

BS EN ISO 13485:2012



BSI Standards Publication

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

BSI
British Standards Institution

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW

National foreword

This British Standard is the UK implementation of EN ISO 13485:2012. It is identical to ISO 13485:2003, incorporating corrigendum August 2009. It supersedes BS EN ISO 13485:2003, which will be withdrawn on 31 August 2012.

The UK participation in its preparation was entrusted by Technical Committee CH/210, Quality management and corresponding general aspects for medical devices, to Subcommittee CH/210/1, Quality systems for medical devices.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

ISO corrigendum August 2009 added the year of publication to the ISO 9001:2000 references in clauses 0.3, 0.4, 1.1, and Annex B. Reference [6] was also replaced in the bibliography.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2012
Published by BSI Standards Limited 2012

ISBN 978 0 580 77860 5

ICS 03.120.10; 11.040.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2012.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

EUROPEAN STANDARD

EN ISO 13485

NORME EUROPÉENNE

EUROPEISCHE NORM

February 2012

ICS 03.120.10; 11.040.01

Supersedes EN ISO 13485:2003

English version

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

Dispositifs médicaux - Systèmes de management de la
qualité - Exigences des fins réglementaires (ISO
13485:2003)

Medizinprodukte - Qualitätsmanagementsysteme -
Anforderungen für regulatorische Zwecke (ISO
13485:2003)

This European Standard was approved by CEN on 24 January 2012.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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



CEN-CENELEC Management Centre,
Avenue Marnix 17, B-1000 Brussels

© 2012 CEN/CENELEC All rights of exploitation in any form and by any means reserved
worldwide for CEN national Members and for CENELEC
Members.

Ref. No. EN ISO 13485:2012 E

Foreword

The text of the International Standard ISO 13485:2003 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices, Working Group 1". The transposition into a European Standard has been managed by the CEN-CENELEC Management Centre (CCMC) with the assistance of the CEN-CENELEC Technical Committee 3 "Quality Management and corresponding general aspects for medical devices".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2012, and conflicting national standards shall be withdrawn at the latest by August 2012.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports quality system requirements of EU Medical Devices Directives. Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of the quality systems of the Medical Devices Directives. It is important that the organization and the Notified Body identify the regulatory requirements that are not covered by the standard. The Annexes Z of this standard shall be used for this purpose, describing the relationship between this European Standard and the conformity assessment requirements of the Medical Devices Directives.

This document supersedes EN ISO 13485:2003.

NOTE The following is specifically intended for organizations that need to comply with one or more of the European Directives for medical devices (90/385/EEC, 93/42/EEC and 98/79/EC) in order to affix CE marking on their products and for other parties involved in that process whilst other Directives might also require a CE marking.

Where organizations wish to implement quality systems¹⁾ in conformance with Directives 90/385/EEC, 93/42/EEC and 98/79/EC, they may use EN ISO 13485:2012. EN ISO 13485:2012 provides a framework to enable a manufacturer to meet some of the quality system requirements for an EC Declaration of Conformity (Annex 2 and Annex 5 of Directive 90/385/EEC; Annex II, V and VI of Directive 93/42/EEC; or Annex III, IV and VII of Directive 98/79/EC).

In seeking compliance with the quality systems requirements of the Medical Devices Directives, organizations may exclude specific requirements from EN ISO 13485. The table below shows the exclusions that are permitted.

¹⁾ The European Directives use the term "quality system" whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Directive 90/385/EEC	Directive 93/42/EEC	Directive 98/79/EC
For Annex 2, no exclusions are permitted	For Annex II, no exclusions are permitted	For Annex III and IV, no exclusions are permitted
For Annex 5, exclusion of 7.3 of EN ISO 13485 is permitted	For Annex V, exclusion of 7.3 from EN ISO 13485 is permitted	For Annex VII, exclusion of 7.3 from EN ISO 13485 is permitted
	For Annex VI, exclusion of 7.3, 7.5.1 and 7.5.2 from EN ISO 13485 are permitted	

It should be noted that where the exclusions described in 1.2 of EN ISO 13485:2012 are exceeded, conformity to EN ISO 13485:2012 shall not be claimed.

The requirements in ISO 13485:2003 describe a systematic approach, within which manufacturers can identify, review and decide on the appropriate manner to incorporate regulatory requirements, other standards, and regulatory guidance documents into their quality management system. In this context, EN ISO 13485 requires the manufacturer to provide quality management system elements including: necessary resources, infrastructure and competent personnel; documentation and records for the operation of the quality management system; systems of internal audit and management review; systems to address nonconformity, corrective action and preventive action.

It should be noted that EN ISO 13485:2012 is a quality management system for medical devices specifically for regulatory purposes. It is based on EN ISO 9001:2000 but in particular the requirements for “customer satisfaction” and “continual improvement” have been modified. Therefore, while EN ISO 13485:2012 has the same format as EN ISO 9001:2000 and most of the same requirements, compliance with EN ISO 13485:2012 does not provide conformity with EN ISO 9001:2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13485:2003 has been approved by CEN as a EN ISO 13485:2012 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 90/385/EEC

ZA.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 90/385/EEC on active implantable medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:2012), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZA.1 and ZA.2 confers presumption of conformity with the requirements on a manufacturer's quality system²⁾ as given in Annexes 2 and 5 of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZA explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes 2 and 5 of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZA.1 and ZA.2 if an application to a Notified Body:

- contains the necessary quality system documentation;
 - has been reviewed and approved by a Notified Body,
- and the undertakings listed in the application are correctly executed by the manufacturer.

ZA.2 Relationship with Annex 2 of Directive 90/385/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex 2, as outlined in Table ZA.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex 2 of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

2) This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZA.1 — Relationship between Annex 2 of Directive 90/385/EEC and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 2	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1 st indent		Not covered
3.1 second sentence 2 nd indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex 2 unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second sentence 3 rd indent		Not covered
3.1 second sentence 4 th indent		Not covered
3.1 second sentence 5 th indent		Not covered
3.2 first paragraph		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 90/385/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 second paragraph, first sentence	4.1, 4.2	Covered
3.2 second paragraph, second sentence	4.1, 4.2	Covered
3.2 second paragraph, third sentence		Not covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2, 5.1.1	Covered
3.2 third paragraph (b) 1 st indent	4.2.2, 5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2 nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3 rd indent	4.1, 7.4, 8.5.1	Covered provided that the processes are documented in accordance with 4.2.1.
3.2 third paragraph (c) 1 st indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled and there is a description of the standards that will be

		applied.
3.2 third paragraph (c) 2 nd indent	7.3.1, 7.3.5, 7.3.6, 7.3.7	Covered
3.2 third paragraph (c) 3 rd indent		Not covered
3.2 third paragraph (c) 4 th indent		Not covered
3.2 third paragraph (c) 5 th indent		Not covered
3.2 third paragraph (d) 1 st indent, sterilization	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (d) 1 st indent, purchasing	7.4	Covered
3.2 third paragraph (d) 1 st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (d) 2 nd indent	4.2, 7.5.3,	Covered
3.2 third paragraph (e)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

ZA.3 Relationship with Annex 5 of Directive 90/385/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex 5, as outlined in Table ZA.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex 5 of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the directive.

Table ZA.2 — Relationship between Annex 5 of Directive 90/385/EEC and the clauses of EN ISO 13485

Paragraph of Directive 90/385/EEC, Annex 5	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 2 nd indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex 5 unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 3 rd indent		Not covered
3.1 second paragraph 4 th indent		Not covered
3.1 second paragraph 5 th indent		Not covered
3.1 second paragraph 6 th indent		Not covered
3.2 first paragraph		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 90/385/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b) 1 st indent	5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2 nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3 rd indent	4.1, 7.4, 8.5.1	Covered provided that the processes are documented in accordance with 4.2.1.
3.2 third paragraph (c)	6.4, 7.5.1, 7.5.2	Covered

1 st indent, sterilization		
3.2 third paragraph (c) 1 st indent, purchasing	7.4	Covered
3.2 third paragraph (c) 1 st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (c) 2 nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 90/385/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

Annex ZB (informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 93/42/EEC

ZB.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 93/42/EEC on medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:2012), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZB.1, ZB.2 and ZB.3 confers presumption of conformity with the requirements on a manufacturer's quality system³⁾ as given in Annexes II, V and VI of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZB explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes II, V and VI of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZB.1, ZB.2 and ZB.3 if the application to a Notified Body:

- contains the necessary quality system documentation;
- has been reviewed and approved by a Notified Body,

and the undertakings listed in the application are correctly executed by the manufacturer.

