product, and corrective and preventive actions can be significantly influenced by information derived from the output of risk management activities.

Additional information on how to establish a risk management process over the life cycle of the medical device can be found in ISO 14971.

7.1.3 Lifetime of the medical device

Decisions related to product lifetime can be made, in part, to control identified residual risks that can increase to unacceptable levels as the period of use of a medical device is extended.

Organizations are required by ISO 13485 to define the lifetime of the medical device for document and record control purposes (see 4.2.3 and 4.2.4). Medical device lifetime may be based on technical, legal, commercial or other considerations.

The basis of the defined lifetime of the medical device should be documented. To assist in determining the lifetime of the medical device, the rationale for the determination should be recorded and may involve consideration of the following:

- a) shelf life of the medical device;
- b) expiry date for medical devices or components which are subject to degradation over time;

- c) number of cycles or periods of use of the medical device, based on life testing of the medical device;
- d) anticipated material degradation;
- e) stability of packaging material;
- f) for implantable devices, the residual risk that results from the entire period of residence of the device inside the patient's body;
- g) for sterile medical devices, the ability to maintain sterility;
- h) organization's ability/willingness or contractual or regulatory obligation to support service;
- i) spare parts cost and availability;
- j) legal considerations including liability. [ISO/TR 14969]



- 1) Has the organization planned and developed the processes needed for product realization in a manner which is consistent with the requirements of the other processes of the QMS?
- 2) As part of the planning for product realization, has the organization determined the following, as appropriate:
 - a) quality objectives and requirements for the product;
 - b) the need to establish processes and 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; and
 - d) records needed to provide evidence that the realization processes and resulting product fulfill requirements?
- 3) Is the output of this planning in a form that is suitable for the organization's method of operations?
- 4) Has the organization established documented requirements for risk management throughout product realization?
- 5) Are records arising from risk management maintained?



- 1) Who is responsible for establishing the requirements for quality objectives, processes, documents, and resources?
- 2) Have all the monitoring, measuring, and validation requirements been established and implemented?
- 3) Have the requirements for a quality plan been reviewed and met?

- 4) Have the methods of record generation and storage requirements been determined and implemented?
- 5) Have risk assessments been performed at various stages and actions identified to reduce or control risks?



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.



Definition

requirement

need or expectation that is stated, generally implied or obligatory
[ISO 9000, 3.1.2]



Guidance

ISO/TR 14969 provides the following guidance on the determination of requirements related to the product:

7.2.1.1 This subclause of ISO 13485 deals with customer-related processes associated with

- design input/output for new product development,
- customer expectations for the delivery of existing product, and
- customer feedback and communications relative to orders placed or product delivered.

7.2.1.2 This subclause focuses mainly on the products and services which the organization is going to provide to its customers. Product and service requirements can cover additional factors, such as

- regulatory or legal requirements of the countries or regions where the product is placed on the market,
- intended use,
- performance expectations,
- design related factors,
- delivery schedules, and
- unspecified customer expectations.

7.2.1.3 For medical devices, an understanding of both stated intended use and any reasonably foreseeable misuse, and indications for use, should be documented. This is of particular importance in the development of new products. The guidance in 7.3 will help the organization to determine if requirements for design and development apply.

The stated intended use and any reasonably foreseeable misuse should also be included in risk management activities (see 7.1 above regarding risk management activities).

7.2.1.4 All parts of a customer's order, contract and expectations need to be understood and reviewed to ensure that they can be met; these activities have previously been referred to as "contract review".

If there are any requirements that are not covered by the organization's usual work processes, particularly any requirements which are felt to be unrealistic or unachievable, the organization might need to discuss them with the customer.

7.2.1.5 The manner in which a customer provides the order might vary in form and could be, for example, a written order, a verbal agreement, a telephone order or an order made via an e-business web address.

One of the most common problems encountered is misunderstanding what was ordered or how it is to be used. Good communication between the organization and the customer is essential to resolve any misunderstandings and, if possible, the organization should develop communication processes to identify and resolve any such misunderstandings.

Written or electronic orders, such as those received by mail, facsimile, email or the Internet, can provide a permanent record of the order details. If telephone and direct computer link orders are received, special provisions need to be made to record and confirm the order. The organization will need methods of handling such orders.

Two examples follow.

- a) One approach to telephone orders is to provide a pad (or even pre-printed forms) for the order receiver to record the details of the order and to read it back to the customer, asking for confirmation.
- b) Another approach is to enter the details directly into a computer system, again seeking confirmation, which could be verbal, by fax or by e-mail,

with the information being saved directly to disk or printed out in hard copy form.

7.2.1.6 At the time the order is received, an appropriate person in the organization should review the order to ensure that the requirements listed in 7.2.2 can be met. In a small business, the appropriate person is frequently the manager.

The organization also needs to determine if there are any design requirements in the order and whether the requirements of 7.3 will apply. The guidance in 7.3 will help the organization to determine if a requirement for design and development apply.

The record of the review may be as simple as a notation on the order that it can be fulfilled, together with the signature of the reviewer and the date. If a more complex review is called for, the organization can determine how the review is recorded but the record should include at least the main details.

7.2.1.7 If the organization tenders for a contract or submits a proposal to a potential customer, the same approach should be taken. Any differences between the organization's offer and the requirements of the customer should be resolved. The organization should make sure that the agreed requirements are appropriately recorded.

If changes to an order or tender, or both, arise for whatever reason, the changes should be reviewed and agreed to in the same manner as the original order or tender. If the changes are accepted, it is essential that everyone in the organization who is affected by the changes is informed.

The relevant documents affected by these changes should be amended as well. [ISO/TR 14969]



- 1) Has the organization determined
 - 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 use or known and intended use?
 - c) statutory and regulatory requirements related to the product?
 - d) any additional requirements?
- 2) Has the organization established documented requirements for risk management?



- 1) Who is responsible for determining the customer requirements?
- 2) Do product requirements include customer as well as regulatory requirements?
- 3) Do we have the current version of the applicable codes and regulations?



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.

**Definition****review**

activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives [ISO 9000, 3.8.7]

**Guidance**

According to ISO/TR 14969

There is no specific medical device guidance beyond the general guidance given in 5.2 and 7.2.1. [ISO/TR 14969, 7.2.2]



- 1) Has the organization reviewed the requirements related to the product?
- 2) Is this review conducted prior to the organization's commitment to supply a product to the customer (e.g., before submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders)?
- 3) Does the review ensure that
 - a) product requirements are defined?
 - b) contract or order requirements differing from those previously expressed are resolved?
 - c) the organization has the ability to meet the defined requirements?
- 4) Are records of the results of the review and actions arising from the review maintained?
- 5) Where the customer provides no documented statement of requirements, have the customer's requirements been confirmed by the organization before acceptance?
- 6) Where product requirements are changed, has the organization ensured that
 - a) the relevant documents are amended?
 - b) the personnel involved are made aware of the changed requirements?



- 1) Who ensures that product requirements are defined and documented?
- 2) Are those product requirements reviewed on a regular basis?
- 3) Who ensures that the customer requirements are appropriate and that the organization is capable of meeting the quality and delivery requirements?
- 4) How are changes initiated by the customer handled?
- 5) How are the organization's staff made aware of the changes?
- 6) Who is responsible for ensuring that order updates are confirmed?
- 7) For such things as electronic or catalogue sales, who reviews the catalogue information for accuracy, and who is responsible for reviewing this information over a period of time?



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 (*see 8.2.1*),
and
- d) *advisory notices (see 8.5.1).*



Definitions

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 of the medical device to the organization that supplied it, or*
- *the destruction of a medical device.*

NOTE Issue of an advisory notice might be required to comply with national or regional regulations. [ISO 13485, 3.3]

customer

organization (3.3.1) or person that receives a **product** (3.4.2)

[ISO 9000, 3.3.5]

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 [ISO 13485, 3.4]

**Guidance**

ISO/TR 14969 provides the following guidance on customer communication:

In addition to stating the need to implement effective means for customer communication and feedback, ISO 13485:2003, 7.2.3, addresses customer complaints and advisory notices. See also applicable guidance provided in 7.2.1.

Advisory notices are addressed in ISO 13485:2003, 8.5.1, where additional guidance is provided for that subclause.

Advisory notices and customer complaints are defined in ISO 13485:2003, 3.3 and 3.4. Medical device regulatory schemes existing in today's world markets have subtle differences in terms, definitions and reporting requirements with regard to complaints, corrective actions and preventive actions. These schemes also have differing responsibilities for the organization, regulators, customers and third parties. It is very important that an organization make provisions to understand and comply with the regulatory schemes of each of the markets intended for its product. Customer communication can also have an effect on the ability of an organization to establish or verify traceability to an end user. This is particularly important for implantable medical devices for which there are specific traceability requirements (see 7.5.3.2.2) or other high-risk devices which might have tracking requirements put upon them by regulators. [ISO/TR 14969, 7.2.3]

See ISO/DIS 10018, *Complaints handling — Guidelines for organizations*.



- 1) Who is responsible for liaising with customers on enquiries, contracts, advisory notices, etc.?
- 2) Who is responsible for handling customer complaints and customer feedback?



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, validation and design transfer activities (see Note) that are appropriate at 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).

NOTE Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.



Definitions

characteristic

distinguishing feature.

NOTE 1 A characteristic can be inherent or assigned.

NOTE 2 A characteristic can be qualitative or quantitative.

NOTE 3 There are various classes of characteristic, such as the following:

- physical (e.g. mechanical, electrical, chemical or biological characteristics);
- sensory (e.g. related to smell, touch, taste, sight, hearing);
- behavioral (e.g. courtesy, honesty, veracity);
- temporal (e.g. punctuality, reliability, availability);
- ergonomic (e.g. physiological characteristic, or related to human safety);
- functional (e.g. maximum speed of an aircraft). [ISO 9000, 3.5.1]

design and development

set of **processes** (3.4.1) that transforms **requirements** (3.1.2) into specified **characteristics** (3.5.1) or into the **specification** (3.7.3) of a **product** (3.4.2), **process** (3.4.1) or **system** (3.2.1) [ISO 9000, 3.4.4]

quality plan

document (3.7.2) specifying which **procedures** (3.4.5) and associated resources shall be applied by whom and when to a specific **project** (3.4.3), **product** (3.4.2), **process** (3.4.1) or contract [ISO 9000, 3.7.5]

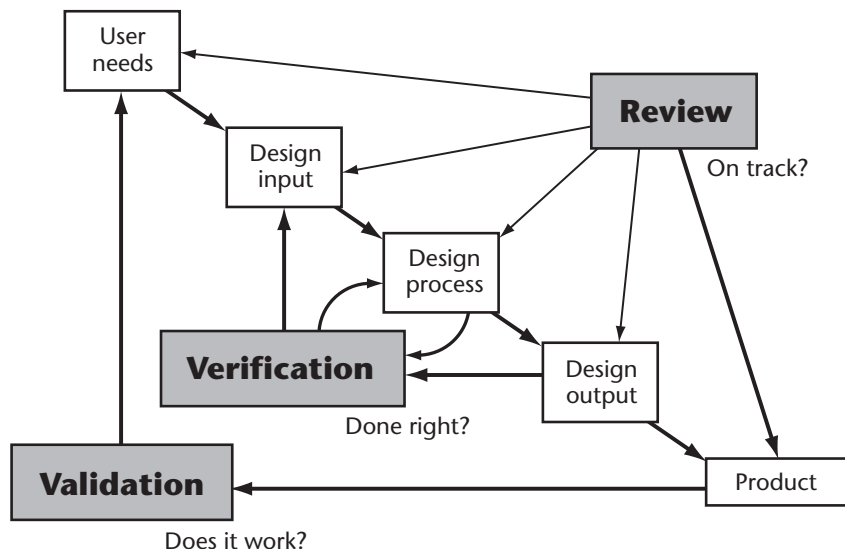
requirement

need or expectation that is stated, generally implied or obligatory [ISO 9000, 3.1.2]



Guidance

The figure below represents a simplified view of the relationships among review, verification, and validation, as applied to the design and development of medical devices. Requirements related to these concepts are included in Clauses 7.3.2 to 7.3.7. The differences and similarities between verification and validation are further described in Clause 7.3.5 (see “Verification vs. validation”).



Adapted from *ISO 9000 for Small Business — What to do — Advice from ISO/TC 176* by Accademia Qualitas and P. Landry.

Design and development acceptance

It is important to note that some regulatory requirements permit organizations to place certain medical devices on the market without demonstrations of conformance with design and development controls. Organizations should determine the applicability of Clause 7.3 on a product-by-product, market-by-market basis, and ensure that any exclusions are reflected in the quality manual.

ISO/TR 14969 provides the following guidance on design and development planning:

Guidance given in 5.4.2 and 7.1 of this Technical Report also applies.

Design and development planning is needed to ensure that the design process is appropriately controlled and that the quality objectives of the medical device are met. The plans should be consistent with the organization's quality management system provisions for quality planning and product realization requirements, including design and development controls.

The following elements would typically be addressed in the design and development plan or plans:

- a) a description of the goals and objectives of the design and development programme; i.e., what is to be developed;
- b) the markets intended (at least a broad preliminary assessment) for the product;
- c) an identification of quality management system documents, procedures and resulting records applicable to controls for design and development;
- d) an identification of organizational responsibilities with respect to assuring quality during the design and development phase, to include interface with any suppliers;
- e) the identification of the major tasks to be undertaken (or stages/phases of the design and development control), expected outputs (deliverables and records) resulting from each task or stage/phase, and individual or organizational responsibilities (staff and resources) for completing each task or stage/phase;
- f) the schedule of major tasks or stages/phases to meet overall programme time constraints;
- g) the identification of appropriate existing and anticipated measurement and monitoring devices for the development of product specifications, verification, validation and production related activities (see also guidance given in 7.6 of this Technical Report);
- h) the selection of reviewers, the composition of review teams, and procedures to be followed by reviewers appropriate to each task or stage/phase;
- i) the risk management activities;
- j) the selection of the suppliers.

Planning enables management to exercise control over the design and development process while providing for predictable timeframes and records. Planning accomplishes all this by clearly communicating policies, procedures and goals to members of the design and development team. It also provides a basis for measuring conformance to quality management system objectives.

Design and development activities should be specified at the level of detail necessary to carry out the design process. The extent of design and development planning is dependent on the size of the developing organization and the complexity of the product to be developed. Some organizations have documented policies and procedures which apply to all design and development activities. For each specific development programme, such organizations can also prepare a plan which spells out the project-dependent elements in detail, and incorporates the general policies and procedures by reference. Other organizations develop a comprehensive design and development plan that is specifically tailored to each individual project.

The inter-relationship of design control and process development can, for some technologies, be very closely related. For others, the relationship is remote. The product should be designed robustly enough to withstand variations in the manufacturing process, and the manufacturing process should be capable and stable to assure continued safe products that perform adequately. Often this results in very interactive product development and process development activities.

The transfer of a design to production should occur after review and approval of specifications and procedures. Planning of product realization should take into account the production (producibility, parts/materials availability, production equipment needs, operator training, etc.) and possible conformity assessment requirements (procedures, methods, equipment). This planning should encompass all of the specifications to ensure that each specification is correctly incorporated into the specific processes or procedures associated with product realization. Failure to do so can lead to production delays and nonconforming product for reasons such as purchase of incorrect raw material grades or quantities, inappropriate manufacturing methods, unvalidated processes, unclear work instructions, incorrect labelling, etc. The adequacy of specifications, methods and procedures can be demonstrated through process validation (see 7.5.2).
[ISO/TR 14969, 7.3.1]



- 1) Has the organization planned and controlled the design and development of the product?
- 2) During the design and development planning, has the organization determined
 - a) the design and development stages?
 - b) the review, verification, and validation that are appropriate to each design and development stage?
 - c) the responsibilities and authorities for design and development?
- 3) Has the organization managed the interfaces between different groups involved in design and development, to ensure effective communication and clear assignment of responsibilities?
- 4) Has the planning output been updated, as appropriate, as the design and development progresses?



- 1) Have we considered the need and usefulness of describing our planning output in the form of a quality plan?



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, performance and safety requirements, according to the intended use,*
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs,
- d) other requirements essential for design and development, and
- e) *output(s) of risk management (see 7.1).*

These inputs shall be reviewed for adequacy and approved.

Requirements shall be complete, unambiguous and not in conflict with each other.



Guidance

ISO/TR 14969 provides the following guidance on design and development inputs:

7.3.2.1 General

The guidance given in 7.2.1 of this Technical Report also applies.

Design and development inputs are typically in the form of product requirement specifications and/or product description with specifications relating to intended use, configuration, composition, incorporated elements, and other design features. The design and development inputs should be specified to the level necessary to permit the design activities to be carried out effectively and to provide a consistent basis for design decisions, design verifications and design validation.

