List of Titles

American National Standard

ANSI/AAMI/ISO 13488:1996

Quality systems—Medical devices—Particular requirements for the application of ISO 9002

AAMI Association for the Advancement of Medical Instrumentation

American National Standard ANSI/AAMI/ISO 13488—1996

Quality systems—Medical devices—Particular requirements for the application of ISO 9002

Approved 24 February 1997 by
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AAMI Standard

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List of Titles

Contents

List of Titles

Committee Representation

Association for the Advancement of Medical Instrumentation

Committee on Quality Management and Corresponding General Aspects for Medical Devices

The adoption of ISO 13488:1996 as an American National Standard was initiated by the AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices, which also serves as a U.S. Technical Advisory Group (TAG) to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Application of Quality Systems to Medical Devices Working Group (U.S. Sub-TAG for ISO/TC 210/WG 1) played an active role in developing the ISO standard, and AAMI working group cochair Mr. Edward Kimmelman also serves as convener of ISO/TC 210/WG 1.

The **AAMI Committee on Quality Management and Corresponding General Aspects for Medical Devices** has the following members:

Cochair:	Robert C. Flink
Members:	Richard Farb, Baxter Healthcare Corporation
	Robert C. Flink, Medtronic, Inc.
	Robert E. James, James & Associates
	Edward R. Kimmelman, BME, JD, Boehringer Manneheim Corporation
	Frank Pokrop, Abbott Labs
	Harvey Rudolph, PhD, Center for Devices and Radiological Health, Food and Drug Administration
	Kimberly A. Trautman, Food and Drug Administration
Alternate:	Charles Sidebottom, Medtronic, Inc.

The committee's **Application of Quality Systems to Medical Devices Working Group** has the following members:

Cochairs:	Edward R. Kimmelman, BME, JD
	Kimberly A. Trautman
Members:	Eric Ankerud, JD, Bausch & Lomb, Inc.
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Les Schnoll, KPMG Quality Registrar
Stanley J. Suedkamp, 3M
Robert P. Tomaselli, Convatec, Bristol-Meyers Squibb
Kimberly A. Trautman, Food and Drug Administration

Alternates:

Fran Akelewicz, CR Bard
Robert Allison, Hill Rom Company
Bradley S. Amundson, SGS International Certification Services, Inc.
Jeffrey A. Beck, Johnson & Johnson Corporation
Leonard S. Berman, PhD, Pall Corporation
Frank Bernardo, Datascope Corporation
Fabrizio Bonanni, Baxter Healthcare Corporation
Patrick Clinch, Getinge International, Inc.
Amiram Daniel, PhD, EXPERTech Associates
Eugene Davis, Sterigenics International
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John R. Gerlich, Pfizer Hospital Products Group
David M. Link, EXPERTech Associates
Debara Reek, Boehringer Manneheim Corporation
Dave Smith, Victoreen, Inc.
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Terres Williams, St Jude Medical, Inc.
Douglas Woodruff, Sherwood Medical Company

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of ISO 13488:1996

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee (TC) 210, *Quality management and corresponding general aspects for medical devices*.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 210, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 210 supports the international harmonization of quality management and corresponding general aspects for medical devices.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every 5 years to reflect technological advances that may have occurred since publication.

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

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

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE—Beginning with the foreword on page viii, this Standard is identical to ISO 13488:1996.

Glossary of equivalent standards

ISO designation	U.S. designation	Equivalency
ISO 5840:1996	ANSI/AAMI/ISO 5840—1996	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199—1996	Identical
ISO 10993-1:1992, Technical Corrigendum 1:1992*	ANSI/AAMI 10993-1—1994	Minor technical variation
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2—1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3—1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4—1993	Identical
ISO 10993-5:1992	ANSI/AAMI/ISO 10993-5—1993	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6—1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7—1995	Identical
ISO TR 10993-9:1994	AAMI TIR 10993-9—1995	Minor technical variation
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10—1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11—1993	Minor technical variation
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12—1996	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134—1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135—1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137—1994	Identical
ISO 11140-1:1995	ANSI/AAMI ST60—1996	Partially equivalent
ISO 11607:1997	ANSI/AAMI/ISO 11607—1997	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1—1995	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409—1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485—1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488—1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155—1996	Identical

*The technical change covered by Technical Corrigendum 1:1992 was incorporated into the text of ANSI/AAMI 10993-1—1994 prior to its publication.