ZB.2 Relationship with Annex II of Directive 93/42/EEC

Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of Annex II, as outlined in Table ZB.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex II of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

³⁾ This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZB.1 — Relationship between Annex II of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex II	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first sentence		Not covered
3.1 second sentence 1 st indent		Not covered
3.1 second sentence 2 nd indent		Not covered
3.1 second sentence 3 rd indent		Not covered
3.1 second sentence 4 th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second sentence 5 th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 6 th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second sentence 7 th indent		Not covered
3.2 first paragraph first sentence		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 first paragraph second sentence	4.1, 4.2	Covered
3.2 second paragraph		Not covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2, 5.1.1	Covered
3.2 third paragraph (b) 1 st indent	4.2.2, 5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2 nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 third paragraph (b) 3 rd indent	4.1, 4.2, 7.4, 8.5.1	Covered provided that control processes are documented in accordance with 4.2.1.
3.2 third paragraph (c)	7.1, 7.2, 7.3	Covered
3.2 third paragraph (c) 1 st indent		Not covered
3.2 third paragraph (c) 2 nd	7.1, 7.2, 7.3.2, 7.3.3,	Covered provided that there is a description of

indent	7.3.6	the standards that will be applied.
3.2 third paragraph (c) 3 rd indent	7.3.1, 7.3.5, 7.3.6, 7.3.7	Covered
3.2 third paragraph (c) 4 th indent	7.3.2, 7.3.3, 7.3.5, 7.3.6	Covered
3.2 third paragraph (c) 5 th indent		Not covered
3.2 third paragraph (c) 6 th indent		Not covered
3.2 third paragraph (c) 7 th indent		Not covered
3.2 third paragraph (c) 8 th indent		Not covered
3.2 third paragraph (c) 9 th indent		Not covered
3.2 third paragraph (c) 10 th indent		Not covered
3.2 third paragraph (d) 1 st indent, sterilization	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (d) 1 st indent, purchasing	7.4	Covered
3.2 third paragraph (d) 1 st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (d) 2 nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (e)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

ZB.3 Relationship with Annex V of Directive 93/42/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex V, as outlined in Table ZB.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex V of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZB.2 — Relationship between Annex V of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex V	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 2 nd indent		Not covered
3.1 second paragraph 3 rd indent		Not covered
3.1 second paragraph 4 th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex V unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5 th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6 th indent	4.1, 5.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 7 th indent		Not covered
3.1 second paragraph 8 th indent		Not covered
3.1 second paragraph 8 th indent (i)		
3.1 second paragraph 8 th indent (ii)		
3.2 first paragraph		Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC.

		The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2	Covered
3.2 third paragraph (b) 1 st indent	5.1, 5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2 nd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.5.2	Covered provided that the methods and criteria chosen by the manufacturer ensure that the requirements of the directive are fulfilled.
3.2 third paragraph (b) 3 rd indent	4.1, 4.2.1, 7.4, 8.5.1	Covered provided that control processes are documented in accordance with 4.2.1.
3.2 third paragraph (c) 1 st indent, sterilization	6.4, 7.5.1, 7.5.2	Covered provided that the explicit requirements of the Directive are incorporated into the quality system documentation.
3.2 third paragraph (c) 1 st indent, purchasing	7.4	Covered
3.2 third paragraph (c) 1 st indent, relevant documents	4.2, 7.1	Covered
3.2 third paragraph (c) 2 nd indent	4.2, 7.5.3	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.5.3.2.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

ZB.4 Relationship with Annex VI of Directive 93/42/EEC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex VI, as outlined in Table ZB.3. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex VI of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZB.3 — Relationship between Annex VI of Directive 93/42/EEC and the clauses of EN ISO 13485

Paragraph of Directive 93/42/EEC, Annex VI	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 2 nd indent		Not covered
3.1 second paragraph 3 rd indent		Not covered
3.1 second paragraph 4 th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex VI unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5 th indent	4.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 6 th indent	4.1, 5.4, 5.5, 5.6	Covered
3.1 second paragraph 7 th indent		Not covered
3.1 second paragraph 8 th indent		Not covered
3.1 second paragraph 8 th indent (i)		Not covered
3.1 second paragraph 8 th indent (ii)		Not covered

3.2 first sentence		Not covered
3.2 second and third sentences	4.1, 4.2	Covered
3.2 second paragraph 1 st indent	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 second paragraph 2 nd indent	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.
3.2 second paragraph 3 rd indent	4.1, 5.6, 7.1, 8.2.2, 8.3, 8.4, 8.5.2, 8.5.3	Covered provided that the methods and acceptance criteria chosen by the manufacturer ensure that the requirements of the Directive are fulfilled.
3.2 second paragraph 4 th indent	4.1, 4.2, 6.1	Covered
3.2 second paragraph 5 th indent	4.1, 4.2.1, 7.4, 8.5.1	Covered provided that control processes are documented in accordance with 4.2.1.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 93/42/EEC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

Annex ZC (informative)

Relationship between this European Standard and the Conformity Assessment Requirements of EU Directive 98/79/EC

ZC.1 General

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means by which a manufacturer may demonstrate conformity, and by which the Notified Body may assess the manufacturer's conformity, with the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices.

Within the limits of the scope of this standard (Clause 1 of EN ISO 13485:2012), compliance with the normative clauses of this standard according to the qualifying remarks presented in Tables ZC.1, ZC.2 and ZC.3 confers presumption of conformity with requirements on a manufacturer's quality system⁴⁾ as given in Annexes III, IV and VII of that Directive and associated EFTA regulations, once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State. This Annex ZC explains to which requirements, under which conditions and to what extent presumption of conformity can be claimed.

The Conformity Assessment Annexes III, IV and VII of the Directive include description of the regulatory process and activities undertaken by the Notified Body, which both are outside of the scope of EN ISO 13485 and therefore not covered by this standard. Furthermore, the requirements of the Directive refer to an application to a Notified Body, not to the requirement for a quality system as such. Accordingly, coverage of legal requirements can only be presumed to the extent listed in Tables ZC.1, ZC.2 and ZC.3 if the application to a Notified Body:

- contains the necessary quality system documentation;
 - has been reviewed and approved by a Notified Body,
- and the undertakings listed in the application are correctly executed by the manufacturer.

ZC.2 Relationship with Annex III of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide a presumption of conformity with all the aspects of Annex III, as outlined in Table ZC.1. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex III of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

⁴⁾ This annex uses the term "quality system" as used in the Directive whereas EN ISO 13485 uses the term "quality management system" in accordance with ISO terminology.

Table ZC.1 — Relationship between Annex III of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex III	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3 first sentence		Not covered
3 1 st indent		Not covered
3 2 nd indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in Annex III unless the explicit legal requirements are incorporated into the quality system documentation.
3 3 rd indent	4.2, 7.1, 7.3, 7.5	Covered
3 4 th indent		Not covered
3 5 th indent		Not covered
3 6 th indent		Not covered
3 7 th indent	6.4, 7.5.1.2, 7.5.1.3, 7.5.2	Covered
3 8 th indent	4.2.1, 7.1.8.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.3, 8.2.4	Covered
3 9 th indent		Not covered
3 10 th indent	4.2.4, 8.2.4	Covered
3 11 th indent		Not covered
3 12 th indent		Not covered
3 13 th indent		Not covered

ZC.3 Relationship with Annex IV of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex IV, as outlined in Table ZC.2. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex IV of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZC.2 — Relationship between Annex IV of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex IV	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 2 nd indent		Not covered
3.1 second paragraph 3 rd indent		Not covered
3.1 second paragraph 4 th indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex IV unless the explicit legal requirements of the Directive are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 5 th indent		Not covered
3.1 second paragraph 6 th indent		Not covered
3.1 second paragraph 7 th indent		Not covered
3.2 first sentence		Not covered
3.2 second sentence	4.1, 4.2	Covered
3.2 second paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 second paragraph (b)	4.2.2	Covered
3.2 second paragraph (b) 1 st indent	5.5.1, 5.5.2	Covered
3.2 second paragraph (b) 2 nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 second paragraph (c) 1 st indent		Not covered

3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 3 rd indent	4.2, 7.1, 7.3, 7.5	Covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 4 th indent		Not covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 5 th indent		Not covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 6 th indent		Not covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 7 th indent	6.4, 7.5.1.2, 7.5.1.3, 7.5.2	Covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 8 th indent	4.2.1, 7.1.8.1, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.4.3, 8.2.3, 8.2.4	Covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 9 th indent		Not covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 10 th indent	4.2.4, 8.2.4	Covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 11 th indent		Not covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 12 th indent		Not covered
3.2 second paragraph (c) 2 nd indent reference to Annex III – section 3 13 th indent		Not covered
3.2 second paragraph (d) 1 st indent	6.4, 7.5.1, 7.5.2	Covered

3.2 second paragraph (d) 2 nd indent	7.4	Covered
3.2 second paragraph (d) 3 rd indent	7.5.1, 7.5.2, 7.4, 4.2	Covered
3.2 second paragraph (e)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

ZC.4 Relationship with Annex VII of Directive 98/79/EC

Compliance with EN ISO 13485 does not provide presumption of conformity with all the aspects of Annex VII, as outlined in Table ZC.3. Therefore, a manufacturer or a Notified Body has to take additional provisions to ensure conformity, and claim or certify conformance, with Annex VII of this Directive. The legal requirements must be examined, applied and verified one by one and the solutions adopted must become part of the quality system in the meaning of the Directive.