The design and development inputs should describe all requirements to the greatest possible extent. Details agreed upon between customer and organization as to the customer, statutory, and regulatory requirements to be met should be included. The record of the design inputs should also include the resolutions of any incomplete, ambiguous or conflicting requirements which have been identified through feedback during other design and development activities. The design and development inputs should identify design criteria, materials, and processes requiring development and analysis,

including prototype testing to verify their feasibility and adequacy. Design inputs should be prepared in a way that facilitates periodic updates. If design inputs have to be changed, a record should indicate what caused the input to be changed, who is responsible for the change, and who needs to be notified. Design and development inputs prepared in this way serve as the definitive up-to-date reference document as the design progresses to completion.

Examples of design and development inputs which are typically defined, reviewed, approved and recorded by the organization, include

- intended use of the device,
- indications for use of the device,
- performance claims,
- performance requirements (including normal use, storage, handling and maintenance),
- user and patient requirements,
- physical characteristics,
- human factors/usability requirements,
- safety and reliability requirements,
- toxicity and biocompatibility requirements,
- electromagnetic compatibility requirements,
- limits/tolerances,
- measurement and monitoring instruments to be used,
- risk management or risk reduction methods suggested by hazard/risk analysis,
- reportable adverse events (see 8.5.1)/complaints/failures for previous products,
- other historical data,
- documentation for previous designs,
- compatibility requirements with respect to accessories and auxiliary devices,
- compatibility requirements with respect to the environment of intended use,
- packaging and labelling (including considerations to deter foreseeable misuse),
- customer/user training requirements,
- regulatory and statutory requirements of intended markets,
- relevant voluntary standards (including industry standards, national, regional or international standards, “harmonized” and other consensus standards),
- manufacturing processes,
- sterility requirements,
- economic and cost aspects,
- lifetime of the medical device requirements, and
- need for servicing.

The design and development input documents should be updated and re-issued as necessary upon completion of design and development reviews. A record should be kept of all “agreed to” changes to the design and development input as it evolves during the design and development process.

The design transfer process (see 7.3.1) should flow more smoothly if, during the design and development input stage, consideration is given to subsequent production (producibility, parts/materials availability, production equipment needs, operator training etc.) and possible conformity assessment requirements (procedures, methods, equipment). Thus the need for process validation should be considered during design and development planning, and is a significant input to design and development.

7.3.2.2 Packaging

Design and development input activities should also address packaging requirements. The packaging material, the packaging process conditions and the anticipated storage and handling conditions during manufacturing, warehousing and distribution are typically considered.

The following should be considered, if applicable:

- compatibility with the device and packaging process;
- compatibility with the sterilization process;
- transportation hazard trials/shipping tests;
- microbial barrier properties of packaging materials for sterile devices;
- integrity of the primary container/package to prevent damage and to maintain sterility or cleanliness as required.

NOTE Additional information relating to packaging of terminally sterilized medical devices is available in ISO 11607.

7.3.2.3 Labelling

The content of labels may be specified in regulatory requirements, general standards and medical device standards. If the medical device is to be supplied to countries with different languages, and the language to be used on the labels has been specified, it is advisable that the label translations be checked by a person with adequate expertise in the specified language and who has technical knowledge of medical devices.

The use of international symbols (if applicable) can reduce translation problems, however such symbols should only be used if they have the appropriate regulatory acceptance in the countries where the medical device has been placed on the market. Product liability aspects might also need to be considered before deciding on the use of symbols.

NOTE Additional information relating to the use of symbols for medical devices is available in ISO 15223 and EN 980. [ISO/TR 14969]



- 1) Has the organization determined the inputs relating to product requirements?
- 2) Has the organization maintained records of inputs relating to product requirements?
- 3) Do the inputs and the records include
 - a) functional and performance requirements?
 - b) applicable statutory and regulatory requirements?
 - c) information derived from similar designs, where applicable?
 - d) other requirements essential for design and development activities?
- 4) Are these inputs reviewed for adequacy?
- 5) Are the requirements complete, unambiguous, and compatible with each other?



- 1) Do we have the current versions of the applicable codes and regulations?
- 2) How are design and development inputs documented?
- 3) Have regulatory requirements regarding the safety and effectiveness of the medical device been identified as design input requirements?



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

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



Guidance

ISO/TR 14969 provides the following guidance on design and development outputs:

Design and development outputs are the product requirements used for purchasing, production, inspection and testing, installation, servicing and service provision.

Throughout the design and development process, the requirements contained in the design description are translated by the organization into outputs. Design and development outputs should be recorded in terms which can be verified and validated against design and development input requirements and need to contain, or make reference to, acceptance criteria.

Design and development outputs can include

- specifications for raw materials, component parts and sub-assemblies,
- drawings and parts list,
- customer training materials,
- process and materials specifications,

- finished medical devices,
 - product and process software,
 - quality assurance procedures (including acceptance criteria),
 - manufacturing and inspection procedures,
 - work environment requirements needed for the device,
 - packaging and labelling specifications,
 - identification and traceability requirements (including procedures, if necessary),
 - installation and servicing procedures and materials,
 - documentation for submission to the regulatory authorities where the medical devices will be marketed, if appropriate, and
 - a record/file to demonstrate that each design was developed and verified in accordance with the design and development planning.
- [ISO/TR 14969, 7.3.3]



- 1) Are the outputs of design and development provided in a form that enables verification against the design and development inputs?
- 2) Are the outputs of design and development approved prior to release?
- 3) Do the design and development outputs
 - a) meet the input requirements for design and development?
 - b) provide appropriate information for purchasing, production, and service provision?
 - c) contain or reference product acceptance criteria?
 - d) specify the characteristics of the product that are essential for its safe and proper use?



- 1) Have we decided how to verify that design and development outputs meet the particular design and development inputs?



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, as well as other specialist personnel (see 5.5.1 and 6.2.1).

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



Definition

review

activity undertaken to determine the suitability, adequacy and **effectiveness** (3.2.14) of the subject matter to achieve established objectives [ISO 9000, 3.8.7]



Guidance

ISO/TR 14969 provides the following guidance on design and development reviews:

7.3.4.1 General

The timing of design and development reviews will be influenced by the maturity and complexity of the product being designed and developed.

At the defined stages of design and development (see 7.3.1), reviews can consider topics such as the following, as appropriate.

- a) Do designs satisfy specified requirements for the product?
- b) Is the input adequate to perform the design and development tasks?
- c) Are product design and processing capabilities compatible?
- d) Have safety considerations been addressed?
- e) What is the potential impact of the product on the environment?

- f) Do designs meet functional and operational requirements, for example, performance and dependability objectives?
- g) Have appropriate materials been selected?
- h) Have appropriate facilities been selected?
- i) Is there adequate compatibility of materials, components and/or service elements?
- j) Is the design satisfactory for all anticipated environmental and load conditions?
- k) Are components or service elements standardized and do they provide for reliability, availability and maintainability?
- l) Is there a provision in tolerances, and/or configuration, for interchangeability and replacement?
- m) Are plans for implementing the design technically feasible (e.g. purchasing, production, installation, inspection and testing)?
- n) If computer software has been used in design computations, modelling or analyses, has the software been appropriately validated, authorized, verified and placed under configuration control?
- o) Have the inputs to such software, and the outputs, been appropriately verified and documented?
- p) Are the assumptions made during the design and development processes valid?
- q) Are the results of model or prototype testing considered?
- r) Have risk management activities been carried out and, if so, are they adequate?
- s) Is the labelling adequate?
- t) Will the design reasonably accomplish the medical use intended?
- u) Is the packaging adequate, particularly for sterile devices?
- v) Is the sterilization process adequate?
- w) Is the device compatible with the sterilization method?
- x) How are changes and their effects controlled during the design and development process?
- y) Are problems being identified and corrected?
- z) Is the product meeting verification and validation goals?
- aa) What is the progress of the planned design and development process?
- bb) Are there opportunities for design and development process improvement?

7.3.4.2 Other specialist personnel

The requirement in ISO 13485 for “other specialist personnel”, in addition to those representing organizational functions who have direct concerns regarding the design and development being reviewed, obliges the organization to include person(s) who are capable of understanding the design and development information being reviewed.

Some national and regional regulatory bodies might require an individual(s) who does not have direct responsibility for the design and development stage being reviewed, as well as “other specialist personnel.” [ISO/TR 14969]



- 1) Have systematic reviews of design and development been conducted at suitable stages?
- 2) Do these reviews
 - a) evaluate the extent to which the design and development process fulfills the requirements?
 - b) identify any problems and propose necessary actions?
- 3) Do the participants in such reviews include representatives of the various design and development stages reviewed as well as any other specialists involved?
- 4) Are records of the results of the reviews and any necessary actions maintained?



- 1) Who is responsible for carrying out a systematic review of the design and development?
- 2) Who is responsible for approving the review results?



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).



Definitions

verification

confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled [ISO 9000, 3.8.4]

objective evidence

data supporting the existence or verity of something [ISO 9000, 3.8.1]



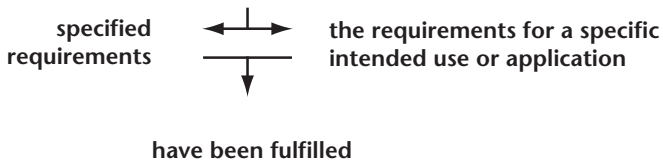
Guidance

The figure below compares the concepts of verification and validation. It reveals the similarities, as well as the important differences, between these two concepts.

Verification

Validation

Confirmation through the provision
of objective evidence, that



*In design and development,
the process of examining*

the result of an activity

a product

to determine conformity with

the stated requirements for that activity

user needs

Verification vs. validation

ISO/TR 14969 provides the following guidance on design and development verification:

Design and development verification is necessary to ensure that the design and development outputs conform to specified requirements (design and development inputs).

Verification activities can include, if appropriate,

- tests (e.g. bench tests, laboratory analyses),
- alternative calculations,
- comparison with proven design,
- inspections, and
- document reviews (e.g. specifications, drawings, plans, reports).

If tests and demonstrations are employed at any stage of the design and development verification, the safety and performance of the product should be verified under conditions which are representative of the full range of circumstances of actual use.

When alternative calculations or comparison with a proven design are employed as forms of design and development verification, the appropriateness of the alternative calculation method, and/or proven design, should be reviewed. This review should confirm that the alternative calculations or comparison with a proven design are actually scientifically valid methods of design verification for the design under consideration.
[ISO/TR 14969, 7.3.5]



- 1) Has verification been performed to ensure that the design and development output has satisfied the design and development input requirements?
- 2) Have records of the results of the verification and any necessary actions been maintained?



- 1) Who is responsible for verifying the design and development output against its corresponding input requirements?
- 2) Have we identified the verification method to be used, how it should be performed, and what records are to be kept?



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. Validation shall be completed prior to the delivery or implementation of the product (see Note 1).

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

As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (see Note 2).

NOTE 1 If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.

NOTE 2 Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.



Definition

validation

confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled [ISO 9000, 3.8.5]



Guidance

ISO/TR 14969 provides the following guidance on design and development validation:

After successful design and development verification, a design and development validation should be performed under actual or simulated conditions for the use of the final medical device. However, validation might need to be performed at earlier stages during product development if there are features which are not possible or practical to validate at the final stage.

Design and development validation goes beyond the technical issues of verifying that the design and development outputs meet the design and development inputs, and is intended to ensure that the medical device meets user requirements and the intended use in the hands of the intended user. This involves consideration of the knowledge and capabilities of the intended user, the operating instructions, compatibility with other systems, the environment in which it will be used, and any restriction on the use of the product.

Some national or regional regulations require clinical evaluations as part of design and development validation. Clinical evaluation can include one or more of the following to ensure that the medical device performs as intended:

- a critical analysis of relevant scientific literature in relation to the medical device being designed and developed;
- historical evidence that similar designs and/or materials are clinically safe;
- a clinical investigation (or trial).

For additional guidance regarding clinical evaluations, see ISO 14155-1.

The medical devices employed for validations should be produced under the conditions specified as “final” for the product (e.g. initial production units recognizing that production equipment or processes might change between production for validation and production for commercial distribution). The validation should be conducted under actual or simulated use conditions; this can involve clinical investigations in accordance with national or regional regulations. These points are important as many validations can be irrelevant or misleading if not done using products representative of the final product and process conditions, or not done under conditions of actual or simulated use.

For medical devices used for *in vitro* diagnosis, evaluation of performance consists of *in vitro* studies undertaken to ensure that the medical device performs as intended in laboratories for medical analyses or other suitable environments outside of the organization’s premises. [ISO/TR 14969, 7.3.6]



- 1) Has design and development validation been performed in accordance with planned arrangements?
- 2) Does the validation ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application?

- 3) Was the validation completed prior to the delivery or implementation of the product?
- 4) Have records of the results of validation and any necessary actions been maintained?



- 1) Have we identified the validation method to be used, how it should be performed, and what records are to be kept?
- 2) Have we recorded results of our design and development validation?



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).



Guidance

ISO/TR 14969 provides the following guidance on control of design and development changes:

- 7.3.7.1** Product design can be changed or modified for a number of reasons, and the change can happen during or after the design and development phase, for example,
- changes required following design and development review (see 7.3.4), design and development verification (see 7.3.5) or design and development validation (see 7.3.6),
 - omissions or errors (e.g. in calculation, material selection) during the design phase which have been identified afterwards,
 - difficulties in manufacturing, installation and/or servicing found after the design and development phases,
 - change requests from engineering,
 - change required in response to risk management activities,

- changes requested by the customer or supplier,
- changes required for corrective or preventive action (see 8.5),
- changes needed to safety, regulatory, or other requirements, and
- improvements to the function or performance of product.

7.3.7.2 Improving one characteristic might have an unforeseen adverse influence on another. For example, the following should be considered in order to help in avoiding this situation.

- a) Will the product still conform to the product requirements?
 - b) Will the product still conform to the product specifications?
 - c) Will the intended use be affected?
 - d) Will the existing risk assessment be adversely affected?
 - e) Will different components of the product or system be affected?
 - f) Will there be a need for further interface design (e.g. physical contact with other components in a product or system)?
 - g) Will the change create problems in manufacture, installation or use?
 - h) Will the design still be verifiable?
 - i) Will the change affect the regulatory status of the product?
- [ISO/TR 14969]



- 1) Have design and development changes been identified and records maintained?
- 2) Have the changes been reviewed, verified, and validated, as appropriate, and approved before implementation?
- 3) Does the review of design and development changes include evaluation of the effect of the changes on the constituent parts and the delivered product?
- 4) Have records of the results of the review of changes and any necessary actions been maintained?



- 1) Have the appropriate departments or personnel reviewed and approved the design and development change before implementation?



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).



Definitions

supplier

organization (3.3.1) or person that provides a **product** (3.4.2)
[ISO 9000, 3.3.6]

requirement

need or expectation that is stated, generally implied or obligatory
[ISO 9000, 3.1.2]



Guidance

ISO/TR 14969 provides the following guidance on the purchasing process:

7.4.1.1 The control of suppliers is a process consisting of establishing criteria, evaluating, selecting and ongoing monitoring. The application of the process depends on the nature and risk associated with the product or service, including outsourced processes (see 4.1), being purchased or otherwise received.

For instance, the process of evaluation and selection, and control might differ when applied to

- an original equipment manufacturer (OEM),
- a logistics service,
- an information technology service,
- a contract sterilizer,
- a supplier of material to the organization's specifications,
- a design and development service,
- a clinical evaluator,
- a consultant,
- a testing and calibration service, or
- a supplier of off-the-shelf components.

7.4.1.2 The evaluation of a supplier can include

- testing of samples of product or service to be provided,
- review of third-party evaluation reports,
- review of historical data, such as records of past performance,
- certification by a third party of the supplier's quality management system, or
- auditing of the supplier's quality management system by the organization.

7.4.1.3 Regardless of the method of evaluation, the organization is required to demonstrate that it has control over the purchased product or outsourced process by possessing objective evidence that the selection of a supplier was based on appraisals appropriate to the product or service being purchased and the supplier's ability to enable the organization to meet the customer and regulatory requirements associated with the medical device.

When monitoring the performance of suppliers, the organization should consider a supplier's third-party certification status, compliance trends and conformance history. The organization should define the frequency of supplier performance monitoring. The organization should also include in the supplier monitoring activities the need for their registration body to visit the supplier for the purpose of obtaining objective evidence that outsourced processes are under control, and that the products or services conform to the organization's specified requirements which might include customer and regulatory requirements. [ISO/TR 14969]



- 1) Has the organization ensured that the purchased product conforms to specified requirements?
- 2) Is the type and extent of control applied to the supplier dependent upon the effect of the purchased product on subsequent product realization or the final product?

- 3) Has the organization evaluated and selected suppliers based on their ability to supply product in accordance with the organization's requirements?
- 4) Has the organization established the criteria for selection, evaluation, and re-evaluation of suppliers?
- 5) Have records of evaluations of suppliers and any necessary actions arising from the evaluation been maintained?



- 1) Have we established documented procedures to ensure that private label purchased products conform to specified purchase requirements, including applicable regulatory requirements?



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 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).