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.

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.

International Standard ISO 13488 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices.*

Introduction

ISO 9002 is a general standard defining quality system requirements. ISO 13488 provides particular requirements for suppliers of medical devices that are more specific than the general requirements specified in ISO 9002.

In conjunction with ISO 9002, this International Standard defines requirements for quality systems relating to the production, installation and servicing of medical devices. It embraces all the principles of good manufacturing practice (GMP) widely used in the manufacture of medical devices. It can only be used in combination with ISO 9002 and is not an independent standard.

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

Other International Standards specify more detailed particular requirements that are additional to those specified here. Suppliers should review the requirements and consider using the relevant International Standards in these areas.

To assist in the understanding of the requirements of this International Standard, an international guidance standard is being prepared.

Quality systems—Medical devices—Particular requirements for the application of ISO 9002

1 Scope

This International Standard specifies, in conjunction with ISO 9002, the quality system requirements for the production and, when relevant, installation and servicing of medical devices.

This International Standard, in conjunction with ISO 9002, is applicable when there is a need to assess a medical device supplier's quality system.

As part of an assessment by a third party for the purpose of regulatory requirements, the supplier may be required to provide access to confidential data in order to demonstrate compliance with this International Standard. The supplier may be required to exhibit these data but is not obliged to provide copies for retention.

NOTE—In this International Standard the term "if appropriate" is used several times. When a requirement is qualified by this phrase, it is deemed to be "appropriate" unless the supplier can document a justification otherwise. A requirement is considered "appropriate" if its non-implementation could result in

— the product not meeting its specified requirements, and/or

— the supplier being unable to carry out corrective action.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance—Vocabulary*.

ISO 9002:1994, *Quality systems—Model for quality assurance in production, installation and servicing*.

ISO 11137:1995, *Sterilization of healthcare products—Requirements for validation and routine control—Radiation sterilization*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402 apply, with the exception that the definition of "product" as given in ISO 9002 applies. In addition, the following definitions apply.

NOTE—These definitions should be regarded as generic, as definitions provided in national regulations may differ slightly.

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

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

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

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

— control of conception,

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

NOTE—In addition to the medical device categories defined hereinafter, the term “medical device” also includes nonactive medical devices and *in vitro* diagnostic devices.

3.2 active medical device: Any medical device (see 3.1) 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 active implantable medical device: Any active medical device (see 3.1 and 3.2) 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.

3.4 implantable medical device: Any medical device (see 3.1) 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.

3.5 sterile medical device: Any medical device labeled as sterile. (See 3.6.1 of ISO 11137:1995.)

NOTE—Requirements for labeling a medical device as sterile may be subject to national or regional regulations or standards.

3.6 labeling: 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—For the purposes of this International Standard the term “marking” as used in ISO 9002 is interpreted to mean “labeling”.

3.7 customer complaint: Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device (see 3.1) that has been placed on the market.

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

— the use of a medical device,

— the modification of a medical device,

— the return to the supplier of a medical device,

— the destruction of a medical device,

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

4 Quality system requirements

4.1 Management responsibility

The requirements given in 4.1 of ISO 9002:1994 apply.

4.2 Quality system

4.2.1 General

The requirements given in 4.2.1 of ISO 9002:1994 apply.

Particular requirement for all medical devices:

The supplier shall establish and document the specified requirements.

NOTE—If this International Standard is used for compliance with regulatory requirements, the relevant requirements of the regulations should be included in the specified requirements.

4.2.2 Quality system procedures

The requirements given in 4.2.2 of ISO 9002:1994 apply.

4.2.3 Quality planning

The requirements given in 4.2.3 of ISO 9002:1994 apply.

Particular requirement for all medical devices:

The supplier shall establish and maintain a file containing documents defining product specifications and quality system requirements (process and quality assurance) for

— complete manufacturing, and

— installation and servicing, if appropriate,

for each type/model of medical device, or referring to the location(s) of this information (see 4.5.2 and 4.16).

4.3 Contract review

The requirements given in 4.3 of ISO 9002:1994 apply.