Table ZC.3 — Relationship between Annex VII of Directive 98/79/EC and the clauses of EN ISO 13485

Paragraph of Directive 98/79/EC, Annex VII	Clause(s) of EN ISO 13485	Comments/Qualifying remarks
3.1 first paragraph		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 1 st indent	4.1, 4.2	Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation meant in 3.2 of Annex VII unless the explicit legal requirements of the Directive are incorporated into the quality system documentation. See also coverage of 3.2 below.
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 1 st indent		Not covered
3.1 second paragraph 1 st indent		Not covered
3.2 first paragraph		Not covered
3.2 second paragraph	4.1, 4.2	Covered
3.2 third paragraph (a)	4.2.1, 5.1, 5.3, 5.4.1	Covered
3.2 third paragraph (b)	4.2.2	Covered

3.2 third paragraph (b) 1 st indent	5.5.1, 5.5.2	Covered
3.2 third paragraph (b) 2 nd indent	5.6, 8.2.2, 8.3, 8.5.2	Covered
3.2 third paragraph (c) 1 st indent	6.4, 7.5.1, 7.5.2	Covered
3.2 third paragraph (c) 2 nd indent	7.4	Covered
3.2 third paragraph (c) 3 rd indent	4.2, 7.5.1, 7.5.2, 7.4	Covered
3.2 third paragraph (d)	4.2, 7.1, 7.6, 8.2.4	Covered provided that the frequency at which tests are carried out is documented and that test results can be traced to the test equipment used.

WARNING — The preceding text and tables are specifically intended for organizations that need to comply with the European Directive 98/79/EC in order to affix CE marking on their products and for other parties involved in that process. Other Directives might also be applicable and require a CE marking.

Contents

Page

Foreword	iv
0 Introduction	v
0.1 General	v
0.2 Process approach	v
0.3 <i>Relationship with other standards</i>	v
0.4 Compatibility with other management systems	vi
1 Scope	1
1.1 General	1
1.2 Application	1
2 Normative references	2
3 Terms and definitions	2
4 Quality management system	4
4.1 General requirements	4
4.2 Documentation requirements	4
5 Management responsibility	6
5.1 Management commitment	6
5.2 Customer focus	6
5.3 Quality policy	6
5.4 Planning	7
5.5 Responsibility, authority and communication	7
5.6 Management review	8
6 Resource management	8
6.1 Provision of resources	8
6.2 Human resources	9
6.3 Infrastructure	9
6.4 Work environment	9
7 Product realization	10
7.1 Planning of product realization	10
7.2 Customer-related processes	10
7.3 Design and development	11
7.4 Purchasing	13
7.5 Production and service provision	14
7.6 Control of monitoring and measuring devices	17
8 Measurement, analysis and improvement	17
8.1 General	17
8.2 Monitoring and measurement	18
8.3 Control of nonconforming product	19
8.4 Analysis of data	19
8.5 Improvement	20
Annex A (informative) Correspondence between ISO 13485:2003 and ISO 13485:1996	21
Annex B (informative) Explanation of differences between ISO 13485:2003 and ISO 9001:2000	25
Bibliography	57

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

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

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

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

0 Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization for the design 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.

0.2 Process approach

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

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

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

Often the output from one process directly forms the input to the next.

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

0.3 Relationship with other standards

0.3.1 Relationship with ISO 9001:2000

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

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

Where the text of this International Standard is not identical to the text of ISO 9001:2000, 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.

0.4 Compatibility with other management systems

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

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management.

However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Medical devices — Quality management systems — Requirements for regulatory purposes

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices 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 9001:2000 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001:2000 unless their quality management systems conform to all the requirements of ISO 9001:2000 (see Annex B).

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.*

2 Normative references

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

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

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.

3.1

active implantable medical device

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

3.2

active medical device

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

3.3

advisory notice

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

- the use of a medical device,
- the modification of a medical device,
- the return 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.

3.4

customer complaint

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

3.5

implantable medical device

medical device intended

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

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

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

3.6

labelling

written, printed or graphic matter

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

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

NOTE Some regional and national regulations refer to "labelling" as "information supplied by the manufacturer."

3.7

medical device

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

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- *supporting or sustaining life,*
- *control of conception,*
- *disinfection of medical devices,*
- *providing information for medical purposes by means of in vitro examination of specimens derived from the human body,*

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.

NOTE This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [15].

3.8

sterile medical device

category of medical device intended to meet the requirements for sterility

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

4 Quality management system

4.1 General requirements

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

The organization shall

- a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyse these processes, and
- f) *implement actions necessary to achieve planned results and maintain the effectiveness of these processes.*

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

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

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

4.2 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.

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.

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.

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.

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.

5.2 Customer focus

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

5.3 Quality policy

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,

- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

- a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

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

Top management shall establish the interrelation of all personnel who manage, perform and 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).

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.

5.5.3 Internal communication

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

5.6 Management review

5.6.1 General

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

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

5.6.2 Review input

The input to management review shall include information on

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

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.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

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

6.2 Human resources

6.2.1 General

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

6.2.2 Competence, awareness and training

The organization shall

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

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

6.3 Infrastructure

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

- 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).

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).*

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.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

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

7.2.2 Review of requirements related to the product

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

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

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

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

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

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

7.2.3 Customer communication

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

- a) product information,
- b) enquiries, contracts or order handling, including amendments,
- c) customer feedback, including customer complaints (see 8.2.1), and
- d) advisory notices (see 8.5.1).

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.*

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.

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.

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).

7.3.5 Design and development verification

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

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. 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.

7.3.7 Control of design and development changes

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

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

7.4 Purchasing

7.4.1 Purchasing process

The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements.

The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

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

7.4.2 Purchasing information

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

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

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

To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).

7.4.3 Verification of purchased product

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

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

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

7.5 Production and service provision

7.5.1 Control of production and service provision

7.5.1.1 General requirements

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

- a) the availability of information that describes the characteristics of the product,
- b) *the availability of documented procedures, 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.

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.

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).

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.*

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).

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)

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).

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)].

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.

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).

7.5.3.3 Status identification

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

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

7.5.4 Customer property

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

NOTE Customer property can include intellectual property or confidential health information.

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).

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.

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.

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).

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.

8.2.3 Monitoring and measurement of processes

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

8.2.4 Monitoring and measurement of product

8.2.4.1 General requirements

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1).

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

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

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

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

8.3 Control of nonconforming product

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

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

- a) by taking action to eliminate the detected nonconformity;
- b) *by authorizing its use, release or acceptance under concession;*
- 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).

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).

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.