Guidance

ISO/TR 14969 provides the following guidance on purchasing information:

The organization's purchasing information (including the requirement for supplier records) should define appropriate requirements and communicate

them to the supplier to ensure the quality of the purchased product or service, including outsourced processes.

Typically, these requirements are formalized in an agreement between the organization and the supplier. Examples of purchasing information include

- technical information and specifications,
- test and acceptance requirements,
- quality requirements for products, services and outsourced processes,
- environmental requirements,
- regulatory requirements,
- certification requirements,
- requirements for specific equipment,
- special instructions (e.g. traceability records), and
- conditions for the review and updating of the agreement.

The degree or specificity of the purchasing information should be dependent upon the effect of the purchased product or service on the medical device (see 7.4.1), for example, as determined during risk management activities.

For example, when cleaning operations in environmentally controlled areas are carried out by a supplier, a written contract specifying the limits of responsibility of the organization and the supplier should be considered in order that product is not contaminated by cleaning agents or personnel, or that areas are left uncleaned due to oversight. This contract should include details of the documented cleaning procedure and specify the training to be given to cleaning staff.

Specifications should define any special conditions required for storage or transport of the purchased product that could significantly affect the safety, effectiveness, or intended use of the medical device.

The organization may make reference to applicable technical information such as national or international standards and test methods. Another approach is for information to be clearly and precisely stated to the supplier on the purchase order. Responsibility for reviewing and approving the purchasing data should be clearly assigned to appropriate personnel to prevent the purchase of incorrect materials. The revision status of documents referenced in the purchasing data should be identified to ensure that the correct versions of materials are purchased.

Depending on an organization's traceability requirements (see 7.5.3.2 of this Technical Report), purchasing documents and records might need to be identified and retained; i.e. when evaluating the traceability requirements, consideration should be given to what purchasing information and records may also need to be retained to facilitate traceability. For example, if it is important to know to what specification revision a purchased part was ordered, then this information should be kept as part of the purchasing documents or records. [ISO/TR 14969, 7.4.2]



- 1) Does the purchasing information 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?
 - c) QMS requirements?
- 2) Has the organization ensured the adequacy of specified purchase requirements prior to their communication to the supplier?



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 maintained (see 4.2.4).



Definitions

inspection

conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging [ISO 9000, 3.8.2]

verification

confirmation, through the provision of **objective evidence** (3.8.1), that specified **requirements** (3.1.2) have been fulfilled [ISO 9000, 3.8.4]

**Guidance**

ISO/TR 14969 provides the following guidance on verification of purchased product:

Inspection on receipt is one method for the organization to verify that purchased product delivered to the organization's facilities fulfils specified requirements. If the purchased product is claimed to conform to the supplier's specification, the organization should check that the product meets the agreed specification. This check can be accomplished by various approaches, such as certification of suppliers, certificates of conformance, skip lot testing, 100% or sampling inspection, as determined by the requirements of the organization's quality management system.

The organization's documented procedures (see ISO 13485:2003, 7.4.1) should specify the method of verifying that shipments received are in accordance with specifications, are complete, have proper identity, and are undamaged. The procedures should also include provisions for verifying that incoming product is accompanied by the required supporting documentation (e.g. certificates of conformity, acceptance test reports). Appropriate action in the event of nonconformities should be specified (see 8.3) so that the nonconformity can be dealt with in a consistent manner (including identification, segregation and documentation) and without undue delay. Analysis of previous receiving inspection data, in-plant rejection history or customer complaints will influence the organization's decisions regarding the amount of inspection required, and the need to reassess a supplier.

This subclause does not imply that incoming product has to be inspected and tested by the organization. Incoming inspection might not be required if the necessary confidence in the product can be obtained by other defined processes or procedures, particularly if the information given by a supplier is considered sufficient.

The organization's documented procedures should define who is authorized to allow incoming product to be used before conformity to specified requirements for quality is demonstrated. Such a procedure ensures that decisions are made at a level in the organization that is aware of the possible impact on product realization if the incoming products do not subsequently meet the requirements. The organization's procedures should also define how such product will be positively identified and controlled in the event that subsequent inspection finds nonconformities, in order to facilitate corrective action.

These requirements apply to all products received from outside the organization's quality management system, whether payment occurs or not. [ISO/TR 14969, 7.4.3]



- 1) Has the organization established and implemented the inspection or other activities necessary to ensure that the purchased product meets specified requirements?
- 2) Where the organization or its customer intends to perform verification on the supplier's premises, has the organization stated the intended verification arrangements and method of release in the purchasing information?



- 1) Have we identified verification methods to ensure that purchased products and services meet specified requirements?



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, documented requirements, work instructions, and reference materials and reference measurement procedures 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 operations for labelling and packaging.*

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 amount manufactured and amount approved for distribution. The batch record shall be verified and approved.

NOTE A batch can be a single medical device.



Guidance

ISO/TR 14969 provides the following guidance on the control of production and service provision:

7.5.1.1.1 The generic guidance with respect to infrastructure given in 6.3 applies.

In considering which controlled conditions are applicable for a given process, an organization should consider the impact on quality or regulatory compliance. If, in the absence of the control, there is an adverse or potentially adverse affect on quality or regulatory compliance, then control is necessary. The amount of control and level of detail may be commensurate with the degree of criticality (e.g. based on the output of risk management activities) of the process in achieving the requirements for quality and the degree of training of product realization personnel.

Reference materials may be physical or visual, such as product examples indicating permissible colour variation, or visual such as photos of known non-conformities. Reference materials should be available at the point of use. An individual procedure could be in the form of a simple flowchart, or a processing sequence, combined with a checklist [see 4.2.1 d)].

Suitable equipment should be designed and selected so that process and product specifications are met. It should be verified that new and/or significantly modified equipment meets purchasing/design specifications and is capable of operating within its defined limits and the process operating limits.

7.5.1.1.2 The risk of labelling and packaging errors can be minimized by the introduction of appropriate controls such as

- segregation of packaging and labelling operations from other manufacturing (or other packaging and labelling) operations,
- avoidance of packaging and labelling product of similar appearance in close proximity,

- line identification,
- application of line clearance procedures,
- destruction of unused batch-coded materials on completion of packaging and labelling,
- use of roll-feed labels,
- use of a known number of labels and reconciliation of usage,
- on-line printing, including batch coding,
- use of electronic code encoders/readers and label counters,
- use of labels designed to provide clear product differentiation,
- inspection of label content before use, and
- proper storage of labels in areas of restricted access.

7.5.1.1.3 Records that facilitate traceability and review of the manufacture of a batch of product, derived during the manufacture of that batch, should be contained in a batch record, and are frequently collated in a single file. Such files can be referred to as a “Device History Record”, “Batch Manufacturing Record”, “Lot History Record” or “Lot Record” (see Annex A, section C) [see Appendix 3, section C, of this Handbook].

If it is not practical to include all the relevant documents in the batch record, then the record should list the titles of those documents and their location(s).

Batch records should be prepared from the currently approved versions of the specifications.

The forms that constitute the batch records should be designed and reproduced by an appropriate method to avoid clerical errors. A batch record should have a unique batch identification and relate to an individual manufacturing batch.

During manufacture, relevant information should be entered onto the batch record. Such information can include:

- the quantity of raw materials, components and intermediate products, and their batch number, if appropriate,
- the date of start and completion of different stages of production, including sterilization records if appropriate,
- the quantity of product manufactured,
- the signed results of all inspections and tests,
- the designation of the product line used, and
- any deviation from the manufacturing specifications. [ISO/TR 14969]



- 1) Does the organization plan and carry out the production and service provision under controlled conditions?

- 2) Do the controlled conditions include, as applicable
 - a) the availability of information that describes the characteristics of the product?
 - b) the availability of work instructions?
 - 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?
- 3) Are records available for each batch of medical devices to provide traceability and identify the number manufactured and approved for distribution?



- 1) Have we established procedures or work instructions to ensure that production and service provision is carried out as planned, under controlled conditions?
- 2) Are records available for each batch of medical devices manufactured?



7.5.1.2 Control of production and service provision — Specific requirements

7.5.1.2.1 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, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.

**Guidance**

ISO/TR 14969 provides the following guidance on the cleanliness of the product and contamination control:

The organization is required to define the product cleanliness requirements. In order to achieve these requirements (including the removal of process agents, if these agents could reasonably be expected to have an adverse affect on product quality), the organization can establish documented procedures, work instructions, and reference materials and reference measurement procedures as necessary.

Process agents, also known as ancillary materials, manufacturing materials or auxiliary materials, are any materials or substances used in, or used to facilitate, a manufacturing process, such as cleaning agents, mould-release agents, lubricating oils, or other substances which are not intended to be included in the finished devices. Process agents should be adequately identified and labelled to avoid confusion and processing errors. Consideration of the entire supply chain (components and manufacturing) are areas that are typically addressed (see also 7.5.5).

Some medical devices might need to be cleaned and/or decontaminated prior to servicing to ensure that employees and other product are not exposed to some form of contamination. In such cases, they should be decontaminated by appropriate, approved procedures.

NOTE Additional information relating to cleaning procedures is available in ISO 12891-1. [ISO/TR 14969, 7.5.1.2]

**7.5.1.2.2 Installation activities**

If appropriate, the organization shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.

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

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



Guidance

ISO/TR 14969 provides the following guidance on installation activities:

Installation of a medical device is the activity of putting the device into service in the location where it will be used. This activity might involve permanent connection to services (e.g. electrical supply, plumbing, waste disposal). Final testing of installed medical devices is carried out after it is in its location for use and connected to all relevant services. For medical devices, installation does not mean implantation in, or fitting to, a patient. The responsibility for installation should be clearly defined to ensure proper functioning of the medical device.

If a medical device must be assembled or installed at the user's site, instructions should be provided by the organization to guide correct assembly, installation, testing and/or calibrations. Special attention should be paid to ensure correct installation of safety control mechanisms and safety control circuits.

In certain cases (e.g. if required by a regulation, or if performance parameters of a medical device have to be controlled), the organization should provide instructions which allow the installer to confirm correct operation of the device. The results of installation or commissioning tests should be recorded (see 4.2.4). [ISO/TR 14969, 7.5.1.2.2]



7.5.1.2.3 Servicing activities

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

Records of servicing activities carried out by the organization shall be maintained (see 4.2.4).

NOTE Servicing can include, for example, repair and maintenance.

**Guidance**

ISO/TR 14969 provides the following guidance on servicing activities:

If the functionality of products depends on servicing or maintenance for proper use of the products, and if the organization provides for some or all of the product servicing by either warranty or contract, then the organization's quality management system should include provisions for the type and extent of servicing provided. The following activities are considered as appropriate:

- a) clarification of servicing responsibilities among the organization, distributors and users;
- b) planning of service activities, whether carried out by the organization or by a separate agent;
- c) validation of design and function of special-purpose tools or equipment for handling and servicing products after installation;
- d) control of measuring and test equipment used in field servicing and tests;
- e) provision and suitability of documentation, including instructions for use in dealing with the spares or parts lists, and in servicing of the product;
- f) provision for adequate back-up, to include technical advice and support, customer training, and spares or parts supply;
- g) training of servicing personnel;
- h) provision of competent servicing personnel;
- i) feedback of information which would be useful for improving product or servicing design;
- j) other customer support activities.

Even when not specified in a contract, the guidance given here can be helpful to the organization.

The organization should establish a system for receiving service requests to determine if there are customer complaints or requirements that are not being met. [ISO/TR 14969, 7.5.1.2.3]



- 1) Have we established procedures or work instructions for servicing activities?
- 2) Do we maintain records of servicing activities?

**7.5.1.3 Particular requirements for sterile medical devices**

The organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch (see 4.2.4). Sterilization records shall be traceable to each production batch of medical devices (see 7.5.1.1).

**Guidance**

According to ISO/TR 14969

The process parameters for sterilization processes usually applied to medical devices are identified in the relevant International Standards.

NOTE Additional information regarding sterilization is available in ISO 11134, ISO 11135, ISO 11137, ISO 13683, ISO 14160 and ISO 14937. [ISO/TR 14969, 7.5.1.3]

**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.

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 provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.

Records of validation shall be maintained (see 4.2.4)



Definition

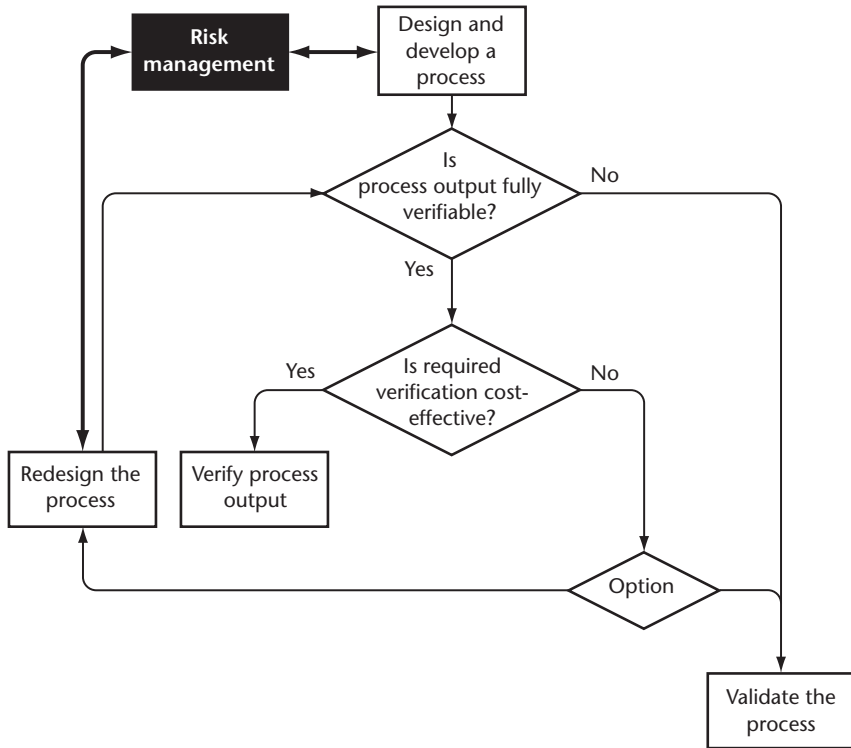
validation

confirmation, through the provision of **objective evidence** (3.8.1), that the **requirements** (3.1.2) for a specific intended use or application have been fulfilled [ISO 9000, 3.8.5]



Guidance

The decision tree in the figure below illustrates the relationship between the process validation requirement and verifiability.



Process validation decision tree

ISO/TR 14969 provides the following guidance on the validation of processes for product and service provision:

7.5.2.1.1 General

7.5.2.1.1.1 Process validation is the mechanism or activity used by the organization to ensure that a process whose output is not fully verifiable is capable of consistently providing product that meets specifications. Process validation includes the development of a plan, the staged conduct of a number of evaluations of a particular process, and the collection and interpretation of recorded data. These activities can be considered to fall into a model consisting of four phases:

- review and approval of equipment specifications;
- initial qualification of the equipment used and provision of necessary services — also known as installation qualification (IQ);
- demonstration that the process will produce acceptable results and establishment of limits (worst case) of the process parameters — also

- known as operational qualification (OQ);
- d) establishment of long-term process stability — also known as performance qualification (PQ).

7.5.2.1.1.2 The following is a list of examples of processes that normally — should be validated, or

- can be satisfactorily covered by verification, or
- need individual consideration of the circumstances of use and the controls in place to determine whether some or all of the elements of validation are required.

7.5.2.1.1.3 Processes that should be validated include

- sterilization,
- maintenance of specified conditions in environmentally controlled areas,
- aseptic processing,
- sealing of sterile packaging,
- lyophilization, and
- heat-treatment.

7.5.2.1.1.4 Processes that can be satisfactorily covered by verification include

- manual cutting,
- testing for colour, turbidity, total pH for solutions,
- visual inspection of printed circuit boards, and
- manufacturing and testing of wiring harnesses.

7.5.2.1.1.5 Processes that need individual consideration of the circumstances of use and the controls in place to determine whether some or all of the elements of validation are required include

- cleaning,
- manual assembly,
- numerical control cutting, and
- filling.

7.5.2.1.1.6 Cleaning processes might be required to remove process agents and/or particulate contamination. Such cleaning processes should be validated as to the effectiveness of the process for removing the contamination in accordance with a documented procedure (see 7.5.2). Records of validation are maintained (see ISO 13485:2003, 4.2.4). The process parameters used for the cleaning processes should be routinely monitored in accordance with documented procedures. Records of this monitoring should be maintained (see ISO 13485:2003, 4.2.4).

When a cleaning process is intended to remove contamination (e.g. microbiological, viral, chemical, radioactive), the validation protocol, the results of the validation and the final operating procedure should be reviewed or approved by a qualified person.

NOTE Additional information regarding microbial monitoring is available in ISO 11737-1.

7.5.2.1.1.7 Process validation planning should include, but not be limited to, the following considerations:

- the accuracy and variability of the process parameters, including the settings of the equipment used;
- the skill, capability and knowledge of operators to conform to quality requirements;
- the adequacy of control of all processes, including environmental parameters;
- the qualification of processes and equipment, as appropriate;
- the acceptance criteria and the process for handling process performance that does not meet these criteria;
- the circumstances that require process revalidation.