4.4 Design control

See 4.4 of ISO 9002:1994.

4.5 Document and data control

4.5.1 General

The requirements given in 4.5.1 of ISO 9002:1994 apply.

4.5.2 Document and data approval and issue

The requirements given in 4.5.2 of ISO 9002:1994 apply.

Particular requirement for all medical devices:

The supplier shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that specifications to which medical devices have been manufactured are available for at least the lifetime of the medical device as defined by the supplier.

4.5.3 Document and data changes

The requirements given in 4.5.3 of ISO 9002:1994 apply.

4.6 Purchasing

4.6.1 General

The requirements given in 4.6.1 of ISO 9002:1994 apply.

4.6.2 Evaluation of subcontractors

The requirements given in 4.6.2 of ISO 9002:1994 apply.

4.6.3 Purchasing data

The requirements given in 4.6.3 of ISO 9002:1994 apply.

Particular requirement for all medical devices:

To the extent required by the particular requirements for traceability given in 4.8, the supplier shall retain copies (see 4.16) of relevant purchasing documents.

4.6.4 Verification of purchased product

The requirements given in 4.6.4 of ISO 9002:1994 apply.

4.7 Control of customer-supplied product

The requirements given in 4.7 of ISO 9002:1994 apply.

4.8 Product identification and traceability

The requirements given in 4.8 of ISO 9002:1994 apply.

Particular requirement for all medical devices:

a) Identification

The supplier shall establish and maintain procedures to ensure that medical devices returned to the supplier for reprocessing to specified requirements are identified and distinguished at all times from normal production (see 4.15.1).

b) Traceability

The supplier shall establish, document and maintain procedures for traceability. The procedures shall define the extent of traceability and shall facilitate corrective and preventive action (see 4.14).

Additional requirements for active implantable medical devices and implantable medical devices:

When defining the extent of traceability, the supplier shall include all components and materials used and records of the environmental conditions [see 4.9 b)4)] when these could cause the medical device not to satisfy its specified requirements.

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

4.9 Process control

The requirements given in 4.9 of ISO 9002:1994 apply.

Particular requirements for all medical devices:

a) Personnel

The supplier shall establish, document and maintain requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or environment could adversely affect the quality of the product.

The supplier shall ensure that all personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained person (see 4.18).

b) Environmental control in manufacture

For medical devices

1) that are supplied sterile, or

2) that are supplied non-sterile and intended for sterilization before use, or

3) if the microbiological and/or particulate cleanliness or other environmental conditions are of significance in their use, or

4) if the environmental conditions are of significance in their manufacture,

the supplier shall establish and document requirements for the environment to which product is exposed.

If appropriate, the environmental conditions shall be controlled and/or monitored.

c) Cleanliness of product

The supplier shall establish, document and maintain requirements for the cleanliness of product if

1) product is cleaned by the supplier prior to sterilization and/or its use, or

2) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or

3) product is supplied to be used non-sterile and its cleanliness is of significance in use, or

4) process agents are to be removed from product during manufacture.

If appropriate, product cleaned in accordance with 1) or 2) above need not be subject to the preceding particular requirements [i.e. a) Personnel, and b) Environmental control in manufacture] prior to the cleaning procedure.

d) Maintenance

The supplier shall establish and document requirements for maintenance activities when such activities may affect product quality.

Records of such maintenance shall be kept (see 4.16).

e) Installation

If appropriate, the supplier shall establish and document both instructions and acceptance criteria for installing and checking the medical device.

Records of installation and checking performed by the supplier or its authorized representative shall be retained (see 4.16).

If the contract (see 4.3) allows installation other than by the supplier or its authorized representative, the supplier shall provide the purchaser with written instructions for installation and checking.

f) Computer software used in process control

The supplier shall establish and maintain documented procedures for the validation of the application of computer software which is used for process control. The results of validation shall be recorded (see 4.16).

Additional requirement for sterile medical devices:

The supplier shall subject the medical device to a validated sterilization process and record (see 4.16) all the control parameters of the sterilization process.

4.10 Inspection and testing

4.10.1 General

The requirements given in 4.10.1 of ISO 9002:1994 apply.

4.10.2 Receiving inspection and testing

The requirements given in 4.10.2 of ISO 9002:1994 apply.