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.*

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.*

Annex A
(informative)

Correspondence between ISO 13485:2003 and ISO 13485:1996

Table A.1 — Correspondence between ISO 13485:1996 and 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]	
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

Table A.1 (continued)

ISO 13485:1996	ISO 13485:2003
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
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

Table A.2 — Correspondence between ISO 13485:2003 and ISO 13485:1996

ISO 13485:2003	ISO 13485:1996
1 Scope	1
1.1 General	
1.2 Application	
2 Normative reference	2
3 Terms and definitions	3
4 Quality management system [title only]	
4.1 General requirements	4.2.1
4.2 Documentation requirements [title only]	
4.2.1 General	4.2.2
4.2.2 Quality manual	4.2.1
4.2.3 Control of documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of records	4.16
5 Management responsibility [title only]	
5.1 Management commitment	4.1.1
5.2 Customer focus	4.3.2
5.3 Quality policy	4.1.1
5.4 Planning [title only]	
5.4.1 Quality objectives	4.1.1
5.4.2 Quality management system planning	4.2.3
5.5 Responsibility, authority and communication [title only]	
5.5.1 Responsibility and authority	4.1.2.1
5.5.2 Management representative	4.1.2.3
5.5.3 Internal communication	
5.6 Management review [title only]	
5.6.1 General	4.1.3
5.6.2 Review input	
5.6.3 Review output	
6 Resource management [title only]	
6.1 Provision of resources	4.1.2.2
6.2 Human resources [title only]	
6.2.1 General	4.1.2.2
6.2.2 Competence, awareness and training	4.18
6.3 Infrastructure	4.9
6.4 Work environment	4.9 + 4.15.1
7 Product realization [title only]	
7.1 Planning of product realization	4.2.3 + 4.10.1

Table A.2 (continued)

ISO 13485:2003	ISO 13485:1996
7.2 Customer-related processes [title only]	
7.2.1 Determination of requirements related to the product	4.3.2 + 4.4.4
7.2.2 Review of requirements related to the product	4.3.2 + 4.3.3 + 4.3.4
7.2.3 Customer communication	4.3.2
7.3 Design and development [title only]	
7.3.1 Design and development planning	4.4.2 + 4.4.3
7.3.2 Design and development inputs	4.4.4
7.3.3 Design and development outputs	4.4.5
7.3.4 Design and development review	4.4.6
7.3.5 Design and development verification	4.4.7
7.3.6 Design and development validation	4.4.8
7.3.7 Control of design and development changes	4.4.9
7.4 Purchasing [title only]	
7.4.1 Purchasing process	4.6.2
7.4.2 Purchasing information	4.6.3
7.4.3 Verification of purchased product	4.6.4 + 4.10.2
7.5 Production and service provision [title only]	
7.5.1 Control of production and service provision	4.9 + 4.15.6 + 4.19
7.5.2 Validation of processes for production and service provision	4.9
7.5.3 Identification and traceability	4.8 + 4.10.5 + 4.12
7.5.4 Customer property	4.7
7.5.5 Preservation of product	4.15.2 + 4.15.3 + 4.15.4 + 4.15.5
7.6 Control of monitoring and measuring devices	4.10 + 4.20.1 + 4.20.2
8 Measurement, analysis and improvement [title only]	
8.1 General	4.11.1 + 4.11.2
8.2 Monitoring and measurement [title only]	
8.2.1 Feedback	
8.2.2 Internal audit	4.17
8.2.3 Monitoring and measurement of processes	4.17 + 4.20.1 + 4.20.2
8.2.4 Monitoring and measurement of product	4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2
8.3 Control of nonconforming product	4.13.1 + 4.13.2
8.4 Analysis of data	4.20.1 + 4.20.2
8.5 Improvement [title only]	
8.5.1 General	4.1.3
8.5.2 Corrective action	4.14.1 + 4.14.2
8.5.3 Preventive action	4.14.1 + 4.14.3

Annex B (informative)

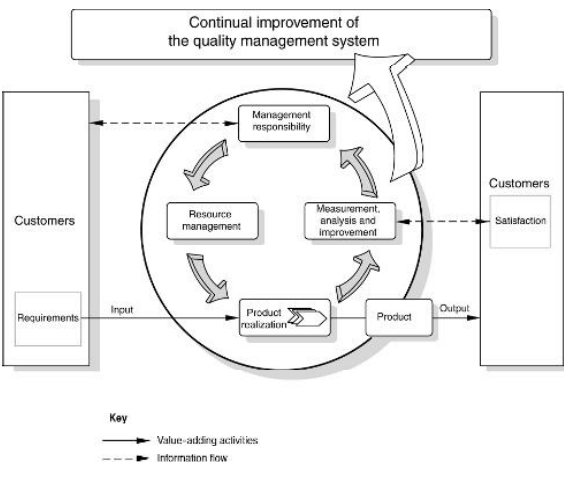
Explanation of differences between ISO 13485:2003 and ISO 9001:2000

This annex documents the similarities and differences between requirements clauses and subclauses and key informative clauses and subclauses of this International Standard and ISO 9001:2000. It also provides a rationale for the differences between this International Standard and ISO 9001:2000.

- a) For those clauses or subclauses of this International Standard that are quoted directly and unchanged from ISO 9001:2000, the fact that these subclauses are presented unchanged is noted in this annex by a phrase appearing in square brackets [].
- b) For those clauses or subclauses from ISO 9001:2000 that are changed in this International Standard by the addition of information or by tailoring it to be consistent with medical device regulations, the entire original ISO 9001:2000 text of the clause or subclause is reproduced in the left-hand column of this annex. The text of the corresponding clause or subclause in this International Standard is shown in the right-hand column.
- c) For those clauses or subclauses where this International Standard has deleted or amended the text of ISO 9001:2000 by the deletion or significant modification of a substantive requirement, the entire original ISO 9001:2000 text of the clause or subclause is reproduced in the left-hand column of this annex. The text of the corresponding clause or subclause in this International Standard and the reasons for the text changes are given in the right-hand column.
- d) The reasons for the differences between this International Standard and ISO 9001:2000 are given in the right-hand column. Where no "reason for differences" is given for an individual clause or differences between the two International Standards arises from the objective of ISO 13485 to reflect the subclause, the text current regulations and facilitate the harmonization of new medical device regulations around the world.

ISO 9001:2000	ISO 13485:2003
<p>0 Introduction</p> <p>0.1 General</p> <p>The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p>The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.</p>	<p>0 Introduction</p> <p>0.1 General</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>It is emphasized that the quality management system requirements specified in this International Standard are complementary to technical requirements for products.</i></p> <p>Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.</p>

ISO 9001:2000	ISO 13485:2003
<p>This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.</p> <p>The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.</p>	<p>The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.</p> <p><i>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.</i></p> <p>Reason for differences: Except for the contents of paragraph 4 of 0.1 of ISO 13485, any changes to the text of 0.1 of ISO 9001:2000 is intended only to tailor this text for application to the medical device sector.</p>
<p>0.2 Process approach</p> <p>This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.</p> <p>For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.</p> <p>The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".</p> <p>An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.</p> <p>When used within a quality management system, such an approach emphasizes the importance of</p> <ul style="list-style-type: none"> a) understanding and meeting requirements, b) the need to consider processes in terms of added value, c) obtaining results of process performance and effectiveness, and 	<p>0.2 Process approach</p> <p><i>This International Standard is based on a process approach to quality management.</i></p> <p><i>Any activity that receives inputs and converts them to outputs can be considered as a process.</i></p> <p><i>For an organization to function effectively, it has to identify and manage numerous linked processes.</i></p> <p>Often the output from one process directly forms the input to the next.</p> <p>The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".</p> <p>Reason for differences: Much of the guidance contained in 0.2 of ISO 9001:2000 is being considered for inclusion in ISO/TR14969, the Technical Report that is intended to provide guidance for the implementation of the requirements of ISO 13485. This information is included in this subclause of ISO 9001:2000 because no such guidance document as ISO/TR 14969 exists. Because ISO/TR 14969 is being developed, the guidance text is not included in this subclause in ISO 13485.</p>

ISO 9001:2000	ISO 13485:2003
<p>d) continual improvement of processes based on objective measurement.</p> <p>The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.</p> <p>NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.</p> <p>Plan: establish the objectives and processes to deliver results in accordance with customer requirements and the organization’s policies.</p> <p>Do: implement the processes.</p> <p>Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.</p> <p>Act: take actions to continually improve process performance.</p>  <p>Figure 1 — Model of a process-based quality management system</p>	

ISO 9001:2000	ISO 13485:2003
<p>0.3 Relationship with ISO 9004</p> <p>The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.</p> <p>ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.</p> <p>ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.</p>	<p>0.3 Relationship with other standards</p> <p>0.3.1 Relationship with ISO 9001:2000</p> <p><i>While this is a stand-alone standard, it is based on ISO 9001:2000.</i></p> <p><i>Those clauses or subclauses that are quoted directly and unchanged from ISO 9001:2000 are in normal font. The fact that these subclauses are presented unchanged is noted in Annex B.</i></p> <p><i>Where the text of this International Standard is not identical to the text of ISO 9001:2000, the sentence or indent containing that text as a whole is shown in italics (and blue italics for electronic versions). The nature and reasons for the text changes are noted in Annex B.</i></p> <p>0.3.2 Relationship with ISO/TR 14969</p> <p><i>ISO/TR 14969 is a Technical Report intended to provide guidance for the application of ISO 13485.</i></p> <p>Reason for differences: There is no significant relationship between ISO 13485 and ISO 9004. The key relationships that benefit from explanation in this introductory subclause are the ones between ISO 13485 and ISO 9001:2000 and ISO/TR 14969.</p>
<p>0.4 Compatibility with other management systems</p> <p>This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.</p> <p>This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.</p>	<p>0.4 Compatibility with other management systems</p> <p><i>This International Standard follows the format of ISO 9001:2000 for the convenience of users in the medical device community.</i></p> <p><i>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.</i></p> <p>However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.</p> <p>Reason for differences: The first paragraph of 0.4 of ISO 13485 emphasizes the alignment of ISO 13485 with ISO 9001:2000.</p>