7.5.2.1.1.8 Some processes require that operators have extra training and/or be specially qualified, or that the process itself should have specific approval, as in the following example.

When qualifying an operator in sterile package sealing, if visual or other non-destructive examination for soundness of the seal would give no information on weld strength, the operator is required to be trained and qualified to carry out the sealing process according to a validated process procedure in order to provide assurance of seal strength.

When introducing a new or significantly changed process, including any new manufacturing and test methods, the process should be evaluated to determine whether validation is necessary.

NOTE Additional guidance on process validation is available in GHTF.SG3.N99-10.

7.5.2.1.2 Statistical methods and tools for process validation

There are many statistical methods and tools which may be used in process validation. Control charts, capability studies, designed experiments, tolerance analysis, robust design methods, failure modes and effects analysis (FMEA), sampling plans and mistake-proofing are some examples.

7.5.2.1.3 Computer software used in process control

The requirements of ISO 13485 regarding the validation of the application of computer software used in process control apply, whether or not such software is purchased, developed, maintained, or modified for automated production or process control purposes.

NOTE Additional information relating to the validation of the application of computer software is available in, for example, Good Automated Manufacturing Practice (GAMP) guidelines. [ISO/TR 14969]



- 1) Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement?
- 2) Does the organization validate any processes where deficiencies become apparent only after the product is in use or the service has been delivered?
- 3) Does this validation demonstrate the ability of these processes to achieve planned results?
- 4) Has the organization established arrangements for the following processes, as applicable:
 - a) defining criteria for review and approval of the processes?
 - b) approval of equipment and qualification of personnel?
 - c) use of specific methods and procedures?
 - d) determining requirements for records?
 - e) revalidation?



- 1) Have we identified those processes where the results cannot be verified by subsequent monitoring and measurement?
- 2) Are these processes validated to ensure that specified requirements are met?
- 3) How do we maintain records of validation of processes?



7.5.2.2 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.

Records of validation of each sterilization process shall be maintained (see 4.2.4).

**Guidance**

ISO/TR 14969 provides the following guidance on particular requirements for sterile medical devices:

Sterilization is an example of a process that cannot be verified by inspection and testing of the medical device. Therefore, sterilization processes must be validated before use and the process must be closely controlled and monitored (see 7.5.2.1). International Standards are available covering the development, validation and routine control of sterilization process and the aseptic manufacture of sterile medical devices. Sterilization processes validated and controlled in accordance with the requirements of existing International Standards should not be assumed to be effective in inactivating the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy (BSE), and Creutzfeld-Jakob disease. Specific recommendations have been produced in certain countries or regions for the processing of materials which are potentially contaminated with these agents.

NOTE Additional information regarding sterilization is available in ISO 11134, ISO 11135, ISO 11137, ISO 13683, ISO 14160, ISO 14937. Additional information regarding aseptic processing of medical devices is available in ISO 13408-1.

It is important to be aware that exposure to a properly validated and accurately controlled sterilization process is not the only factor associated with ensuring that the medical device is sterile. It can also be important that attention be given to the microbiological status of incoming raw materials and their subsequent storage, and to the control of the environment in which the medical device is manufactured, assembled and packaged (see 6.4). [ISO/TR 14969, 7.5.2.2]



- 1) Have we validated the sterilization process used for each medical device?



7.5.3 Identification and traceability

7.5.3.1 Identification

The organization shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification.

The organization shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product [see 6.4 d)].



Guidance

ISO/TR 14969 provides the following guidance on identification:

7.5.3.1.1 Identification of raw materials, components and finished medical devices is important for a number of reasons, including

- controlling material throughout manufacture,
- demonstrating product source, status and safety requirements,
- permitting traceability, and
- facilitating fault diagnosis in the event of quality problems.

Identification of product may be achieved by marking, tagging, or specifying a physical location for the product or its container. For example, on visually identical parts, if the functional characteristics are different, then different colours could be used. For bulk product or product from continuous processes, the identification could be by marking of batches or well-defined lots and accompanying documents.

7.5.3.1.2 It is usual for finished medical devices to be identified by a batch/lot/serial number or by electronic means. The extent to which raw materials and components need to be identified and related to the finished medical device batch/lot or serial number can depend upon a number of factors such as

- raw materials involved,
- type of medical device,
- effect of failure of the medical device or components, or raw materials used therein,
- specified requirements,
- traceability, if necessary,

- design and development input, and
- regulatory requirements.

Any marking materials used for product identification, if applied to medical devices or components, should not have a deleterious effect on the safety or performance of the medical device. [ISO/TR 14969]



- 1) Have we identified all components and materials used in the manufacture of the finished medical device?
- 2) Have we established procedures for handling returned product?
- 3) Do we distinguish returned product from conforming product?



7.5.3.2 Traceability

7.5.3.2.1 General

The organization shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5).

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.



Definitions

configuration management

coordinated activities to direct and control configuration

NOTE Configuration management generally concentrates on technical and organizational activities that establish and maintain control of a product and its **product configuration information** (3.9) throughout the live cycle of the product. [ISO 10007, 3.6]

product configuration information

requirements for product design, realization, verification, operation and support [ISO 10007 3.9]

traceability

ability to trace the history, application or location of that which is under consideration

NOTE 1 When considering **product** (3.4.2), traceability can relate to

- the origin of materials and parts,
- the processing history, and
- the distribution and location of the product after delivery.

NOTE 2 In the field of metrology the definition in VIM:1993, 6.10, is the accepted definition. [ISO 9000, 3.5.4]



Guidance

ISO/TR 14969 provides the following guidance on traceability:

Identification of product by batch/lot/serial number or electronic means permits traceability in two directions: forward to customers (also known as “device tracking”); and backward to raw materials, components and processes used in manufacturing. The former is important if it is necessary to track medical devices to the user (e.g. patients or hospitals), and the latter enables investigation of quality problems and feedback for the prevention of nonconforming product.

Product traceability involves the ability to trace the history, application or location of a product or activity by means of recorded identification. Traceability is typically required when there is a need to trace a

nonconformity back to its source and to determine the location of the remainder of the affected batch.

The organization typically ensures traceability throughout the production and warehousing process, and up to the point when the medical device leaves the organization's possession. The organization may choose to limit the traceability activities to particular parts of its operation.

NOTE Additional information regarding the use of configuration management as a means to maintain identification and traceability is available in ISO 10007. [ISO/TR 14969, 7.5.3.2.1]



- 1) Where traceability is a requirement, has the organization controlled and recorded the unique identification of the product?



- 1) Have we specified unique identification of individual products or batches?



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

In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if 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 to allow traceability and that such records are available for inspection.

Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4)

**Guidance**

ISO/TR 14969 provides the following guidance on particular requirements for active implantable medical devices and implantable medical devices:

A traceability system for implantable and active implantable medical devices is essential because it might not be possible to inspect the device while it is in use. Traceability can, therefore, avoid unnecessary explanation of implanted devices by precisely identifying those implants which incorporated a component subsequently identified to be faulty, or for which some process control has subsequently been shown to be inadequate. Regulatory requirements for certain higher risk implants may require additional traceability beyond the organization's possession, and the quality management system should take account of these as appropriate.

The organization can achieve traceability by each individual product having an identifier (e.g. serial number, date code, batch code, lot number) unique to the source of operation. Separate identifiers could be required for changes in operative personnel, changes in raw materials, changes in tooling, new or different machine set-ups, changes in process methods, etc. Traceability identifiers should appear on applicable inspection and stock records (see 4.2.4).

There can be situations where traceability requires identification of the specific personnel involved in each phase of medical device processing or delivery. A sequence of individuals may perform successive service functions, each of which is to be traceable. The recording of identification evidence through signatures on serially numbered documents is an example. Each individual's identification evidence should be traceable.

[ISO/TR 14969, 7.5.3.2.2]



- 1) Who is responsible for ensuring that our agents or distributors maintain distribution records?
- 2) Have we ensured that our agents or distributors maintain distribution records and that they are kept in accordance with Clause 4.2.4 of ISO 13485?



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.



Guidance

ISO/TR 14969 provides the following guidance on status identification:

Status can be indicated by marking, location, tagging or signing, either physically or by electronic means.

The status should indicate whether or not product has been inspected and tested, and

- accepted as fully meeting requirements,
- accepted with identified nonconformities under concession,
- on hold awaiting further analysis/decision, or
- rejected as unsatisfactory.

Separate physical location of these categories of product is often the most certain method of assuring both the status and accurate disposition.

However, in an automated process, accurate disposition can equally as well be achieved by other means, such as by using a computer database.

Any marking materials, used for indication of inspection and test status, applied to medical devices or components should not have a deleterious effect on medical device safety or performance. [ISO/TR 14969, 7.5.3.3]



- 1) Where appropriate, has the organization identified the product by suitable means throughout product realization?
- 2) Has the organization identified the product status with respect to monitoring and measurement requirements?



- 1) Are we continually informed of the inspection and test status of a product throughout production, installation, and servicing?



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 or confidential health information.



Guidance

ISO/TR 14969 provides the following guidance on customer property:

The organization should identify responsibilities in relation to property and other assets owned by customers and under the control of the organization, in order to protect the value of the property.

Examples of such property are

- raw materials or components supplied for inclusion in product (including packaging materials),
- product supplied for repair, maintenance or upgrading,
- product supplied for further processing (e.g. packaging, sterilization or testing),
- services provided on behalf of the customer (such as transport of customer property to a third party), and
- customer intellectual property (including specifications, drawings and proprietary information).

The organization retains the responsibility for the protection of customer property awaiting further processing when it provides these to external

organizations for services such as storage and contract sterilization.
[ISO/TR 14969, 7.5.4]



- 1) Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?
- 2) Does the organization identify, verify, protect, and safeguard customer property provided for use or for incorporation into the product?
- 3) If any customer property is lost, damaged, or otherwise found to be unsuitable for use, is this reported to the customer and are records maintained?



- 1) Does Clause 7.5.4 of ISO 13485 apply to my organization?
- 2) Who is responsible for control of customer-supplied product?
- 3) Does the scope of the procedure cover all customer-supplied material, components, etc.?
- 4) How are deficiencies in the customer-supplied product or service recorded?
- 5) Who contacts the customer if problems occur with its product?
- 6) Have material control procedures been referenced?



7.5.5 Preservation of product

The organization shall establish documented procedures or documented work instructions 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 or documented work instructions 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).

**Guidance**

ISO/TR 14969 provides the following guidance on the preservation of product:

Consideration should be given to the various types of delivery and variations in environmental conditions which can be encountered.

The organization's method for handling product might need to consider providing equipment (such as antistatic wrist straps, gloves and protective clothing) and transportation units (such as pallets, containers, conveyors, vessels, tanks, rigging, pipelines and vehicles). This is necessary so that damage, deterioration or contamination due to vibration, shock, abrasion, corrosion, temperature variation, electrostatic discharge, radiation or any other conditions occurring during handling and storage, can be prevented. Maintenance of handling equipment is another factor to be considered.

Packaging materials and the packaging process should provide adequate protection against damage to the product. During storage and transportation up to the point of use, the packaging materials and labelling (see 7.3.3) of medical devices are intended to provide appropriate protection against damage, deterioration or contamination.

The organization must provide suitable storage facilities, considering not only physical security but also environmental conditions (e.g. temperature and humidity). It might be appropriate to check product periodically in storage to detect possible deterioration. Consideration might need to be given to administrative procedures for product expiration dates, stock rotation and lot segregation.

Examples of preservation measures include the maintaining of

- sterile conditions for medical equipment,
- dust- and static-free conditions for semiconductors,
- temperature/humidity and hygienic conditions, and
- protection for fragile products.

The identification of product with a limited shelf life or expiration date, or product which requires special protection during storage and transportation, is important to ensure that such product is not used if the shelf life or expiration date has expired. The organization therefore should define the medical device shelf life applicable under specified storage conditions. Such special storage conditions must be controlled and recorded (see ISO 13485:2003, 4.2.4). [ISO/TR 14969, 7.5.5]



- 1) Does the organization preserve the conformity of product during internal processing and delivery to the intended destination?
- 2) Does this preservation include identification, handling, packaging, storage, and protection?
- 3) Does this preservation also apply to the constituent parts of a product?



- 1) Do we have components and products with a limited shelf life or with special storage requirements?
- 2) How are these products identified?
- 3) What controls are in place to assess the condition of products in stock?
- 4) How are receipt and dispatch from storage rooms authorized?
- 5) What handling methods are in place to prevent damage and deterioration of the product?



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.

NOTE See ISO 10012 for guidance related to measurement management systems.



Definitions

measuring equipment

measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a **measurement process** (3.10.2) [ISO 9000, 3.10.4]

measurement process

set of operations to determine the value of a quantity [ISO 9000, 3.10.2]



Guidance

ISO/TR 14969 provides the following guidance on control of monitoring and measuring devices:

7.6.1 The requirements refer explicitly to monitoring and measuring devices, including test software. It is helpful to approach the subject of control of monitoring and measuring devices from the perspective that measuring is itself a process involving materials, equipment and procedures. The intent of the requirements is to give the organization confidence in the monitoring and measuring devices that it uses to ensure that product meets customer and regulatory requirements.

Statistical methods are important in showing which monitoring and measuring devices are used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

The requirements of this subclause are also applied by the organization when demonstrating the conformity of product to the specified requirements. This can involve measurements subsequent to production and inspection of product (e.g. during handling, storage, packaging, preservation, delivery or servicing).

Documented procedures should include details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

7.6.2 Some monitoring and measuring devices are not used for purposes which affect the quality of the product or service provided by the organization. As a result, the following examples are not necessarily part of the organization's control programme:

- instruments which are used to provide an indication only (e.g. a pressure gauge used only to determine the existence of line pressure), but are not used to control the actual manufacturing process, or a pressure gauge on a fire extinguisher or on a sprinkler system;
- instruments which are associated with business administration (e.g. clocks to control working times, thermostats to control operator comfort);
- instruments which can be attached to process equipment, but are not used for process control.

7.6.3 Some monitoring and measuring devices which require initial calibration or certification need not be included in the control programme. Examples of such equipment are

- mercury-in-glass thermometers,
- steel rulers, and
- laboratory volumetric measurement glassware that is not exposed to processes or environments which might affect its calibration.

Monitoring and measuring materials intended to provide a qualitative reference should be stored and maintained in a location which does not compromise the integrity of the material.

7.6.4 Software applications related to the control and/or calibration of monitoring and measuring devices should be validated. Examples include software used for

- controlling the instrument calibration process,
- determining the control or calibration status of instruments based on the data generated during the process, and
- scheduling the calibration of equipment, if the scheduling is not backed up by a manual (e.g. calibration label or other system).

NOTE Additional information regarding the management of monitoring and measuring equipment is available in ISO 10012. [ISO/TR 14969]

See also ISO 17025.



- 1) Has the organization determined the monitoring and measurement to be undertaken, and the monitoring and the measuring devices needed, to provide evidence of conformity of product to determined requirements?
- 2) Has the organization established processes to ensure that monitoring and measurement can be carried out?
- 3) Are these processes carried out in a manner that is consistent with the monitoring and measurement requirements?

- 4) Where necessary to ensure valid results, are the monitoring and measuring devices calibrated or verified at specified intervals?
- 5) Has the calibration been done against measurement standards traceable to international or national measurement standards? Where no such standards exist, has the basis for calibration or verification been recorded?
- 6) Where necessary to ensure valid results, are the monitoring and measuring devices
 - a) adjusted or readjusted as necessary?
 - b) identified to enable the calibration status to be determined?
 - c) safeguarded from adjustments that would invalidate the measurement result?
 - d) protected from damage and deterioration during handling, maintenance, and storage?
- 7) Does the organization
 - a) assess and record the validity of the previous measuring results when the monitoring and measuring devices are found not to conform to requirements?
 - b) take appropriate action regarding nonconforming monitoring and measuring devices and any product affected?
- 8) Are records of the results of calibration and verification maintained?
- 9) When computer software is used in the monitoring and measurement of specified requirements, has the ability of this software to satisfy the intended application been confirmed? Was this confirmation undertaken prior to initial use and is it reconfirmed as necessary?



- 1) Who is responsible for ensuring control of all monitoring and measuring devices?
- 2) Do we have a list of all measuring and monitoring devices needed to provide evidence of the conformity of the product to determined requirements?
- 3) How are the monitoring and measuring devices identified in this list?
- 4) What is the calibration procedure?
- 5) How is calibration status indicated on measuring equipment?
- 6) How are monitoring and measuring devices safeguarded from adjustments?
- 7) How are monitoring and measuring devices protected from damage and deterioration?

- 8) Have we confirmed the ability of computer software to satisfy the intended application?



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 might require documented procedures for implementation and control of the application of statistical techniques.