4.10.3 In-process inspection and testing

The requirements given in 4.10.3 of ISO 9002:1994 apply.

4.10.4 Final inspection and testing

The requirements given in 4.10.4 of ISO 9002:1994 apply.

4.10.5 Inspection and test records

The requirements given in 4.10.5 of ISO 9002:1994 apply.

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

The supplier shall record (see 4.16) the identity of personnel performing any inspection or testing.

4.11 Control of inspection, measuring and test equipment

The requirements given in 4.11 of ISO 9002:1994 apply.

4.12 Inspection and test status

The requirements given in 4.12 of ISO 9002:1994 apply.

4.13 Control of nonconforming product

4.13.1 General

The requirements given in 4.13.1 of ISO 9002:1994 apply.

4.13.2 Review and disposition of nonconforming product

The requirements given in 4.13.2 of ISO 9002:1994 apply.

Particular requirements for all medical devices:

The supplier shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. The identity of the person(s) authorizing the concession shall be recorded (see 4.16).

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

4.14 Corrective and preventive action

4.14.1 General

The requirements given in 4.14.1 of ISO 9002:1994 apply.

Particular requirements for all medical devices:

The supplier shall establish and maintain a documented feedback system to provide early warning of quality problems and for input into the corrective and/or preventive action system.

If this International Standard is used for compliance with regulatory requirements which require the supplier to gain experience from the post-production phase, the review of this experience shall form part of the feedback system.

The supplier shall maintain records (see 4.16) of all customer complaint investigations. When the investigation determines that the activities at remote premises contributed to the customer complaint, relevant information shall be communicated between the supplier and the remote premises.

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

If this International Standard is used for compliance with regulatory requirements, the supplier shall establish, document and maintain procedures to notify the regulatory authority of those incidents which meet the reporting criteria.

The supplier shall establish, document and maintain procedures for the issue of advisory notices for medical devices. These procedures shall be capable of being implemented at any time.

4.14.2 Corrective action

The requirements given in 4.14.2 of ISO 9002:1994 apply.

4.14.3 Preventive action

The requirements given in 4.14.3 of ISO 9002:1994 apply.

4.15 Handling, storage, packaging, preservation and delivery

4.15.1 General

The requirements given in 4.15.1 of ISO 9002:1994 apply.

Particular requirements for all medical devices:

The supplier shall establish and maintain documented procedures for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded (see 4.16).

If appropriate, special arrangements shall be established, documented and maintained for the control of used product in order to prevent contamination of other product, the manufacturing environment or personnel.

4.15.2 Handling

The requirements given in 4.15.2 of ISO 9002:1994 apply.

4.15.3 Storage

The requirements given in 4.15.3 of ISO 9002:1994 apply.

4.15.4 Packaging

The requirements given in 4.15.4 of ISO 9002:1994 apply.

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

The supplier shall record the identity of persons who perform the final labeling operation (see 4.16).

4.15.5 Preservation

The requirements given in 4.15.5 of ISO 9002:1994 apply.

4.15.6 Delivery

The requirements given in 4.15.6 of ISO 9002:1994 apply.

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

The supplier shall ensure that the name and address of the shipping package consignee is included in the quality records (see 4.16).

4.16 Control of quality records

The requirements given in 4.16 of ISO 9002:1994 apply.

Particular requirements for all medical devices:

The supplier shall retain the quality records for a period of time at least equivalent to the lifetime of the medical device as defined by the supplier, but not less than 2 years from the date of dispatch from the supplier.

NOTE 1 National or regional regulations may require a period longer than 2 years.

The supplier shall establish and maintain a record for each batch of medical devices that provides traceability to the extent specified in 4.8 and identifies the quantity manufactured and quantity approved for distribution. The batch record shall be verified and authorized.

NOTE 2 A batch may be a single medical device.

4.17 Internal quality audits

The requirements given in 4.17 of ISO 9002:1994 apply.

4.18 Training

The requirements given in 4.18 of ISO 9002:1994 apply.

4.19 Servicing

The requirements given in 4.19 of ISO 9002:1994 apply.

4.20 Statistical techniques

The requirements given in 4.20 of ISO 9002:1994 apply.