ISO 9001:2000	ISO 13485:2003
	Risk management is a key requirement in many activities and requirements associated with quality management systems for medical device organizations.
<p>1 Scope</p> <p>1.1 General</p> <p>This International Standard specifies requirements for a quality management system where an organization</p> <p>a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and</p> <p>b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.</p> <p>NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.</p>	<p>1 Scope</p> <p>1.1 General</p> <p><i>This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.</i></p> <p><i>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 9001:2000 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001:2000 unless their quality management systems conform to all the requirements of ISO 9001:2000 (see Annex B).</i></p> <p>Reason for differences: This subclause uses and explains terms that are appropriate for the medical device sector. In addition, the terms “customer satisfaction” and “continual improvement” are eliminated as they are not relevant in a standard whose objective is to facilitate the harmonization of medical device regulations for quality management systems around the world.</p> <p>Paragraph 2 is intended to clarify that the intent of ISO 13485 is to facilitate the harmonization of regulatory quality management system requirements around the world, to point out that this intent requires the addition of some requirements not found in ISO 9001:2000 and the deletion of some requirements that are found in ISO 9001:2000, and to clarify the fact that adherence to ISO 13485 cannot result in the claim of adherence to ISO 9001:2000.</p> <p>The term “and related services” has been added twice to modify the term “medical devices” because “medical device” does not include “services” in its definition. This is in contrast to ISO 9001:2000, where the term “product” does include “services” as part of its definition.</p>

ISO 9001:2000	ISO 13485:2003
<p>1.2 Application</p> <p>All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.</p> <p>Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.</p> <p>Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.</p>	<p>1.2 Application</p> <p><i>All requirements of this International Standard are specific to organizations providing medical devices, regardless of the type or size of the organization.</i></p> <p><i>If regulatory requirements permit exclusions of design and development controls (see 7.3), this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that must be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with this International Standard reflect exclusion of design and development controls [see 4.2.2 a) and 7.3].</i></p> <p><i>If any requirement(s) in Clause 7 of this International Standard is 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)].</i></p> <p><i>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)].</i></p> <p><i>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</i></p> <ul style="list-style-type: none"> <i>a) the product to meet specified requirements, and/or</i> <i>b) the organization to carry out corrective action.</i> <p>Reason for differences: The text clarifies the fact that the requirements of ISO 13485 are specific to the medical device sector. In addition, it amplifies the relationship between exclusions for design and development that might have regulatory impact in certain locations in the world. Finally, it distinguishes between the requirements in Clause 7 which an organization may with regulatory justification exclude from its quality management system (limited to 7.3), even though they may perform activities to which those requirements relate, and those which the organization may with justification not include its quality management system because they relate to activities not performed by the organization.</p>

ISO 9001:2000	ISO 13485:2003
<p>2 Normative reference</p> <p>The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.</p> <p>ISO 9000:2000, <i>Quality management systems — Fundamentals and vocabulary</i></p>	<p>2 Normative references</p> <p><i>The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.</i></p> <p>ISO 9000:2000, <i>Quality management systems — Fundamentals and vocabulary</i></p> <p>Reason for differences: The ISO 13485 text reflects a revision required by the 2001 edition of the ISO/IEC Directives, Part 2.</p>
<p>3 Terms and definitions</p> <p>For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.</p> <p>The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:</p> <p style="text-align: center;">supplier ----> organization ----> customer</p> <p>The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “sub-contractor”.</p> <p>Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.</p>	<p>3 Terms and definitions</p> <p>For the purposes of this <i>document</i>, the terms and definitions given in ISO 9000 apply, <i>together with the following.</i></p> <p>The following terms, used in this edition of <i>ISO 13485</i> to describe the supply chain, have been changed to reflect the vocabulary currently used:</p> <p style="text-align: center;">supplier ----> organization ----> customer</p> <p><i>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 “sub-contractor”.</i></p> <p>Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.</p> <p>Wherever requirements are specified as applying to “medical devices”, the requirements apply equally to related services as supplied by the organization.</p> <p><i>The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.</i></p> <p>Reason for differences: The text is tailored for use in the medical device sector and also includes a caveat related to the fact that local regulations might have a definition that supercedes that contained or referenced in ISO 13485. Definitions 3.1 to 3.8 are specific to the medical device sector.</p>

ISO 9001:2000	ISO 13485:2003
<p>4 Quality management system</p> <p>4.1 General requirements</p> <p>The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.</p> <p>The organization shall</p> <ul style="list-style-type: none"> a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyze these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes. <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.</p> <p>NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.</p>	<p>4 Quality management system</p> <p>4.1 General requirements</p> <p><i>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.</i></p> <p>The organization shall</p> <ul style="list-style-type: none"> a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure and analyse these processes, and f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes. <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).</p> <p>NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.</p> <p>Reason for differences: The resulting text is consistent with the objectives of reflecting the current regulations and facilitating the harmonization of new medical device regulations around the world. Current regulations are targeted at the effectiveness of the quality management system to consistently produce safe and effective products.</p>

ISO 9001:2000	ISO 13485:2003
<p>4.2 Documentation requirements</p> <p>4.2.1 General</p> <p>The quality management system documentation shall include</p> <ul style="list-style-type: none"> a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard (see 4.2.4). <p>NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.</p> <p>NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <ul style="list-style-type: none"> a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. <p>NOTE 3 The documentation can be in any form or type of medium.</p>	<p>4.2 Documentation requirements</p> <p>4.2.1 General</p> <p>The quality management system documentation shall include</p> <ul style="list-style-type: none"> a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, e) records required by this International Standard (see 4.2.4), <i>and</i> f) <i>any other documentation specified by national or regional regulations.</i> <p><i>Where this International Standard specifies that a requirement, procedure, activity or special arrangement be “documented”, it shall, in addition, be implemented and maintained.</i></p> <p><i>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.</i></p> <p>NOTE 1 The extent of the quality management system documentation can differ from one organization to another due to</p> <ul style="list-style-type: none"> a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. <p>NOTE 2 The documentation can be in any form or type of medium.</p> <p>Reason for differences: The text in 4.2.1 of ISO 13485 includes all of the requirements contained in the corresponding subclause of ISO 9001:2000, with the addition of a general statement related to regulations that might contain documentation requirements and a specific requirement for a file containing specified documents for</p>

ISO 9001:2000	ISO 13485:2003
	each type/model of medical device. In addition, the text includes the documentation requirements for activities and special arrangements. The resulting text is consistent with the objectives of reflecting the current regulations and facilitating the harmonization of new medical device regulations around the world.
<p>4.2.2 Quality manual</p> <p>The organization shall establish and maintain a quality manual that includes</p> <ul style="list-style-type: none"> a) the scope of the quality management system, including details of and justification for any exclusion (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system. 	<p>4.2.2 Quality manual</p> <p>The organization shall establish and maintain a quality manual that includes</p> <ul style="list-style-type: none"> a) <i>the scope of the quality management system, including details of and justification for any exclusion and/or non-application (see 1.2),</i> 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. <p><i>The quality manual shall outline the structure of the documentation used in the quality management system.</i></p>
<p>4.2.3 Control of documents</p> <p>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.</p> <p>A documented procedure shall be established to define the controls needed</p> <ul style="list-style-type: none"> a) to 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. 	<p>4.2.3 Control of documents</p> <p>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.</p> <p>A documented procedure shall be established to define the controls needed</p> <ul style="list-style-type: none"> a) <i>to review and approve documents for adequacy prior to issue,</i> 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.

ISO 9001:2000	ISO 13485:2003
	<p><i>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.</i></p> <p><i>The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that 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.</i></p>
<p>4.2.4 Control of records</p> <p>Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.</p>	<p>4.2.4 Control of records</p> <p>Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.</p> <p><i>The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.</i></p>
<p>5 Management responsibility</p> <p>5.1 Management commitment</p> <p>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by</p> <ul style="list-style-type: none"> a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. 	<p>5 Management responsibility</p> <p>5.1 Management commitment</p> <p><i>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by</i></p> <ul style="list-style-type: none"> a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.