Definitions

conformity

fulfilment of a **requirement** (3.1.2) [ISO 9000, 3.6.1]

effectiveness

extent to which planned activities are realized and planned results achieved [ISO 9000, 3.2.14]

efficiency

relationship between the result achieved and the resources used [ISO 9000, 3.2.15]



Guidance

ISO/TR 14969 provides the following guidance on measurement, analysis, and improvement:

8.1.1 If documented procedures for inspection and testing activities are required, they usually include details of test methods, acceptance and rejection criteria, and equipment to be used.

The organization's procedures should ensure that the integrity of the inspection and test results are not compromised, particularly if testing is done by persons with potential conflicts of interest, such as suppliers or production personnel.

Measurement, and analysis include the following considerations:

- measurement data should be converted to information and knowledge to be of benefit to the organization;
- measurement, and analysis of products and processes, should be used to establish appropriate priorities for the organization;
- measurement methods employed by the organization should be reviewed as necessary.

8.1.2 The use of statistical methods can be beneficial to the organization in a wide range of circumstances, including data collection, analysis and application. These techniques are useful for demonstrating process capability, as well as product conformity to specified requirements. They assist in deciding what data to obtain, and in making the best use of the data to gain a better understanding of customer requirements and expectations.

Statistical methods can also find uses in

- designing product and processes,
- controlling processes,
- avoiding nonconformity,
- analysing problems,
- determining risk,
- investigating root causes,
- establishing product and process limits,
- forecasting,
- verifying and validating products or processes, and
- measuring or assessing quality characteristics.

8.1.3 Among the statistical methods which can be beneficial for these purposes are the following:

- graphical methods (histograms, sequence charts, scatter plots, Pareto diagrams, cause and effect diagrams, etc.) which help diagnose problems and suggest appropriate computational approaches for further statistical diagnosis;
- statistical control charts for monitoring and controlling production and measurement processes for all types of product (hardware, software, processed materials and services);
- design of experiments for determining which candidate variables have significant influence on process and product performance, and for quantifying the effect;

- regression analysis, which provides a quantitative model for the behaviour of a process or a product when the conditions of process operation or product design are changed;
- analysis of variance (separating the total observed variability), leading to variance component estimates useful for designing sample structures for control charts, for product characterization and release, and for prioritizing quality improvement efforts based on the magnitudes for the variance components;
- methods of sampling and acceptance;
- sampling at all stages of production;
- statistical methods for inspections and testing.

8.1.4 Once the appropriate statistical techniques are chosen, it is important to implement those techniques in such a manner that appropriate data are collected and evaluated, and the results are reported to the relevant departmental functions, so that necessary actions can be taken. The data resulting from the application of statistical techniques can be an effective means of demonstrating conformity to requirements for quality and can be used as quality records. The documentation of such techniques and the records resulting from them might be subject to regulatory requirements.

NOTE Additional information regarding statistical techniques is available in ISO/TR 10017. [ISO/TR 14969]



- 1) Has the organization planned and implemented the monitoring, measurement, analysis, and improvement processes needed to
 - a) demonstrate conformity of the product?
 - b) ensure conformity of the QMS?
 - c) ensure the effectiveness of the QMS?
- 2) Does this include determination of applicable methods, including statistical techniques, and the extent of their use?



- 1) Who is responsible for the planning of the monitoring and measurement activities for
 - a) determining conformity of the product?
 - b) determining conformity of the QMS?
 - c) ensuring the effectiveness of the QMS?
- 2) Who determines the applicable methods, including the statistical techniques, and the extent of their use?

- 3) What forms do we use and what information is maintained in our records?



8.2 Monitoring and measurement

8.2.1 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 procedure for a feedback system [see 7.2.3 c)] 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).



Guidance

ISO/TR 14969 provides the following guidance on feedback:

Management should recognise that many sources exist for obtaining customer-related information. This information is useful for providing feedback related to the quality of medical devices and related services. The organization should identify relevant sources of such information and establish an effective process to collect, analyse and use the information for monitoring quality problems. The process established has to be documented, so that regulatory requirements are met.

Examples of customer-related information that demonstrates whether or not the requirements of customers have been met, include

- customer and user surveys,
- feedback on aspects of the medical device,
- customer complaints (see 8.5.1),
- customer requirements and contract information,
- regulatory authority compliance-related communications,

- peer-reviewed journals, and
- service delivery data.

As part of a regulated organization's requirement to provide early warning of quality problems, vigilance or post-market surveillance systems are typically implemented.

NOTE Additional information regarding vigilance and post-market surveillance systems is available on the websites of many regulatory authorities. [ISO/TR 14969, 8.2.1]



- 1) Who is responsible for monitoring information relating to our ability to meet customer requirements?
- 2) What forms are used to collect the information?
- 3) Have we established a feedback system to provide early warning of quality problems?
- 4) Have we established a documented procedure for this feedback system?



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 for guidance related to quality auditing.



Definitions

audit

systematic, independent and documented **process** (3.4.1) for obtaining **audit evidence** (3.9.4) and evaluating it objectively to determine the extent to which **audit criteria** (3.9.3) are fulfilled [ISO 9000, 3.9.1]

audit criteria

set of policies, **procedures** (3.4.5) or **requirements** (3.1.2)

NOTE Audit criteria are used as a reference against which **audit evidence** (3.9.4) is compared. [ISO 9000/FDAM1, 3.9.3]

audit evidence

records (3.7.6), statements of fact or other **information** (3.7.1) which are relevant to the **audit criteria** (3.9.3) and verifiable [ISO 9000, 3.9.4]

audit findings

results of the evaluation of the collected **audit evidence** (3.9.4) against **audit criteria** (3.9.3) [ISO 9000, 3.9.5]

audit programme

set of one or more **audits** (3.9.1) planned for a specific time frame and directed toward a specific purpose [ISO 9000, 3.9.2]

auditor

person with the demonstrated personal attributes and **competence** (3.1.6) to conduct an **audit** (3.9.1)

NOTE The relevant personal attributes for an auditor are described in ISO 19011. [ISO 9000/FDAM1, 3.9.9]

nonconformity

non-fulfilment of a **requirement** (3.1.2) [ISO 9000, 3.6.2]

NOTE: Please consult Appendix 1 to review the latest audit terms and definitions.

**Guidance**

ISO/TR 14969 provides the following guidance on internal audits:

Planning for internal audits should be flexible in order to permit changes in emphasis based on findings and objective evidence obtained during the audit. Relevant input from the area to be audited, as well as from other interested parties such as customers, corporate audit plans, or third-party assessment organizations, should be considered in the development of internal audit plans.

The results of audits are usually stated in a written report (see 4.2.4) which indicates the deficiencies found. Avoiding undue delay is usually accomplished by including appropriate target dates for responding to audit findings. The audit results can be communicated and used as an input to management review (see ISO 13485:2003, 5.6.2).

A series of limited, well-defined audits can be as effective as one single comprehensive audit. Such an audit system can be operated flexibly to give special, or repeat, attention to any areas of weakness or of other concern.

In addition to the periodic internal audits, a special internal audit can be initiated for the following purposes:

- when verifying that the quality management system continues to meet specified requirements and is being implemented, if required, within the framework of a contractual relationship;
- when undergoing significant changes in functional areas (e.g. reorganizations or procedural revisions);
- when investigating safety, performance or dependability of the products which are, or which are suspected to be, in jeopardy due to nonconformities;
- when verifying which required corrective actions have been taken and have been effective.

Internal audits may be partially or fully subcontracted. [ISO/TR 14969, 8.2.2]

For additional guidance, consult ISO 19011, *Guidelines for quality and/or environmental management systems auditing*.



- 1) Has the organization conducted internal audits at planned intervals to determine whether the QMS
 - a) conforms to the planned arrangements?
 - b) conforms to the requirements of ISO 13485?
 - c) conforms to the QMS requirements established by the organization?
 - d) is effectively implemented and maintained?
- 2) Has an audit program been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?
- 3) Have the audit criteria, scope, frequency, and methods been defined?
- 4) Do the selection of auditors and conduct of audits ensure the objectivity and impartiality of the audit process?
- 5) Does the organization ensure that auditors do not audit their own work?
- 6) Have the responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records been defined in a documented procedure?
- 7) Has the management responsible for the area being audited ensured that actions are taken, without undue delay, to eliminate detected nonconformities and their causes?
- 8) Do follow-up activities include the verification of the actions taken and the reporting of verification results?



- 1) Who is responsible for conducting and reporting audit results?
- 2) How are auditors selected to ensure objectivity and impartiality of the audit?
- 3) Are the audits scheduled and conducted in accordance with documented procedures, using a written checklist or equivalent?

- 4) Do the audit records show the deficiencies found and the corrective actions required?
- 5) Who is responsible for training personnel to audit the QMS?
- 6) Are authorizations made for follow-up audits when required?
- 7) Have internal audit staff members been trained in auditing techniques?
- 8) Are auditors competent to perform internal audits?
- 9) Have we established which documents make up the audit records?



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.



Definitions

corrective action

action to eliminate the cause of a detected **nonconformity** (3.6.2) or other undesirable situation [ISO 9000, 3.6.5]

correction

action to eliminate a detected **nonconformity** (3.6.2) (ISO 9000, 3.6.6]



Guidance

Monitoring and measurement of the QMS include processes such as product realization, management review, internal audits, and training.



- 1) Has the organization applied suitable methods for monitoring and, where applicable, measurement of the QMS processes?
- 2) Do these methods demonstrate the ability of the processes to achieve planned results?
- 3) When planned results are not achieved, has corrective action been taken, as appropriate, to ensure conformity of the product?



- 1) Who is responsible for
 - a) determining which of the QMS processes need to be measured and how they will be measured?
 - b) monitoring the QMS processes?
- 2) Do the results show that the processes achieve the planned results?
- 3) What are the methods of handling corrective actions when the planned results are not achieved?



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 7.5.1.1).

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.

**Guidance**

ISO/TR 14969 provides the following guidance on monitoring and measurement of product:

8.2.4.1.1 In-process inspection and testing includes all such activities between the acceptance of incoming materials and submission of the medical device for final inspection. The results of in-process inspection and testing can be used both for process control and for the early identification of nonconforming product.

Final inspection involves activities (examination, inspection, measurement or test) upon which the final release of product is based. Records of previously performed inspection and testing results can also be reviewed.

The specified requirements forming the basis of final inspection and test should include all designated release criteria. These should be directly related to the type of medical device involved and its intended use. Final inspection and testing should provide objective evidence of conformity with all designated release criteria that have not been confirmed through previous inspection and testing. Final testing can include, if practical, testing under simulated or actual conditions of use, and using medical products selected from a lot or batch.

In the case of medical devices that are assembled and/or installed at the user's premises, any additional inspection and testing should be carried out after completion of assembly/installation. In such cases, these inspection and testing activities might not be carried out by the organization, but the organization should ensure the availability of all necessary information about the inspection and test procedure and the results expected (see also 6.3, 6.4, 7.5.1, 7.5.1.2 and 7.5.2).

8.2.4.1.2 When selecting measurement methods for ensuring that product conforms to requirements and when considering customer requirements, the organization should consider the following:

- the types of product characteristics, which then determine the types of measurement, suitable measurement means, the accuracy required and skills needed;
- the equipment, software and tools required;
- the location of suitable measurement points in the realization process sequence;
- the characteristics to be measured at each point, and the documentation and acceptance criteria to be used;
- the customer-established points for observation or verification of selected characteristics of the product;

- the inspections or testing required to be observed or performed by regulatory authorities;
- the timing and manner in which the organization intends, or is required by the customer or regulatory authorities, to engage qualified third parties to perform activities within the quality management system;
- the qualification of people, materials, products, processes and the quality management system;
- the final inspection to confirm that verification activities have been completed and accepted;
- recording the results of product measurements.

The organization's inspection and test records (see 4.2.4) should facilitate assessment of in-process and finished products having fulfilled the requirements for quality. Purchased product is verified under the provisions of ISO 13485:2003, 7.4.3.

8.2.4.1.3 As applicable, records of monitoring and measurements can

- identify the inspection/test procedure(s) and revision level used (see also 4.2.3),
- identify the test equipment used,
- include test data,
- be signed and dated by the person responsible for the inspection or test,
- clearly identify the number of products examined and the number of products accepted, and
- record the disposition of any products failing inspection or test, and the reasons for failure. [ISO/TR 14969]



- 1) Do results of monitoring and measurement show evidence of conformity of the product to the acceptance criteria at the various stages of the product realization process?
- 2) Does the organization monitor and measure the characteristics of the product to verify that product requirements are fulfilled?
- 3) Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements?
- 4) Is evidence of conformity to the acceptance criteria maintained?
- 5) Do the records indicate the person(s) authorizing release of product?
- 6) Does the organization ensure that product release and service delivery do not proceed until all the planned arrangements have been satisfactorily completed?



- 1) Who is responsible for determining what characteristics of the product are to be monitored and measured?
- 2) Who performs the work and authorizes the release of the product?
- 3) How is product held until inspection or testing is complete?
- 4) How is nonconforming product identified?



8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices

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



Guidance

ISO/TR 14969 provides the following guidance on particular requirements for active implantable medical devices and implantable medical devices:

In addition to inspection and test records (see 4.2.4), the organization should record the identity of personnel performing any inspection or testing of active implantable or implantable devices to facilitate failure investigation, and corrective and preventive actions. [ISO/TR 14969, 8.2.4.2]



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;*
- c) by taking action to preclude its original intended use or application.

The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4).

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 process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).

**Definition****nonconformity**

non-fulfilment of a **requirement** (3.1.2) [ISO 9000, 3.6.2]

**Guidance**

ISO/TR 14969 provides the following guidance on the control of nonconforming product:

8.3.1 People in the organization should be empowered with the authority and responsibility to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities.

Top management of the organization should ensure the establishment of an effective process to provide for review and disposition of identified nonconformities.

Nonconforming product includes nonconforming product occurring in the organization's own facilities as well as to nonconforming product received or delivered by the organization.

8.3.2 Procedures established and maintained by the organization should have the following purposes:

- to determine which product is involved in the nonconformity (e.g. what production time interval, production machines or products) and the number of products involved;
- to identify the nonconforming product to make sure that it can be distinguished from the conforming product (see 7.5.3);
- to document the existence and source of the nonconformity;
- to evaluate the nature of the nonconformity;
- to consider the alternatives for the disposition of the nonconforming product;
- to decide upon and record what disposition should be made;
- to control (e.g. by physical segregation) the subsequent processing of the nonconforming product consistent with the disposition decision;
- to notify others who might be affected by the nonconformity including, if appropriate, the customer.

8.3.3 When a nonconformity is determined, the organization should take steps to investigate and eliminate the reason for the occurrence of the nonconformity as well as determine what to do with (disposition of) the nonconforming product.

“Correction” refers to repair, rework, or adjustment and relates to the disposition of an existing nonconformity, whereas the “Corrective Action” relates to the elimination of the causes of nonconformity (see 8.5.2).

If the nonconforming product is to be used, accepted or released, the organization should decide to do so either by correcting the nonconforming product and then reevaluating it, or by using the product as is.

If the organization chooses to use, accept or release nonconforming product when a nonconformity exists, the organization has made a “concession”. Concessions are a tool used to minimize the financial impact to the organization as it relates to the disposition of nonconforming products. In such instances of concessions being made, the organization may not relinquish regulatory responsibilities for medical devices and related services. Each concession should be reviewed to ensure that the nonconformity does not conflict with any regulatory requirement. The identity of the person(s) within the organization who authorizes each concession is maintained in a record, and this record should include information documenting that regulatory requirements have been fully met.

Actions taken when nonconforming product is detected after delivery or use has started is sometimes referred to as “product recall.” Because the term “recall” has different definitions in different national or regional jurisdictions, its use in ISO 13485 has been avoided when describing such activities.

8.3.4 The procedures for dealing with nonconformities discovered in product which has already been shipped can include taking such actions as

- withdrawing products from sale,
- withdrawing products from distribution,
- giving advice to customers (this can take the form of checks to be carried out before use, providing additional guidance on the use of the product or the replacement of certain products), or
- in extreme cases, requesting the physical return or destruction of products.

Information concerning nonconforming product should be provided to all appropriate personnel, so that action is taken, if necessary, to identify and correct the cause of the nonconformity and prevent recurrence (see 8.5). Information concerning nonconforming products might require the review and updating of risk management activities.

Any product returned to the organization should be treated as nonconforming product.

For any returned product for which there is a risk of contamination (e.g. microbiological, viral, chemical, radioactive), consideration should be given to regulatory requirements for hazardous materials.

NOTE Additional information regarding decontamination is available in ISO 12891-1.

8.3.5 Control should be established over the disposal of nonconforming material designated as scrap to ensure that

- its status is clearly identified,
- it cannot be confused with conforming product,
- it cannot re-enter the production system, and
- it is disposed of safely. [ISO/TR 14969]



- 1) Has the organization ensured that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery?
- 2) Have the controls and related responsibilities and authorities for dealing with nonconforming product been defined in a documented procedure?
- 3) Does the organization deal with nonconforming product in 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 by a relevant authority and, where applicable, by the customer; or
 - c) by taking action to preclude its original intended use or application?
- 4) Have records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, been maintained?
- 5) When nonconforming product is corrected, is it subjected to reverification to demonstrate conformity to the requirements?
- 6) When nonconforming product is detected after delivery or use, does the organization take action appropriate to the effects, or potential effects, of the nonconformity?
- 7) Has the organization documented the rework process in a work instruction that has undergone the same authorization and approval as the original work instruction?



- 1) Who is responsible for
 - a) identifying and holding nonconforming product?
 - b) reviewing and authorizing the disposition of nonconforming product?
- 2) How are other areas of the organization notified when they may be affected by a nonconforming product?
- 3) What are our disposition mechanisms?
- 4) What information is provided to the relevant authority or, where applicable, the customer?
- 5) What records are maintained and where are they maintained?
- 6) Is corrected nonconforming product subject to reverification?
- 7) What is our process regarding the actions to be taken when nonconforming product is detected after delivery or use?
- 8) Have we determined and documented any adverse effects of reworking the product?



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 if 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) *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).

**Guidance**

An organization may choose to extend its data analysis to other sources to gain information on the QMS. Other sources may include

- a) customer complaints;
- b) cycle times;
- c) supplier performance;
- d) process performance;
- e) scrap, repair, and rework rates; and
- f) missed delivery dates.

ISO/TR 14969 provides the following guidance on the analysis of data:

Data should be collected and analysed in order to verify the ongoing suitability and effectiveness of the quality management system, and to determine if there are any trends or patterns that require attention. Negative trends should be considered for improvement. The results of the analysis of data should be considered for input to management reviews and risk management activities.

Analysis of data can help to determine the root cause of existing or potential problems, and thereby to guide decisions about the corrective and preventive actions needed for improvement.

For an evaluation of the effectiveness of the quality management system, data and information from relevant parts of the organization should be integrated and analysed. The results of this analysis can be used by the organization to determine

- trends in product conformance,
- the extent to which customer requirements are being met,
- process effectiveness,
- supplier performance, and
- success of performance improvement objectives. [ISO/TR 14969, 8.4]



- 1) Has the organization determined, collected, and analyzed appropriate data to demonstrate the suitability and effectiveness of the QMS?
- 2) Has the organization determined, collected, and analyzed appropriate data to evaluate where improvement of the effectiveness of the QMS can be made?

- 3) Does the analysis of data provide information relating to
 - a) feedback?
 - b) conformity to product requirements?
 - c) characteristics and trends of processes and products, including opportunities for preventive action?
 - d) suppliers?



- 1) Have we determined who is responsible for data analysis?
- 2) What actions are taken with the results of the analysis?
- 3) Are the results of the analysis of data compared with previous results to evaluate if there have been improvements made to the QMS?
- 4) Are the results from the analysis of data one of the inputs to the management review process?



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 and implementation of advisory notices. These procedures shall be capable of being implemented at any time.

Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).

If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).

If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.



Definitions

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 of the medical device to the organization that supplied it, or*
- *the destruction of a medical device.*

NOTE Issue of an advisory notice might be required to comply with national or regional regulations. [ISO 13485, 3.3]

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 [ISO 13485, 3.4]

effectiveness

extent to which planned activities are realized and planned results achieved [ISO 9000, 3.2.14]



Guidance

ISO/TR 14969 provides the following guidance on improvement:

8.5.1.1 Improvement activities

For the purposes of ISO 13485, “improvement” activities are those which identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system to meet the requirements of the customer. If the need for corrective or

preventive action is identified, this is an indication that the quality management system has not been suitable or fully effective in a particular area. Correcting the problem or potential problem by implementing corrective or preventive action to bring the quality management system back to a fully suitable and effective state is considered to be improvement.

8.5.1.2 Customer complaints

8.5.1.2.1 Any customer complaint received by the organization on a product should be evaluated. Customer complaints and warranty claims are the most common external indications of product deficiency that might be subject to correction, corrective action to prevent recurrence of the problem, or preventive action to prevent the occurrence of the problem.

Some organizations might consider other sections within the same organizations to be customers. In this case internal complaints can be treated as customer complaints and processed accordingly. If nonconforming product is involved, this should also be handled according to the requirements of ISO 13485:2003, 8.3.

In evaluating the complaint, the organization should consider whether the medical device

- fails to conform to its specification, or
- conforms with its specifications but nevertheless causes problems in use.

For instance, a complaint with a medical device conforming to its specifications might be caused by a design fault. Complaints related to handling might indicate inadequate instructions for use.

Regulatory requirements can place requirements on organizations to monitor the use of their medical devices and to inform regulatory authorities of certain defined experience in use.

The organization should formally designate a person(s) (by role or position) to collect and coordinate all written and oral customer complaints about medical devices. This person(s) should have the authority to ensure immediate review of any complaint, particularly those relating to injury, death or any hazard.

The investigation of a complaint can determine that activities outside the organization might be involved. The other organization site can be unrelated (e.g. a supplier or representative/agent), but can also be within the same organization (e.g. another division or the Head Office). Whoever the other party is, arrangements have to be such that there is two-way communication of whatever information is needed to properly investigate and resolve the complaint. This will normally be provided for in the contract with the other party.

8.5.1.2.2 The documented complaints system should cover the following:
— establishing responsibility for operating the system;

- evaluating the complaint;
- creating records and statistical summaries to enable the major causes of complaints to be determined;
- taking any corrective action;
- segregating and disposing of customer returns and faulty stock (special attention might need to be given to decontamination);
- filing of customer correspondence and other relevant records (the retention time for these should be defined).

8.5.1.2.3 The records of complaint investigations should contain enough information to show that the complaint was properly reviewed, for example a determination of whether or not

- there was an actual medical device failure to perform per specifications,
- the medical device was being used to treat or diagnose a patient,
- a death, injury or illness was involved, or
- there was any relationship between the medical device and the reported incident or adverse event.

“Illness” and “injury” are frequently defined by national and regional regulations.

8.5.1.2.4 An investigation record typically includes

- the name of the medical device,
- the date the complaint was received,
- the control number used,
- the name and address of the complainant,
- the nature of the complaint,
- the results of the investigation,
- the correction(s) made,
- the corrective action taken,
- the justification if no action is taken,
- the dates of the investigation,
- the name of the investigator, and
- the reply (if any) to the complainant.

Customer complaints should be considered for review and update of risk management activities.

8.5.1.3 Advisory notices

8.5.1.3.1 National or regional regulatory requirements might require that advisory notices be reported to designated regulatory authorities.

In some countries “advisory notices” are considered to include notices of medical devices that need to be corrected in order to be safe and perform as intended, as well as nonconforming devices that cannot be corrected and have to be removed from the market. In other countries, an advisory notice is a notice of correction needed to a medical device in order to maintain its safety and effectiveness and a notice of nonconforming devices that have to

be removed from the market is defined as a “recall”. Many countries have specific regulatory procedures for processing advisory notices and recall. These must be included in the quality management system.

The nature and seriousness of the hazard or nonconformity, the intended use of the medical device, and the potential for patient injury or failure to meet regulatory requirements, will determine whether it will be necessary to issue an advisory notice and to report to national or regional regulatory authorities. These factors will also determine the urgency and extent of the action.

8.5.1.3.2 The procedures for generating, authorizing and issuing an advisory notice should specify

- the management arrangements which enable the procedure to be activated, even in the absence of key personnel,
- the level of management authorized to initiate corrective action, and the method of determining the affected products,
- the system for determining the disposition of returned product (e.g. rework, repackage, scrap), and
- the communication system (which includes the necessity to report to local or national authorities), the points of contact and the methods of communication between the organization and national or regional regulatory authorities.

8.5.1.3.3 An advisory notice should provide

- a description of the medical device and model designation,
- the serial numbers or other identification (for instance batch or lot numbers) of the medical devices concerned,
- the reason for the issue of the notice,
- any advice regarding possible hazards, and
- any consequent actions to be taken.

If a medical device is returned to the organization, the progress of agreed corrective actions should be monitored and, if appropriate, the quantities of product physically returned to the organization or scrapped locally or corrected locally should be reconciled. [ISO/TR 14969]

For additional guidance about complaint, consult ISO/DIS 10018.



- 1) Has the organization established documented procedures for the issue and implementation of advisory notices?
- 2) Do the procedures include the relevant regulatory requirements, if applicable?
- 3) Have records of customer complaints been maintained?



- 1) Who is responsible for handling advisory notices to
 - a) customers?
 - b) regulatory agencies?
- 2) Who is responsible for investigating customer complaints?
- 3) Does the investigation include activities outside the organization that might have contributed to the complaint?
- 4) Who is responsible for notifying the regulatory authority of any issues that require notification?
- 5) When a customer complaint is not followed by corrective and/or preventive action, do we authorize and record the reason?



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, including, if appropriate, updating documentation (see 4.2),*
- e) *recording of the results of any investigation and of action taken (see 4.2.4), and*
- f) *reviewing the corrective action taken and its effectiveness.*



Definitions

corrective action

action to eliminate the cause of a detected **nonconformity** (3.6.2) or other undesirable situation

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas **preventive action** (3.6.4) is taken to prevent occurrence.

NOTE 3 There is a distinction between **correction** (3.6.6) and corrective action [ISO 9000, 3.6.5]

correction

action to eliminate a detected **nonconformity** (3.6.2)

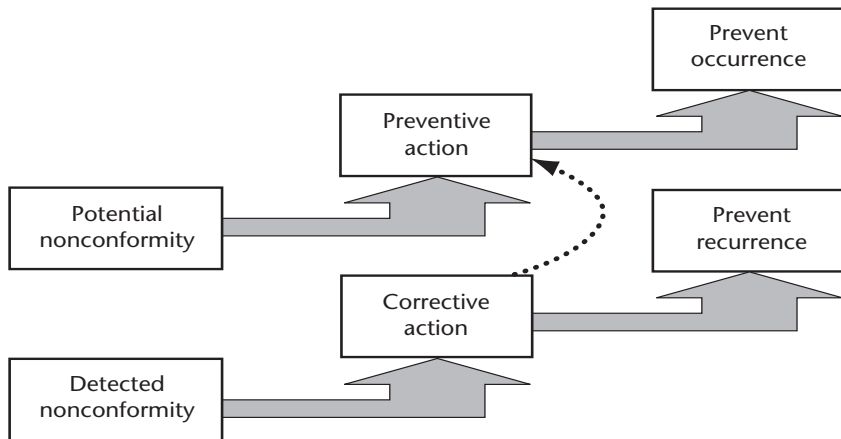
NOTE 1 A correction can be made in conjunction with a **corrective action** (3.6.5).

NOTE 2 A correction can be, for example, **rework** (3.6.7) or **regrade** (3.6.8). [ISO 9000, 3.6.6]



Guidance

The figure below illustrates the difference between corrective action (see Clause 8.5.2) and preventive action (see Clause 8.5.3).



Process validation decision tree

ISO/TR 14969 provides the following guidance on corrective action:

8.5.2.1 Corrective action is the action taken to prevent recurrence of a nonconformity which has already occurred. If nonconforming product is involved, this is handled according to ISO 13485:2003, 8.3, and the action taken to prevent recurrence of the nonconforming product is handled under ISO 13485:2003, 8.5.2.

The organization's corrective action procedures should clearly establish

- who is responsible for taking the corrective action,
- when and how this corrective action will be carried out, and
- how the effectiveness of the corrective action will be verified.

An important element in the programme is the dissemination of information on corrective actions to those directly responsible for ensuring quality.

8.5.2.2 Causes of detected nonconformities should promptly be identified so that corrective action can be taken and recurrence prevented. These causes can include the following:

- failures, malfunctions or nonconformities in incoming materials, processes, tools, equipment or facilities in which products are processed, stored or handled, including the equipment and systems therein;
- inadequate or non-existent procedures and documentation;
- non-compliance with procedures;
- inadequate process control;
- poor scheduling;
- lack of training;
- inadequate working conditions;

- inadequate resources (human or material);
- inherent process variability.

8.5.2.3 Input to corrective action can come from many sources, including the following:

- inspection and test records;
- validation study results;
- nonconformity records;
- observations during process monitoring;
- audit observations;
- field, service or customer complaints;
- regulatory authority or customer observations;
- observations and reports by personnel;
- supplier problems;
- management review results;
- solicited information on new or modified products;
- published literature;
- published reports of failures of similar products.

8.5.2.4 Effective implementation of corrective action typically includes

- clear and accurate identification of the nonconformity and the affected medical device(s),
- identification of the recipient(s) of the affected medical devices (see 7.5.3.2),
- consideration of what other medical device(s), process(es) or procedure(s) might have been affected,
- identification of the root cause of the nonconformity,
- identification of the action required to prevent recurrence of the problem,
- any necessary approvals required before any action is taken,
- a record that the identified corrective action was taken, and
- a check that the corrective action taken was effective (i.e. verification that the nonconformity is unlikely to recur and that no new risks have been introduced by the corrective action).

8.5.2.5 The degree of corrective action taken should be dependent upon and related to the risk, size and nature of the problem and its effect(s) on product quality. For example, the level of investigation to determine the cause of the nonconformity, the work done to determine and verify the appropriateness of corrective action, and the level of documentation kept, would be far more extensive for a nonconformity relating to the failure of a medical device compared to a less serious nonconformity such as the failure to conduct an internal audit when scheduled.

Corrective action should be implemented without undue delay.
[ISO/TR 14969]



- 1) Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?
- 2) Are corrective actions appropriate to the effects of the nonconformities encountered?
- 3) Has a documented procedure been 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) recording of the results of action taken?
 - f) reviewing corrective action taken?



- 1) Do we have a documented procedure that specifies requirements for reviewing nonconformities and determining their causes?
- 2) Who is responsible for determining and implementing the actions needed to ensure that the nonconformity does not recur?
- 3) Who is responsible for reviewing the results of the corrective actions taken and verifying that they are effective?
- 4) What records are maintained and where are they stored?



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) *recording of the results of any investigations and of action taken (see 4.2.4), and*
- e) *reviewing preventive action taken and its effectiveness.*



Definition

preventive action

action to eliminate the cause of a potential **nonconformity** (3.6.2) or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas **corrective action** (3.6.5) is taken to prevent recurrence. [ISO 9000, 3.6.4]



Guidance

ISO/TR 14969 provides the following guidance on preventive action:

Preventive action is taken when a potential nonconformity is identified as the result of an analysis of records and other relevant sources of information.

The degree of preventive action taken should be dependent upon and related to the risk, size and nature of the problem and its effect(s) on product quality.

Sources for information for initiating preventive actions include

- purchased product rejected on receipt,
- evidence that previous decisions affecting product conformity were false,
- products requiring rework,
- in-process problems, wastage levels,
- final inspection failures,
- customer feedback,
- warranty claims,
- process measurements,
- statistical process control documents,
- identification of results that are out-of-trend but not out-of-specification,
- difficulties with suppliers (see 7.4.1),
- service reports, and
- the need for concessions. [ISO/TR 14969, 8.5.3]



- 1) Has the organization determined the actions necessary to eliminate the causes of potential nonconformities in order to prevent their occurrence?
- 2) Are the preventive actions appropriate to the effects of the potential problems?
- 3) Has a documented procedure been 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 the action needed?
 - d) recording the results of action taken (see 4.2.4)?
 - e) reviewing the preventive action taken and its effectiveness?



- 1) Do we have a documented procedure that specifies requirements for determining potential nonconformities and their causes?
- 2) Who is responsible for implementing the necessary actions to prevent the occurrence of nonconformities?
- 3) Who is responsible for determining the effectiveness of the procedure?
- 4) What records are to be maintained and where are they stored?

Appendix 1

Vocabulary Clause —

ISO 9000:2000, ISO 13495:2003, and ISO 19011:2002

Alphabetical order

This Appendix contains the definitions in the normative vocabulary clause of ISO 9000:2000 and the definitions in Clause 3 of ISO 13485, as well as other relevant definitions from ISO 19011 and from the latest draft amendment of ISO 9000:2000, FDAM1:2005.

During the process of making the revisions for the 2000 edition of the ISO 9000 family of Standards, great care was taken in the translations to use the correct English words and terms to describe the concepts and requirements. The objective was to use simple, technically accurate terms and, to the greatest extent possible, to rely on common dictionary definitions. As with most technical subjects, there are some terms that have a very specific meaning that is different from their commonly used dictionary definitions. In all other cases, common dictionary definitions (e.g., from *The Canadian Oxford Dictionary*) are used. Definitions of terms from ISO 9000 or ISO 13485 have normative status, which takes precedence over their common dictionary definitions.

NOTE: Unless otherwise indicated, the reference in the left-hand column of this table is from ISO 9000.