ISO 9001:2000	ISO 13485:2003
	<p><i>NOTE For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.</i></p> <p>Reason for differences: This text is consistent with the objective of reflecting the current regulation and facilitating the harmonization of new medical device regulations around the world. Current regulations are targeted at the effectiveness of the quality management system to consistently produce safe and effective products.</p>
<p>5.2 Customer focus</p> <p>Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).</p>	<p>5.2 Customer focus</p> <p><i>Top management shall ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1).</i></p> <p>Reason for differences: The rewording of the text is consistent with the position that customer satisfaction is not an appropriate regulatory objective of medical devices. As a result, this text is consistent with the objective of ISO 13485 to facilitate the harmonization of quality management system regulations around the world.</p>
<p>5.3 Quality policy</p> <p>Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, 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. 	<p>5.3 Quality policy</p> <p>Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> a) is appropriate to the purpose of the organization, <i>b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system,</i> 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. <p>Reason for differences: The text of 5.3 of ISO 13485 eliminates from item b) the commitment to continually improve the effectiveness of the quality management system and substitutes the commitment to maintain the effectiveness of the quality management system. This substitution is consistent with the objective of current regulations and is intended to facilitate the harmonization of quality management system regulations around the world.</p>
	<p>5.4 Planning</p> <p>[The text of 5.4 in ISO 13485 is identical to that in the corresponding subclause of ISO 9001:2000.]</p>

ISO 9001:2000	ISO 13485:2003
<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p>Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.</p>	<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p><i>Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.</i></p> <p><i>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.</i></p> <p><i>NOTE National or regional regulation 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).</i></p>
<p>5.5.2 Management representative</p> <p>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:</p> <p>a) ensuring that processes needed for the quality management system are established, implemented and maintained;</p> <p>b) reporting to top management on the performance of the quality management system and any need for improvement; and</p> <p>c) ensuring the promotion of awareness of customer requirements throughout the organization.</p> <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p>	<p>5.5.2 Management representative</p> <p>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes</p> <p>a) ensuring that processes needed for the quality management system are established, implemented and maintained;</p> <p>b) reporting to top management on the performance of the quality management system and any need for improvement (see 8.5); and</p> <p>c) <i>ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.</i></p> <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p>
	<p>5.5.3 Internal communication</p> <p>[The text of 5.5.3 in ISO 13485 is identical to that in the corresponding subclause of ISO 9001:2000.]</p>
<p>5.6 Management review</p>	<p>5.6 Management review</p> <p>5.6.1 General</p> <p>[The text of 5.6.1 in ISO 13485 is identical to that in the corresponding subclause of ISO 9001:2000.]</p>

ISO 9001:2000	ISO 13485:2003
<p>5.6.2 Review input</p> <p>The input to management review shall include information on</p> <ul style="list-style-type: none"> a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement. 	<p>5.6.2 Review input</p> <p><i>The input to management review shall include information on</i></p> <ul style="list-style-type: none"> 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) <i>new or revised regulatory requirements</i>
<p>5.6.3 Review output</p> <p>The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> a) improvement of the effectiveness of the quality management system and its processes b) improvement of product related to customer requirements, and c) resource needs. 	<p>5.6.3 Review output</p> <p>The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> a) <i>improvements needed to maintain the effectiveness of the quality management system and its processes,</i> b) improvement of product related to customer requirements, and c) resource needs.
<p>6 Resource management</p> <p>6.1 Provision of resources</p> <p>The organization shall determine and provide the resources needed</p> <ul style="list-style-type: none"> a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements. 	<p>6 Resource management</p> <p>6.1 Provision of resources</p> <p>The organization shall determine and provide the resources needed</p> <ul style="list-style-type: none"> a) <i>to implement the quality management system and to maintain its effectiveness, and</i> b) <i>to meet regulatory and customer requirements.</i>
<p>6.2 Human resources</p>	<p>6.2 Human resources</p> <p>6.2.1 General</p> <p>[The text of 6.2.1 in ISO 13485 is identical to that in the corresponding subclause of ISO 9001:2000.]</p>

ISO 9001:2000	ISO 13485:2003
<p>6.2.2 Competence, awareness and training</p> <p>The organization shall</p> <ul style="list-style-type: none"> 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, training, skills and experience (see 4.2.4). 	<p>6.2.2 Competence, awareness and training</p> <p>The organization shall</p> <ul style="list-style-type: none"> 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). <p><i>NOTE National or regional regulations might require the organization to establish documented procedures for identifying training needs.</i></p>
<p>6.3 Infrastructure</p> <p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</p> <ul style="list-style-type: none"> a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication). 	<p>6.3 Infrastructure</p> <p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</p> <ul style="list-style-type: none"> a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication). <p><i>The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.</i></p> <p><i>Records of such maintenance shall be maintained (see 4.2.4).</i></p>
<p>6.4 Work environment</p> <p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p>	<p>6.4 Work environment</p> <p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements. <i>The following requirements shall apply.</i></p> <ul style="list-style-type: none"> a) <i>The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel</i>

ISO 9001:2000	ISO 13485:2003
	<p><i>and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1).</i></p> <p><i>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).</i></p> <p><i>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)].</i></p> <p><i>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).</i></p>
<p>7 Product realization</p> <p>7.1 Planning of product realization</p> <p>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <p>a) quality objectives and requirements for the product;</p> <p>b) the need to establish processes, documents, and provide resources specific to the product;</p> <p>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;</p> <p>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).</p> <p>The output of this planning shall be in a form suitable for the organization's method of operations.</p>	<p>7 Product realization</p> <p>7.1 Planning of product realization</p> <p>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <p>a) quality objectives and requirements for the product;</p> <p>b) the need to establish processes, documents, and provide resources specific to the product;</p> <p>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;</p> <p>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).</p> <p>The output of this planning shall be in a form suitable for the organization's method of operations.</p>

ISO 9001:2000	ISO 13485:2003
<p>NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.</p> <p>NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.</p>	<p><i>The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.).</i></p> <p>NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.</p> <p>NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.</p> <p>NOTE 3 See ISO 14971 for guidance related to risk management.</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulations and facilitating the harmonization of new medical device regulations around the world. Risk management is a key activity that determines the nature and amount of activity in many of the areas addressed by the medical device organization's quality management system.</p>
<p>7.2 Customer-related processes</p>	<p>7.2 Customer-related processes</p> <p>7.2.1 Determination of requirements related to the product</p> <p>[The text of 7.2.1 in ISO 13485 is identical to that in the corresponding subclause of ISO 9001:2000.]</p>
<p>7.2.2 Review of requirements related to the product</p> <p>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <ul style="list-style-type: none"> a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).</p>	<p>7.2.2 Review of requirements related to the product</p> <p>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <ul style="list-style-type: none"> a) <i>product requirements are defined and documented,</i> b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).</p>

ISO 9001:2000	ISO 13485:2003
<p>Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.</p> <p>NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.</p>	<p>Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.</p> <p>NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.</p>
<p>7.2.3 Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <ul style="list-style-type: none"> a) product information, b) enquiries, contracts or order handling, including amendments, c) customer feedback, including customer complaints. 	<p>7.2.3 Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <ul style="list-style-type: none"> a) product information, b) enquiries, contracts or order handling, including amendments, c) customer feedback, including customer complaints (<i>see 8.2.1</i>), and d) <i>advisory notices (see 8.5.1)</i>.
<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p>The organization shall plan and control the design and development of product.</p> <p>During the design and development planning, the organization shall determine</p> <ul style="list-style-type: none"> a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p> <p>Planning output shall be updated as appropriate, as the design and development progresses (see 4.2.3).</p>	<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p><i>The organization shall establish documented procedures for design and development.</i></p> <p>The organization shall plan and control the design and development of product.</p> <p>During the design and development planning, the organization shall determine</p> <ul style="list-style-type: none"> a) the design and development stages, b) <i>the review, verification, validation and design transfer activities (see Note) that are appropriate at each design and development stage, and</i> c) the responsibilities and authorities for design and development. <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p>

ISO 9001:2000	ISO 13485:2003
	<p><i>Planning output shall be documented, and updated as appropriate, as the design and development progresses (see 4.2.3).</i></p> <p><i>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.</i></p> <p>Reason for differences: This text is consistent with the objective of reflecting the current regulations and facilitating the harmonization of new medical device regulations around the world. In general, ISO 13485 retains the same level of documented procedure requirements contained in ISO 9001:1994, the standard with which many local regulations are consistent.</p>
<p>7.3.2 Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include</p> <ul style="list-style-type: none"> a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. <p>These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</p>	<p>7.3.2 Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include</p> <ul style="list-style-type: none"> a) <i>functional, performance and safety requirements, according to the intended use,</i> 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) <i>output(s) of risk management (see 7.1).</i> <p><i>These inputs shall be reviewed for adequacy and approved.</i></p> <p>Requirements shall be complete, unambiguous and not in conflict with each other.</p>
<p>7.3.3 Design and development outputs</p> <p>The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p> <ul style="list-style-type: none"> a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, 	<p>7.3.3 Design and development outputs</p> <p>The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p> <ul style="list-style-type: none"> a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision,