Active implantable medical device ISO 13485, 3.1	<i>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</i>
Active medical device ISO 13485, 3.2	<i>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</i>

Advisory notice ISO 13485, 3.3	<i>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</i> <ul style="list-style-type: none"> — the use of a medical device, — the modification of a medical device, — the return of the medical device to the organization that supplied it, or — the destruction of a medical device <i>NOTE Issue of an advisory notice might be required to comply with national or regional regulations.</i>
Audit 3.9.1	<p>systematic, independent and documented process (3.4.1) for obtaining audit evidence (3.9.4) and evaluating it objectively to determine the extent to which audit criteria (3.9.3) are fulfilled</p> <p>NOTE Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization (3.3.1) itself for internal purposes and can form the basis for an organization's self-declaration of conformity (3.6.1).</p> <p>External audits include what are generally termed "second-" or "third-party audits".</p> <p>Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf.</p> <p>Third-party audits are conducted by external independent organizations. Such organizations provide certification or registration of conformity with requirements such as those of ISO 9001 and ISO 14001:1996.</p> <p>When quality and environmental management systems (3.2.2) are audited together, this is termed a "combined audit".</p> <p>When two or more auditing organizations cooperate to audit a single auditee (3.9.8) jointly, this is termed "joint audit".</p>

Audit ISO 9000 FDAM1, 3.9.1	<p>systematic, independent and documented process (3.4.1) for obtaining audit evidence (3.9.4) and evaluating it objectively to determine the extent to which the audit criteria (3.9.3) are fulfilled</p> <p>NOTE 1 Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization (3.3.1) itself for management review and other internal purposes, and may form the basis for an organization's (3.3.1) declaration of conformity (3.6.1). In many cases, particularly in smaller organizations (3.3.1), independence can be demonstrated by the freedom from responsibility for the activity being audited.</p> <p>NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization (3.3.1), such as customers (3.3.5), or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations (3.3.1), such as those providing certification/registration of conformity (3.6.1) to the requirements (3.1.2) of ISO 9001 or ISO 14001.</p> <p>NOTE 3 When two or more management systems (3.2.2) are audited together, this is termed a combined audit.</p> <p>NOTE 4 When two or more auditing organizations (3.3.1) co-operate to audit a single auditee (3.9.7), this is termed a joint audit.</p>
Audit ISO 19011, 3.1	<p>systematic, independent and documented process for obtaining audit evidence (3.3) and evaluating it objectively to determine the extent to which audit criteria (3.2) are fulfilled</p> <p>NOTE 1 Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization itself for management review and other internal purposes and may form the basis for an organization's self-declaration of conformity. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.</p> <p>NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing registration or certification of conformity to the requirements of ISO 9001 or ISO 14001.</p> <p>NOTE 3 When a quality management system and an environmental management system are audited together, this is termed a combined audit.</p> <p>NOTE 4 When two or more auditing organizations cooperate to audit a single auditee (3.7), this is termed a joint audit.</p>

Audit client 3.9.7	organization (3.3.1) or person requesting an audit (3.9.1)
Audit client ISO 9000 FDAM1, 3.9.7	organization (3.3.1) or person requesting an audit (3.9.1) NOTE The audit client may be the auditee (3.9.8) or any other organization (3.3.1) which has the regulatory or contractual right to request an audit (3.9.1).
Audit conclusion 3.9.6	outcome of an audit (3.9.1) provided by the audit team (3.9.10) after consideration of the audit objectives and all audit findings (3.9.5)
Audit criteria 3.9.3	set of policies, procedures (3.4.5) or requirements (3.1.2) used as a reference
Audit criteria ISO 9000 FDAM1, 3.9.3	set of policies, procedures (3.4.5) or requirements (3.1.2) NOTE Audit criteria are used as a reference against which audit evidence (3.9.4) is compared.
Audit evidence 3.9.4	records (3.7.6), statements of fact or other information (3.7.1) which are relevant to the audit criteria (3.9.3) and verifiable NOTE Audit evidence can be qualitative or quantitative.
Audit evidence ISO 9000 FDAM1, 3.9.4	records (3.7.6), statements of fact or other information (3.7.1) which are relevant to the audit criteria (3.9.3) and verifiable NOTE Audit evidence may be qualitative or quantitative.
Audit findings 3.9.5	results of the evaluation of the collected audit evidence (3.9.4) against audit criteria (3.9.3) NOTE Audit findings can indicate either conformity or nonconformity with audit criteria, or opportunities for improvement.
Audit programme 3.9.2	set of one or more audits (3.9.1) planned for a specific time frame and directed toward a specific purpose
Audit programme ISO 9000 FDAM1, 3.9.2	set of one or more audits (3.9.1) planned for a specific time frame and directed toward a specific purpose NOTE An audit programme includes all activities necessary for planning, organizing and conducting the audits (3.9.1).
Audit plan ISO 9000 FDAM1, 3.9.12	description of the activities and arrangements for an audit (3.9.1)
Audit scope ISO 9000 FDAM1, 3.9.13	extent and boundaries of an audit (3.9.1) NOTE The audit scope generally includes a description of physical locations, organizational units, activities and processes (3.4.1), as well as the time period covered.

Audit team 3.9.10	one or more auditors (3.9.9) conducting an audit (3.9.1) NOTE 1 One auditor in the audit team is generally appointed as audit team leader. NOTE 2 The audit team can include auditors-in-training and, where required, technical experts (3.9.11). NOTE 3 Observers can accompany the audit team but do not act as part of it.
Audit team ISO 9000 FDAM1, 3.9.10	one or more auditors (3.9.9) conducting an audit (3.9.1), supported if needed by technical experts (3.9.11) NOTE 1 One auditor (3.9.9) of the audit team is appointed as the audit team leader. NOTE 2 The audit team may include auditors (3.9.9) in training.
Auditee 3.9.8	organization (3.3.1) being audited
Auditor 3.9.9	person with the competence (3.9.12) to conduct an audit (3.9.1)
Auditor ISO 9000 FDAM1, 3.9.9	person with the demonstrated personal attributes and competence (3.1.6) to conduct an audit (3.9.1) NOTE The relevant personal attributes for an auditor are described in ISO 19011.
Capability 3.1.5	ability of an organization (3.3.1), system (3.2.1) or process (3.4.1) to realize a product (3.4.2) that will fulfil the requirements (3.1.2) for that product NOTE Process capability terms in the field of statistics are defined in ISO 3534-2.
Characteristic 3.5.1	distinguishing feature NOTE 1 A characteristic can be inherent or assigned. NOTE 2 A characteristic can be qualitative or quantitative. NOTE 3 There are various classes of characteristic, such as the following: — physical (e.g. mechanical, electrical, chemical or biological characteristics); — sensory (e.g. related to smell, touch, taste, sight, hearing); — behavioral (e.g. courtesy, honesty, veracity); — temporal (e.g. punctuality, reliability, availability); — ergonomic (e.g. physiological characteristic, or related to human safety); — functional (e.g. maximum speed of an aircraft).
Competence 3.9.12	demonstrated ability to apply knowledge and skills

Competence ISO 9000 FDAM1, 3.1.6	demonstrated ability to apply knowledge and skills NOTE The concept of competence is defined differently in ISO 19011 and ISO/IEC 17024 for the specific purposes of these standards.
Competence ISO 19011, 3.14	demonstrated personal attributes and demonstrated ability to apply knowledge and skills
Concession 3.6.11	permission to use or release a product (3.4.2) that does not conform to specified requirements (3.1.2) NOTE A concession is generally limited to the delivery of a product that has nonconforming characteristics (3.5.1) within specified limits for an agreed time or quantity of that product.
Conformity 3.6.1	fulfilment of a requirement (3.1.2) NOTE 1 This definition is consistent with ISO/IEC Guide 2 but differs from it in phrasing to fit into the ISO 9000 concepts. NOTE 2 The term “conformance” is synonymous but deprecated.
Continual improvement 3.2.13	recurring activity to increase the ability to fulfil requirements (3.1.2) NOTE The process (3.4.1) of establishing and finding opportunities for improvement in a continual process through the use of audit findings (3.9.5) and audit conclusions (3.9.6), analysis of data, management reviews (3.8.7) or other means and generally leads to corrective action (3.6.5) or preventive action (3.6.4).
Contract ISO 9000 FDAM1, 3.3.8	binding agreement
Correction 3.6.6	action to eliminate a detected nonconformity (3.6.2) NOTE 1 A correction can be made in conjunction with a corrective action (3.6.5). NOTE 2 A correction can be, for example, rework (3.6.7) or regrade (3.6.8).
Corrective action 3.6.5	action to eliminate the cause of a detected nonconformity (3.6.2) or other undesirable situation NOTE 1 There can be more than one cause for a nonconformity. NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action (3.6.4) is taken to prevent occurrence. NOTE 3 There is a distinction between correction (3.6.6) and corrective action.
Customer 3.3.5	organization (3.3.1) or person that receives a product (3.4.2) EXAMPLE Consumer, client, end-user, retailer, beneficiary and purchaser. NOTE A customer can be internal or external to the organization.

Customer complaint ISO 13485, 3.4	<i>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</i>
Customer satisfaction 3.1.4	customer's perception of the degree to which the customer's requirements (3.1.2) have been fulfilled NOTE 1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction. NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.
Defect 3.6.3	non-fulfilment of a requirement (3.1.2) related to an intended or specified use NOTE 1 The distinction between the concepts defect and nonconformity (3.6.2) is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term "defect" should be used with extreme caution. NOTE 2 The intended use as intended by the customer (3.3.5) can be affected by the nature of the information, such as operating or maintenance instructions, provided by the supplier (3.3.6).
Dependability 3.5.3	collective term used to describe the availability performance and its influencing factors: reliability performance, maintainability performance and maintenance support performance NOTE Dependability is used only for general descriptions in non-quantitative terms. [IEC 60050-191:1990].
Design and development 3.4.4	set of processes (3.4.1) that transforms requirements (3.1.2) into specified characteristics (3.5.1) or into the specification (3.7.3) of a product (3.4.2), process (3.4.1) or system (3.2.1). NOTE 1 The terms "design" and "development" are sometimes used synonymously and sometimes used to define different stages of the overall design and development process. NOTE 2 A qualifier can be applied to indicate the nature of what is being designed and developed (e.g. product design and development or process design and development).
Deviation permit 3.6.12	permission to depart from the originally specified requirements (3.1.2) of a product (3.4.2) prior to realization NOTE A deviation permit is generally given for a limited quantity of product or period of time, and for a specific use.

Document 3.7.2	<p>information (3.7.1) and its supporting medium EXAMPLE Record (3.7.6), specification (3.7.3), procedure document, drawing, report, standard. NOTE 1 The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof. NOTE 2 A set of documents, for example specifications and records, is frequently called “documentation”. NOTE 3 Some requirements (3.1.2) (e.g. the requirement to be readable) relate to all types of documents, however there can be different requirements for specifications (e.g. the requirement to be revision controlled) and records (e.g. the requirement to be retrievable).</p>
Effectiveness 3.2.14	extent to which planned activities are realized and planned results achieved
Efficiency 3.2.15	relationship between the result achieved and the resources used
Grade 3.1.3	<p>category or rank given to different quality requirements (3.1.2) for products (3.4.2), processes (3.4.1) or systems (3.2.1) having the same functional use EXAMPLE Class of airline ticket and category of hotel in a hotel guide. NOTE When establishing a quality requirement, the grade is generally specified.</p>
Implantable medical device ISO 13485, 3.5	<p><i>medical device intended</i> — <i>to be totally or partially introduced into the human body or a natural orifice, or</i> — <i>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</i> NOTE <i>This definition applies to implantable medical devices other than active implantable medical devices.</i></p>
Information 3.7.1	meaningful data
Infrastructure 3.3.3	<organization> system of facilities, equipment and services needed for the operation of an organization (3.3.1)
Inspection 3.8.2	<p>conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging [ISO/IEC Guide 2]</p>

Interested party 3.3.7	person or group having an interest in the performance or success of an organization (3.3.1) EXAMPLE Customers (3.3.5), owners, people in an organization, suppliers (3.3.6), bankers, unions, partners or society. NOTE A group can comprise an organization, a part thereof, or more than one organization.
Labelling ISO 13485, 3.6	<i>written, printed or graphic matter</i> — <i>affixed to a medical device or any of its containers or wrappers, or</i> — <i>accompanying a medical device,</i> <i>related to identification, technical description, and use of the medical device, but excluding shipping documents</i> NOTE Some regional and national regulations refer to “labelling” as “information supplied by the manufacturer.”
Management 3.2.6	coordinated activities to direct and control an organization (3.3.1) NOTE In English, the term “management” sometimes refers to people, i.e. a person or group of people with authority and responsibility for the conduct and control of an organization. When “management” is used in this sense it should always be used with some form of qualifier to avoid confusion with the concept “management” defined above. For example, “management shall ...” is deprecated whereas “ top management (3.2.7) shall...” is acceptable.
Management system 3.2.2	system (3.2.1) to establish policy and objectives and to achieve those objectives NOTE A management system of an organization (3.3.1) can include different management systems, such as a quality management system (3.2.3), a financial management system or an environmental management system.
Measurement control system 3.10.1	set of interrelated or interacting elements necessary to achieve metrological confirmation (3.10.3) and continual control of measurement processes (3.10.2)
Measurement management system ISO 9000 FDAM1, 3.10.1	set of interrelated and interacting elements necessary to achieve metrological confirmation (3.10.3) and continual control of management processes (3.10.2)
Measurement process 3.10.2	set of operations to determine the value of a quantity

Measuring equipment 3.10.4	measuring instrument, software, measurement standard, reference material or auxiliary apparatus or combination thereof necessary to realize a measurement process (3.10.2)
Medical device ISO 13485, 3.7	<p><i>any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of</i></p> <ul style="list-style-type: none"> — <i>diagnosis, prevention, monitoring, treatment or alleviation of disease,</i> — <i>diagnosis, monitoring, treatment, alleviation of or compensation for an injury,</i> — <i>investigation, replacement, modification, or support of the anatomy or of a physiological process,</i> — <i>supporting or sustaining life,</i> — <i>control of conception,</i> — <i>disinfection of medical devices,</i> — <i>providing information for medical purposes by means of in vitro examination of specimens derived from the human body,</i> <p><i>and which does not achieve its primary 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.</i></p> <p><i>NOTE This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15].</i></p>
Metrological characteristic 3.10.5	distinguishing feature which can influence the results of measurement NOTE 1 Measuring equipment (3.10.4) usually has several metrological characteristics. NOTE 2 Metrological characteristics can be the subject of calibration.

Metrological confirmation 3.10.3	<p>set of operations required to ensure that measuring equipment (3.10.4) conforms to the requirements (3.1.2) for its intended use</p> <p>NOTE 1 Metrological confirmation generally includes calibration or verification (3.8.4), any necessary adjustment or repair (3.6.9), and subsequent recalibration, comparison with the metrological requirements for the intended use of the equipment, as well as any required sealing and labelling.</p> <p>NOTE 2 Metrological confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented.</p> <p>NOTE 3 The requirements for the intended use include such considerations as range, resolution, maximum permissible errors, etc.</p> <p>NOTE 4 Metrological confirmation requirements are usually distinct from and are not specified in product requirements.</p>
Metrological function 3.10.6	function with organizational responsibility for defining and implementing the measurement control system (3.10.1)
Nonconformity 3.6.2	non-fulfilment of a requirement (3.1.2)
Objective evidence 3.8.1	<p>data supporting the existence or verity of something</p> <p>NOTE Objective evidence may be obtained through observation, measurement, test (3.8.3), or other means.</p>
Organization 3.3.1	<p>group of people and facilities with an arrangement of responsibilities, authorities and relationships</p> <p>EXAMPLE Company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof.</p> <p>NOTE 1 The arrangement is generally orderly.</p> <p>NOTE 2 An organization can be public or private.</p> <p>NOTE 3 This definition is valid for the purposes of quality management systems (3.2.3) standards. The term "organization" is defined differently in ISO/IEC Guide 2.</p>
Organizational structure 3.3.2	<p>arrangement of responsibilities, authorities and relationships between people</p> <p>NOTE 1 The arrangement is generally orderly.</p> <p>NOTE 2 A formal expression of the organizational structure is often provided in a quality manual (3.7.4) or a quality plan (3.7.5) for a project (3.4.3).</p> <p>NOTE 3 The scope of an organizational structure can include relevant interfaces to external organizations (3.3.1).</p>

Preventive action 3.6.4	action to eliminate the cause of a potential nonconformity (3.6.2) or other undesirable potential situation NOTE 1 There can be more than one cause for a potential nonconformity. NOTE 2 Preventive action is taken to prevent occurrence whereas corrective action (3.6.5) is taken to prevent recurrence.
Procedure 3.4.5	specified way to carry out an activity or a process (3.4.1) NOTE 1 Procedures can be documented or not. NOTE 2 When a procedure is documented, the term “written procedure” or “documented procedure” is frequently used. The document (3.7.2) that contains a procedure can be called a “procedure document”.
Process 3.4.1	set of interrelated or interacting activities which transforms inputs into outputs NOTE 1 Inputs to a process are generally outputs of other processes. NOTE 2 Processes in an organization (3.3.1) are generally planned and carried out under controlled conditions to add value. NOTE 3 A process where the conformity (3.6.1) of the resulting product (3.4.2) cannot be readily or economically verified is frequently referred to as a “special process”.