ISO 9001:2000	ISO 13485:2003
<p>c) contain or reference product acceptance criteria, and</p> <p>d) specify the characteristics of the product that are essential for its safe and proper use.</p>	<p>c) contain or reference product acceptance criteria, and</p> <p>d) specify the characteristics of the product that are essential for its safe and proper use.</p> <p><i>Records of the design and development outputs shall be maintained (see 4.2.4).</i></p> <p><i>NOTE Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.</i></p>
<p>7.3.4 Design and development review</p> <p>At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)</p> <p>a) to evaluate the ability of the results of design and development to meet requirements, and</p> <p>b) to identify any problems and propose necessary actions.</p> <p>Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).</p>	<p>7.3.4 Design and development review</p> <p>At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)</p> <p>a) to evaluate the ability of the results of design and development to meet requirements, and</p> <p>b) to identify any problems and propose necessary actions.</p> <p><i>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).</i></p> <p>Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).</p>
	<p>7.3.5 Design and development verification</p> <p>[The text of 7.3.5 in ISO 13485 is identical to that in the corresponding subclause of ISO 9001:2000.]</p>
<p>7.3.6 Design and development validation</p> <p>Design and development validation shall be performed in accordance with planned arrangements (7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4)</p>	<p>7.3.6 Design and development validation</p> <p><i>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).</i></p> <p>Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).</p> <p><i>As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (see Note 2).</i></p>

ISO 9001:2000	ISO 13485:2003
	<p><i>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.</i></p> <p><i>NOTE 2 Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.</i></p>
	<p>7.3.7 Control of design and development changes</p> <p>[The text of 7.3.7 in ISO 13485 is identical to that in the corresponding subclause of ISO 9001:2000.]</p>
<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.</p> <p>The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</p>	<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p><i>The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements.</i></p> <p>The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.</p> <p>The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).</p>
<p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p> <p>a) requirements for approval of product, procedures, processes, and equipment,</p> <p>b) requirements for qualification of personnel, and</p> <p>c) quality management system requirements.</p> <p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	<p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p> <p>a) requirements for approval of product, procedures, processes and equipment,</p> <p>b) requirements for qualification of personnel, and</p> <p>c) quality management system requirements.</p> <p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p> <p><i>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).</i></p>

ISO 9001:2000	ISO 13485:2003
<p>7.4.3 Verification of purchased product</p> <p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p> <p>Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.</p>	<p>7.4.3 Verification of purchased product</p> <p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p> <p>Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.</p> <p><i>Records of the verification shall be maintained (see 4.2.4).</i></p>
<p>7.5 Production and service provision</p> <p>7.5.1 Control of production and service provision</p> <p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ul style="list-style-type: none"> a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities. 	<p>7.5 Production and service provision</p> <p>7.5.1 Control of production and service provision</p> <p>7.5.1.1 General requirements</p> <p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ul style="list-style-type: none"> a) the availability of information that describes the characteristics of the product, b) <i>the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary,</i> 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) <i>the implementation of defined operations for labelling and packaging.</i> <p><i>The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.</i></p> <p>NOTE <i>A batch can be a single medical device.</i></p>

ISO 9001:2000	ISO 13485:2003
	<p>7.5.1.2 Control of production and service provision — Specific requirements</p> <p>7.5.1.2.1 Cleanliness of product and contamination control</p> <p><i>The organization shall establish documented requirements for cleanliness of product if</i></p> <ul style="list-style-type: none"> a) <i>product is cleaned by the organization prior to sterilization and/or its use, or</i> b) <i>product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or</i> c) <i>product is supplied to be used non-sterile and its cleanliness is of significance in use, or</i> d) <i>process agents are to be removed from product during manufacture.</i> <p><i>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.</i></p> <p>7.5.1.2.2 Installation activities</p> <p><i>If appropriate, the organization shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.</i></p> <p><i>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.</i></p> <p><i>Records of installation and verification performed by the organization or its authorized agent shall be maintained (see 4.2.4).</i></p> <p>7.5.1.2.3 Servicing activities</p> <p><i>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.</i></p> <p><i>Records of servicing activities carried out by the organization shall be maintained (see 4.2.4).</i></p> <p>NOTE <i>Servicing can include, for example, repair and maintenance.</i></p>

ISO 9001:2000	ISO 13485:2003
	<p>7.5.1.3 Particular requirements for sterile medical devices</p> <p><i>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).</i></p>
<p>7.5.2 Validation of processes for production and service provision</p> <p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</p> <p>Validation shall demonstrate the ability of these processes to achieve planned results.</p> <p>The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. 	<p>7.5.2 Validation of processes for production and service provision</p> <p>7.5.2.1 General requirements</p> <p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</p> <p>Validation shall demonstrate the ability of these processes to achieve planned results.</p> <p>The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. <p><i>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.</i></p> <p><i>Records of validation shall be maintained (see 4.2.4)</i></p> <p>7.5.2.2 Particular requirements for sterile medical devices</p> <p><i>The organization shall establish documented procedures for the validation of sterilization processes.</i></p>

ISO 9001:2000	ISO 13485:2003
	<p><i>Sterilization processes shall be validated prior to initial use.</i></p> <p><i>Records of validation of each sterilization process shall be maintained (see 4.2.4).</i></p>
<p>7.5.3 Identification and traceability</p> <p>Where appropriate, the organization shall identify the product by suitable means throughout product realization.</p> <p>The organization shall identify the product status with respect to monitoring and measurement requirements.</p> <p>Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).</p> <p>NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.</p>	<p>7.5.3 Identification and traceability</p> <p>7.5.3.1 Identification</p> <p><i>The organization shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification.</i></p> <p><i>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)].</i></p> <p>7.5.3.2 Traceability</p> <p>7.5.3.2.1 General</p> <p><i>The organization shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5).</i></p> <p>Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).</p> <p>NOTE Configuration management is a means by which identification and traceability can be maintained.</p> <p>7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).</i></p>

ISO 9001:2000	ISO 13485:2003
	<p>7.5.3.3 Status identification</p> <p>The organization shall identify the product status with respect to monitoring and measurement requirements.</p> <p><i>The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.</i></p>
<p>7.5.4 Customer property</p> <p>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).</p> <p>NOTE Customer property can include intellectual property.</p>	<p>7.5.4 Customer property</p> <p>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).</p> <p>NOTE Customer property can include intellectual property or confidential health information.</p>
<p>7.5.5 Preservation of property</p> <p>The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p>	<p>7.5.5 Preservation of property</p> <p><i>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.</i></p> <p>This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p> <p><i>The organization shall establish documented procedures 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).</i></p>
<p>7.6 Control of monitoring and measuring devices</p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).</p> <p>The organization shall establish processes to ensure that monitoring and measurement can be carried out</p>	<p>7.6 Control of monitoring and measuring devices</p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).</p> <p><i>The organization shall establish documented procedures to ensure that monitoring and measurement</i></p>

© 2003 International Organization for Standardization

ISO 9001:2000	ISO 13485:2003
<p>and are carried out in a manner that is consistent with the monitoring and measurement requirements.</p> <p>Where necessary to ensure valid results, measuring equipment shall:</p> <ul style="list-style-type: none"> 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. <p>In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).</p> <p>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary (see 7.5.2).</p> <p>NOTE See ISO 10012-1 and ISO 10012-2 for guidance.</p>	<p><i>can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.</i></p> <p>Where necessary to ensure valid results, measuring equipment shall</p> <ul style="list-style-type: none"> 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. <p>In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).</p> <p>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.</p> <p>NOTE See ISO 10012 for guidance related to measurement management systems.</p>
<p>8 Measurement, analysis and improvement</p> <p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <ul style="list-style-type: none"> a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. 	<p>8 Measurement, analysis and improvement</p> <p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <ul style="list-style-type: none"> a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) <i>to maintain the effectiveness of the quality management system.</i>