Product 3.4.2	<p>result of a process (3.4.1)</p> <p>NOTE 1 There are four generic product categories, as follows:</p> <ul style="list-style-type: none"> — services (e.g. transport); — software (e.g. computer program, dictionary); — hardware (e.g. engine mechanical part); — processed materials (e.g. lubricant). <p>Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product “automobile” consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver’s manual), and service (e.g. operating explanations given by the salesman).</p> <p>NOTE 2 Service is the result of at least one activity necessarily performed at the interface between the supplier (3.3.6) and customer (3.3.5) and is generally intangible. Provision of a service can involve, for example, the following:</p> <ul style="list-style-type: none"> — an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired); — an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return); — the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission); — the creation of ambience for the customer (e.g. in hotels and restaurants). <p>Software consists of information and is generally intangible and can be in the form of approaches, transactions or procedures (3.4.5). Hardware is generally tangible and its amount is a countable characteristic (3.5.1). Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials often are referred to as goods.</p> <p>NOTE 3 Quality assurance (3.2.11) is mainly focused on intended product.</p>
Project 3.4.3	<p>unique process (3.4.1), consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements (3.1.2), including the constraints of time, cost and resources</p> <p>NOTE 1 An individual project can form part of a larger project structure.</p> <p>NOTE 2 In some projects the objectives are refined and the product characteristics (3.5.1) defined progressively as the project proceeds.</p> <p>NOTE 3 The outcome of a project may be one or several units of product (3.4.2).</p> <p>NOTE 4 Adapted from ISO 10006:1997.</p>

Qualification process 3.8.6	process (3.4.1) to demonstrate the ability to fulfil specified requirements (3.1.2) NOTE 1 The term “qualified” is used to designate the corresponding status. NOTE 2 Qualification can concern persons, products (3.4.2), processes or systems (3.2.1). EXAMPLE Auditor qualification process, material qualification process.
Quality 3.1.1	degree to which a set of inherent characteristics (3.5.1) fulfils requirements (3.1.2) NOTE 1 The term “quality” can be used with adjectives such as poor, good or excellent. NOTE 2 “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.
Quality assurance 3.2.11	part of quality management (3.2.8) focused on providing confidence that quality requirements (3.1.2) will be fulfilled
Quality characteristic 3.5.2	inherent characteristic (3.5.1) of a product (3.4.2), process (3.4.1) or system (3.2.1) related to a requirement (3.1.2) NOTE 1 Inherent means existing in something, especially as a permanent characteristic. NOTE 2 A characteristic assigned to a product, process or system (e.g. the price of a product, the owner of a product) is not a quality characteristic of that product, process or system.
Quality control 3.2.10	part of quality management (3.2.8) focused on fulfilling quality requirements (3.1.2)
Quality improvement 3.2.12	part of quality management (3.2.8), focused on increasing the ability to fulfil quality requirements (3.1.2) NOTE The requirements can be related to any aspect such as effectiveness (3.2.14), efficiency (3.2.15) or traceability (3.5.4).
Quality management 3.2.8	coordinated activities to direct and control an organization (3.3.1) with regard to quality (3.1.1) NOTE Direction and control with regard to quality generally includes establishment of the quality policy (3.2.4) and quality objectives (3.2.5), quality planning (3.2.9), quality control (3.2.10), quality assurance (3.2.11) and quality improvement (3.2.12).
Quality management system 3.2.3	management system (3.2.2) to direct and control an organization (3.3.1) with regard to quality (3.1.1)

Quality manual 3.7.4	document (3.7.2) specifying the quality management system (3.2.3) of an organization (3.3.1) NOTE Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.
Quality objective 3.2.5	something sought, or aimed for, related to quality (3.1.1) NOTE 1 Quality objectives are generally based on the organization's quality policy (3.2.4). NOTE 2 Quality objectives are generally specified for relevant functions and levels in the organization (3.3.1).
Quality plan 3.7.5	document (3.7.2) specifying which procedures (3.4.5) and associated resources shall be applied by whom and when to a specific project (3.4.3), product (3.4.2), process (3.4.1) or contract NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes. NOTE 2 A quality plan often makes reference to parts of the quality manual (3.7.4) or to procedure documents. NOTE 3 A quality plan is generally one of the results of quality planning (3.2.9).
Quality planning 3.2.9	part of quality management (3.2.8) focused on setting quality objectives (3.2.5) and specifying necessary operational processes (3.4.1) and related resources to fulfil the quality objectives NOTE Establishing quality plans (3.7.5) can be part of quality planning.
Quality policy 3.2.4	overall intentions and direction of an organization (3.3.1) related to quality (3.1.1) as formally expressed by top management (3.2.7) NOTE 1 Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of quality objectives (3.2.5). NOTE 2 Quality management principles presented in this International Standard can form a basis for the establishment of a quality policy (See 0.2).
Record 3.7.6	document (3.7.2) stating results achieved or providing evidence of activities performed NOTE 1 Records can be used, for example, to document traceability (3.5.4) and to provide evidence of verification (3.8.4), preventive action (3.6.4) and corrective action (3.6.5). NOTE 2 Generally records need not be under revision control.
Regrade 3.6.8	alteration of the grade (3.1.3) of a nonconforming product (3.4.2) in order to make it conform to requirements (3.1.2) differing from the initial ones

Release 3.6.13	permission to proceed to the next stage of a process (3.4.1) NOTE In English, in the context of computer software, the term "release" is frequently used to refer to a version of the software itself.
Repair 3.6.9	action on a nonconforming product (3.4.2) to make it acceptable for the intended use NOTE 1 Repair includes remedial action taken on a previously conforming product to restore it for use, for example as part of maintenance. NOTE 2 Unlike rework (3.6.7), repair can affect or change parts of the nonconforming product.
Requirement 3.1.2	need or expectation that is stated, generally implied or obligatory NOTE 1 "Generally implied" means that it is custom or common practice for the organization (3.3.1), its customers (3.3.5) and other interested parties (3.3.7), that the expectation under consideration is implied. NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement. NOTE 3 A specified requirement is one which is stated, for example, in a document (3.7.2). NOTE 4 Requirements can be generated by different interested parties.
Review 3.8.7	activity undertaken to determine the suitability, adequacy and effectiveness (3.2.14) of the subject matter to achieve established objectives NOTE Review can also include the determination of efficiency (3.2.15). EXAMPLE Management review, design and development review, review of customer requirements and nonconformity review.
Rework 3.6.7	action taken on a nonconforming product (3.4.2) to make it conform to the requirements (3.1.2) NOTE Unlike rework, repair (3.6.9) can affect or change parts of the nonconforming product.
Scrap 3.6.10	action on a nonconforming product (3.4.2) to preclude its originally intended use EXAMPLE Recycling, destruction. NOTE In a nonconforming service situation, use is precluded by discontinuing the service.

Specification 3.7.3	document (3.7.2) stating requirements (3.1.2) NOTE A specification can be related to activities (e.g. procedure document, process specification and test specification), or products (3.4.2) (e.g. product specification, performance specification and drawing).
Sterile medical device ISO 13485, 3.8	<i>category of medical device intended to meet the requirements for sterility</i> NOTE The requirements for sterility of a medical device might be subject to national or regional regulations or standards.
Supplier 3.3.6	organization (3.3.1) or person that provides a product (3.4.2) EXAMPLE Producer, distributor, retailer or vendor of a product, or provider of a service or information. NOTE 1 A supplier can be internal or external to the organization. NOTE 2 In a contractual situation a supplier is sometimes called "contractor".
System 3.2.1	set of interrelated or interacting elements
Technical expert 3.9.11	<audit> person who provides specific knowledge of or expertise on the subject to be audited NOTE 1 Specific knowledge or expertise includes knowledge of or expertise on the organization (3.3.1), process (3.4.1) or activity to be audited, as well as language or cultural guidance. NOTE 2 A technical expert does not act as an auditor (3.9.9) in the audit team (3.9.10).
Test 3.8.3	determination of one or more characteristics (3.5.1) according to a procedure (3.4.5)
Top management 3.2.7	person or group of people who directs and controls an organization (3.3.1) at the highest level
Traceability 3.5.4	ability to trace the history, application or location of that which is under consideration NOTE 1 When considering product (3.4.2), traceability can relate to — the origin of materials and parts, — the processing history, and — the distribution and location of the product after delivery. NOTE 2 In the field of metrology the definition of VIM:1993, 6.10, is the accepted definition.

Validation 3.8.5	confirmation, through the provision of objective evidence (3.8.1), that the requirements (3.1.2) for a specific intended use or application have been fulfilled. NOTE 1 The term “validated” is used to designate the corresponding status. NOTE 2 The use conditions for validation can be real or simulated.
Verification 3.8.4	confirmation, through the provision of objective evidence (3.8.1), that specified requirements (3.1.2) have been fulfilled NOTE 1 The term “verified” is used to designate the corresponding status. NOTE 2 Confirmation can comprise activities such as — performing alternative calculations, — comparing a new design specification (3.7.3) with a similar proven design specification, — undertaking tests (3.8.3) and demonstrations, and — reviewing documents prior to issue.
Work environment 3.3.4	set of conditions under which work is performed NOTE Conditions include physical, social, psychological and environmental factors (such as temperature, recognition schemes, ergonomics and atmospheric composition).

Appendix 2

Correspondence between ISO 13485:2003 and ISO 13485:1996

Source: ISO 13485:2003.

ISO 13485:1996	ISO 13485:2003
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]	

ISO 13485:1996	ISO 13485:2003
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
4.11 Control of inspection, measuring and test equipment [title only]	
4.11.1 General	7.6
4.11.2 Control procedure	7.6

ISO 13485:1996	ISO 13485:2003
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	6.4
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

Appendix 3

Terms used in certain regulatory administrations to describe documents referenced in this Technical Report

Source: ISO/TR 14969.

	Document	USA	EU	Japan
A	<p>A compilation of records which describes and records the history of the design activity (see ISO 13485:2003, 4.2.4 and 7.3).</p> <p>Examples include (but are not limited to): calculations, design inputs, requirements and specifications, design testing reports, risk analyses, design reviews, design verification and validation reports (including clinical investigation results), product labelling, and design changes and related records.</p>	<p>DHF</p> <p>Design History File</p>	<p>Part of the Technical Documentation and Design Dossier</p>	<p>Part of Seihin Hyojunsho</p>

	Document	USA	EU	Japan
B	<p>A compilation of documents based on the device design activity which specify how the device is to be produced, including the criteria for testing and acceptance (see ISO 13485:2003, 4.2.1 and 7.1).</p> <p>Examples include (but are not limited to): specifications for raw materials, packaging, and labelling, process/product specifications, engineering drawings, parts lists, work instructions (including equipment operation), sterilization procedures (if applicable), quality plan, and manufacturing/-testing/inspection procedures and acceptance criteria, installation procedures, servicing requirements.</p>	DMR Device Master Record	Part of the Technical Documentation and Design Dossier	Seihin Hyojunsho
C	<p>A compilation of records containing the production/manufacturing history to demonstrate conformity with (approved) pre-production documents (see ISO 13485:2003, 4.2.4).</p> <p>Examples include (but are not limited to): manufacturing test reports, lot or batch records, travellers, functional test reports, actual labelling.</p>	DHR Device History Record	Manufacturing Records	Quality Records

Appendix 4

Contacts

Web sites

Canadian Standards Association: www.csa.ca

Global Harmonization Task Force: www.ghtf.org

ISO: www.iso.ch

Abbreviations

CAN: Canada

CSA: Canadian Standards Association

FDAM1: Final Draft Amendment 1

ISO: International Organization for Standardization

QMS: Quality Management System

Bibliography

The following standards or guidance documents are cited in this Handbook or provide additional information relating to requirements of ISO 13485. The ISO Technical Committee responsible for the 9000 series of Standards, TC 176, has drafted documents on the following support subjects: application, documentation requirements, terminology, the process approach to QMS, and outsourced processes. These documents are free at www.bsi.org.uk/iso-tc176-sc2. It is expected that this site will soon be transferred to the www.iso.ch.

CSA (Canadian Standards Association)

CAN/CSA-ISO 9000-00 (Adopted ISO 9000:2000)

Quality management systems — Fundamentals and vocabulary

CAN/CSA-ISO 9001-00 (Adopted ISO 9001:2000)

Quality management systems — Requirements

CAN/CSA-ISO 9004-00 (Adopted ISO 9004:2000)

Quality management systems — Guidelines for performance improvements

CAN/CSA-ISO 10006-03 (Adopted ISO 10006:2003)

Quality management — Guidelines for quality management in projects

CAN/CSA-ISO 10007-03 (Adopted ISO 10007:2003)
Quality management systems — Guidelines for configuration management

CAN/CSA-ISO 10012-03 (Adopted ISO 10012:2003)
Measurement management systems — Requirements for measurement processes and measuring equipment

CAN/CSA-ISO/TR 10013-01 (Adopted ISO/TR 10013:2001)
Guidelines for quality management system documentation

CAN/CSA-ISO/TR 10017-03 (Adopted ISO/TR 10017:2003)
Guidance on statistical techniques for ISO 9001:2000

CAN/CSA-ISO 11134-98 (R2003) (Adopted ISO 11134:1994)
Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization

CAN/CSA-ISO 11135-98 (R2003) (Adopted ISO 11135:1994)
Medical devices — Validation and routine control of ethylene oxide sterilization

CAN/CSA-ISO 11137-98 (R2003) (Adopted ISO 11137:1995)
Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization

CAN/CSA-ISO 13485:03 (Adopted ISO 13485:2003)
Medical devices — Quality management systems — Requirements for regulatory purposes

CAN/CSA-ISO 14937-01 (Adopted ISO 14937:2000)
Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

CAN/CSA-ISO/TR 14969:05 (Adopted ISO/TR 14969:2004)
Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003

CAN/CSA-ISO 14971-01 (Adopted ISO 14971:2000)
Medical devices — Application of risk management to medical devices

CAN/CSA-ISO 19011-03 (Adopted ISO 19011:2002)
Guidelines for quality and/or environmental management systems auditing

PLUS 9001

The ISO 9000 essentials: A practical handbook for implementing the ISO 9000 standards

Accademia Qualitas

ISO 9000 for Small Business — What to do — Advice from ISO/TC 176

CEN (European Committee for Standardization)

EN 724:1994

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices

EN 928:1995

In vitro diagnostic systems — Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices

EN 980:2003

Graphical symbols for use in the labelling of medical devices

EN 50103:1995

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry

GHTF (Global Harmonization Task Force) Study Group 3 (SG3)

Document No. N99-8, June 29, 1999

Guidance On Quality Systems For The Design And Manufacture Of Medical Devices

Document No. N99-9, June 29, 1999

Design Control Guidance For Medical Device Manufacturers

Document No. N99-10, June 29, 1999

Process Validation Guidance

ISPE/GAMP (International Society of Pharmaceutical Engineers/ Good Automated Manufacturing Process)

Guide for Validation of Automated Systems in Pharmaceutical Manufacture, 2001

ISO (International Organization for Standardization)*ISO 9001 — Introduction and Support Package***Note:** See www.bsi.org.uk/iso-tc176-sc2.

ISO/FDIS 10005:2004

Quality management — Guidelines for quality plans

ISO/DIS 10018:2003

Complaints handling — Guidelines for organizations

ISO 11607:2003

Packaging for terminally sterilized medical devices

ISO 11607 MEDDEV 2.12/1-rev. 4 April-2001

Guidelines on a medical devices vigilance system

ISO 11737-1:1995

*Sterilization of medical devices — Microbiological methods — Part 1:**Estimation of population of microorganisms on products*

ISO 12891-1:1998

Retrieval and analysis of surgical implants — Part 1: Retrieval and handling

ISO 13408-1:1998

Aseptic processing of healthcare products — Part 1: General requirements

ISO/TS 13409:2002

*Sterilization of health care products — Radiation sterilization —**Substantiation of 25 kGy as a sterilization dose for small or infrequent production batches*

ISO 13683:1997

Sterilization of health care products — Requirements for validation and routine control of moist heat sterilization in health care facilities

ISO 14155-1:2003

Clinical investigation of medical devices for human subjects — Part 1: General requirements

ISO 14160:1998

Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants

ISO 14644-1:1999

Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness

ISO 14644-2:2000

Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

ISO 14644-3:2005

Cleanrooms and associated controlled environments — Part 3: Test methods

ISO 14644-4:2001

Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up

ISO 14644-5:2004

Cleanrooms and associated controlled environments — Part 5: Operations

ISO 14644-6 (under development)

Cleanrooms and associated controlled environments — Part 6: Vocabulary

ISO 14644-7:2004

Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

ISO 14644-8 (under development)

Cleanrooms and associated controlled environments — Part 8: Classification of airborne molecular contamination

ISO 15223:2000

Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

ISO/TR 16142:1999

Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

ISO 17025:1999

General requirements for the competence of testing and calibration laboratories