ISO 9001:2000	ISO 13485:2003
<p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p>	<p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p> <p><i>NOTE</i> National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.</p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulations and facilitating the harmonization of new medical device regulations around the world. The objective of medical device regulations is the maintenance of the effectiveness of the quality management system to consistently produce medical devices that are safe and effective, not the continual improvement of the quality management system.</p>
<p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer satisfaction</p> <p>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.</p>	<p>8.2 Monitoring and measurement</p> <p>8.2.1 Feedback</p> <p><i>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to whether the organization has met customer requirements.</i></p> <p>The methods for obtaining and using this information shall be determined.</p> <p><i>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).</i></p> <p><i>If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).</i></p> <p>Reason for differences: Both “customer satisfaction” and “customer perception” are too subjective for implementation as requirements in a regulation. The resulting text is consistent with the objective of reflecting the current regulations and facilitating the harmonization of new medical device regulations around the world.</p>
	<p>8.2.2 Internal audit</p> <p><i>NOTE</i> See ISO 19011 for guidance related to quality auditing.</p> <p>[The text of 8.2.2 of ISO 13485 is identical to that of the corresponding subclause of ISO 9001:2000, with the exception of the NOTE above.]</p>

ISO 9001:2000	ISO 13485:2003
	<p>8.2.3 Monitoring and measurement of processes</p> <p>[The text of 8.2.3 of ISO 13485 is identical to that of the corresponding subclause of ISO 9001:2000]</p>
<p>8.2.4 Monitoring and measurement of product</p> <p>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).</p> <p>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).</p> <p>Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.</p>	<p>8.2.4 Monitoring and measurement of product</p> <p>8.2.4.1 General requirements</p> <p><i>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).</i></p> <p>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).</p> <p><i>Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed.</i></p> <p>8.2.4.2 Particular requirement for active implantable devices and implantable devices</p> <p><i>The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.</i></p>
<p>8.3 Control of nonconforming product</p> <p>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.</p> <p>The organization shall deal with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. <p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p>	<p>8.3 Control of nonconforming product</p> <p>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.</p> <p>The organization shall deal with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> a) by taking action to eliminate the detected nonconformity; b) <i>by authorizing its use, release or acceptance under concession;</i> c) by taking action to preclude its original intended use or application. <p><i>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).</i></p>

ISO 9001:2000	ISO 13485:2003
<p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</p> <p>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.</p>	<p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p> <p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</p> <p>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.</p> <p><i>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).</i></p>
<p>8.4 Analysis of data</p> <p>The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.</p> <p>The analysis of data shall provide information relating to</p> <ul style="list-style-type: none"> a) customer satisfaction (see 8.2.1), 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. 	<p>8.4 Analysis of data</p> <p><i>The organization shall establish documented procedures to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made.</i></p> <p>This shall include data generated as a result of monitoring and measurement and from other relevant sources.</p> <p>The analysis of data shall provide information relating to</p> <ul style="list-style-type: none"> a) <i>feedback</i> (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. <p><i>Records of the results of the analysis of data shall be maintained (see 4.2.4).</i></p>
<p>8.5 Improvement</p> <p>8.5.1 Continual improvement</p> <p>The organization shall continually improve the effectiveness of the quality management system</p>	<p>8.5 Improvement</p> <p>8.5.1 General</p> <p><i>The organization shall identify and implement any changes necessary to ensure and maintain the</i></p>

ISO 9001:2000	ISO 13485:2003
<p>through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</p>	<p><i>continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</i></p> <p><i>The organization shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.</i></p> <p><i>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).</i></p> <p><i>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).</i></p> <p><i>If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures for such notification to regulatory authorities.</i></p> <p>Reason for differences: To make the resulting text consistent with the objective of reflecting the current regulations and facilitating the harmonization of new medical device regulations around the world. Continual improvement of the quality management system is not a current objective of regulations.</p>
<p>8.5.2 Corrective action</p> <p>The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p> <p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and 	<p>8.5.2 Corrective action</p> <p>The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p> <p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) <i>determining and implementing action needed, including, if appropriate, updating documentation (see 4.2),</i> e) <i>recording of the results of any investigation and of action taken (see 4.2.4), and</i>

ISO 9001:2000	ISO 13485:2003
f) reviewing corrective action taken.	f) <i>reviewing the corrective action taken and its effectiveness.</i>
<p>8.5.3 Preventive action</p> <p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p> <p>A documented procedure shall be established to define requirements for</p> <p>a) determining potential nonconformities and their causes,</p> <p>b) evaluating the need for action to prevent occurrence of nonconformities,</p> <p>c) determining and implementing action needed,</p> <p>d) records of the results of action taken (see 4.2.4), and</p> <p>e) reviewing preventive action taken.</p>	<p>8.5.3 Preventive action</p> <p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p> <p>A documented procedure shall be established to define requirements for</p> <p>a) determining potential nonconformities and their causes,</p> <p>b) evaluating the need for action to prevent occurrence of nonconformities,</p> <p>c) determining and implementing action needed,</p> <p>d) <i>recording of the results of any investigations and of action taken (see 4.2.4), and</i></p> <p>e) <i>reviewing preventive action taken and its effectiveness.</i></p>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98
99
100

Bibliography

- [1] ISO 9001:2000, *Quality management systems — Requirements*
- [2] ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*
- [3] ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*
- [4] ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization* (Corrigendum 1 published 1994)
- [5] ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization* (Corrigendum 1 published 1995; Amendment 1 published 2001)
- [6] EN 13641:2002, *Elimination or reduction of risk of infection related to in vitro diagnostic reagents*
- [7] ISO 13683:1997, *Sterilization of health care products — Requirement for validation and routine control of moist heat sterilization in health care facilities*
- [8] ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*
- [9] ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*
- [10] ISO 14160:1998, *Sterilization of medical devices — Validation and routine control of sterilization of single-use medical devices incorporating materials of animal origin by liquid chemical sterilants*
- [11] 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 sterilizing agent*
- [12] ISO/TR 14969:—¹⁾, *Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003*
- [13] ISO 14971:2000, *Medical devices — Application of risk management to medical devices*
- [14] ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*
- [15] Global Harmonization Task Force (GHTF) — Study Group 1 (SG1), Document No. N029R11, dated 2 Feb., 2002

1) To be published.

British Standards Institution (BSI)

BSI is the independent national body responsible for preparing British Standards and other standards-related publications, information and services. It presents the UK view on standards in Europe and at the international level.

BSI is incorporated by Royal Charter. British Standards and other standardisation products are published by BSI Standards Limited.

Revisions

British Standards and PASs are periodically updated by amendment or revision. Users of British Standards and PASs should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using British Standards would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Similarly for PASs, please notify BSI Customer Services.

Tel: +44 (0)20 8996 9001 Fax: +44 (0)20 8996 7001

BSI offers BSI Subscribing Members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of British Standards and PASs.

Tel: +44 (0)20 8996 7669 Fax: +44 (0)20 8996 7001
Email: plus@bsigroup.com

Buying standards

You may buy PDF and hard copy versions of standards directly using a credit card from the BSI Shop on the website www.bsigroup.com/shop. In addition all orders for BSI, international and foreign standards publications can be addressed to BSI Customer Services.

Tel: +44 (0)20 8996 9001 Fax: +44 (0)20 8996 7001
Email: orders@bsigroup.com

In response to orders for international standards, BSI will supply the British Standard implementation of the relevant international standard, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Knowledge Centre.

Tel: +44 (0)20 8996 7004 Fax: +44 (0)20 8996 7005
Email: knowledgecentre@bsigroup.com

BSI Subscribing Members are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration.

Tel: +44 (0)20 8996 7002 Fax: +44 (0)20 8996 7001
Email: membership@bsigroup.com

Information regarding online access to British Standards and PASs via British Standards Online can be found at www.bsigroup.com/BSOL

Further information about British Standards is available on the BSI website at www.bsi-group.com/standards

Copyright

All the data, software and documentation set out in all British Standards and other BSI publications are the property of and copyrighted by BSI, or some person or entity that own copyright in the information used (such as the international standardisation bodies) has formally licensed such information to BSI for commercial publication and use. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI. This does not preclude the free use, in the course of implementing the standard, of necessary details such as symbols, and size, type or grade designations. If these details are to be used for any other purpose than implementation then the prior written permission of BSI must be obtained. Details and advice can be obtained from the Copyright & Licensing Department.

Tel: +44 (0)20 8996 7070
Email: copyright@bsigroup.com

BSI

389 Chiswick High Road London W4 4AL UK

Tel +44 (0)20 8996 9001
Fax +44 (0)20 8996 7001
www.bsigroup.com/standards

raising standards worldwide™

Copyright European Committee for Standardization
Provided by IHS under license with CEN
No reproduction or networking permitted without license from IHS

Not for Resale

