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Quality systems — Medical devices — Guidance on the application of ISO 13485 and ISO 13488

Systèmes qualité — Dispositifs médicaux — Lignes directrices pour l'application de l'ISO 13485 et l'ISO 13488

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Contents

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 14969 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices.*

Annexes A and B of this International Standard are for information only.

Introduction

This International Standard provides guidance to assist in the development, implementation, maintenance and improvement of medical device related quality systems that meet the requirements of ISO 13485 and ISO 13488. These standards specify, in conjunction with ISO 9001 and ISO 9002 respectively, the quality system requirements for medical devices (see Table A.1 in annex A). For this reason, this International Standard also contains guidance applicable to medical devices based on the generic requirements of ISO 9001 and ISO 9002. ISO 13488 differs from ISO 13485 in that the former does not contain requirements for design control. This International Standard also gives guidance on ways to meet globally harmonized regulatory quality system requirements for medical devices.

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

As used in this International Standard, the term “regulatory requirement” includes any part of a law, ordinance, decree or national and/or regional regulatory requirement which applies to quality systems of medical device manufacturers.

Quality systems — Medical devices — Guidance on the application of ISO 13485 and ISO 13488

1 Scope

This International Standard provides guidance for the application of the requirements for medical device quality systems contained in ISO 13485 and ISO 13488. It does not add to, or otherwise change, the requirements of ISO 13485 and ISO 13488. This guidance can be used to better understand alternative methods and approaches among many (not specifically included here) for applying the requirements of ISO 13485 and ISO 13488.

The guidance provided by this International Standard has value for:

— suppliers seeking to implement and maintain quality systems that comply with ISO 13485 and ISO 13488;

— organizations having the responsibility to assess the successful implementation and maintenance of such quality systems; and

— regulatory bodies seeking to enforce regulatory requirements based on the requirements of ISO 13485 and ISO 13488.

These organizations and regulatory bodies should understand the benefits of the guidance given in this International Standard and the special considerations associated with the use of this guidance.

a) For suppliers

The guidance given in this International Standard is applicable to the design, development (ISO 13485 only), production, installation, and servicing of medical devices of all kinds. It describes concepts and methods which can be considered by suppliers who are establishing and maintaining quality systems.

Special considerations: The supplier has the responsibility for determining which of the guidance contained in this International Standard is relevant to its operations and will be incorporated in its quality system. The supplier should understand that if it voluntarily incorporates guidance from this International Standard into its quality system, the guidance needs to be followed, consistent with the requirements of the supplier's quality system. Failure to comply with those incorporated guidance can be determined to be a deficiency by those charged with the responsibility of conducting internal or external quality system assessments, audits and inspections.

The supplier should also understand that its quality system cannot be found deficient for failure to incorporate guidance contained in this International Standard which the supplier determines are not relevant to its operations.

b) For quality system assessors, notified bodies, regulatory enforcement bodies

Guidance contained in this International Standard can be useful as background information for those representing quality system assessors, notified bodies and regulatory enforcement bodies.

Special considerations: The guidance contained in this International Standard should not be used for identifying specific deficiencies of quality systems, unless such guidance is voluntarily incorporated by the supplier into the documentation describing and supporting the supplier's quality system, or unless such guidance is specifically made part of the regulatory requirements relevant to the supplier's operation.

2 Normative references

The following normative documents contain 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 editions of the normative documents 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.

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

ISO 9000-2:1997, *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003.*

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

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

ISO 13485:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001.*

ISO 13488:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002.*

3 Terms and definitions

For the purposes of this International Standard, the tems and definitions given in ISO 8402, ISO 13485 and ISO 13488 apply, with the exception of “product”, where the definition in ISO 9001 and ISO 9002 applies.

NOTE The terms provided in annex B should be regarded as generic, as definitions provided in national regulatory requirements may differ.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

There is no specific medical device guidance beyond the generic guidance given in 4.1.1 of ISO 9000-2:1997.

4.1.2 Organization

4.1.2.1 Responsibility and authority

The generic guidance given in 4.1.2.1 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

When necessary, deputies for personnel having the responsibility and authority to make decisions that control the elements of the quality system and processes should be identified and be capable of assuming the responsibilities.

4.1.2.2 Resources

There is no specific medical device guidance beyond the generic guidance given in 4.1.2.2 of ISO 9000-2:1997.

4.1.2.3 Management representative

There is no specific medical device guidance beyond the generic guidance given in 4.1.2.3 of ISO 9000-2:1997.

4.1.3 Management review

There is no specific medical device guidance beyond the generic guidance given in 4.1.3 of ISO 9000-2:1997.

4.2 Quality system

4.2.1 General

There is no specific medical device guidance beyond the generic guidance given in 4.2.1 of ISO 9000-2:1997.

4.2.2 Quality system procedures

There is no specific medical device guidance beyond the generic guidance given in 4.2.2 of ISO 9000-2:1997.

4.2.3 Quality planning

The generic guidance given in 4.2.3 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

The file referred to in 4.2.3 of ISO 13485 is sometimes referred to by different terms (see annex B).

4.3 Contract review

4.3.1 General

There is no specific medical device guidance beyond the generic guidance given in 4.3.1 of ISO 9000-2:1997.

4.3.2 Review

There is no specific medical device guidance beyond the generic guidance given in 4.3.2 of ISO 9000-2:1997.

4.3.3 Amendment to contract

There is no specific medical device guidance beyond the generic guidance given in 4.3.3 of ISO 9000-2:1997.

4.3.4 Records

There is no specific medical device guidance beyond the generic guidance given in 4.3.4 of ISO 9000-2:1997.

4.4 Design control

4.4.1 General

The generic guidance given in 4.4.1 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

The extent of medical device evaluations, verifications and validations should be commensurate with the nature of the risks and the benefits associated with the use of the medical device.

Risk analysis using techniques such as fault tree analysis (FTA) and failure mode and effects analysis (FMEA) can be utilized at various stages of the design process. Such techniques can also help to determine the nature of possible design flaws and the risks associated with them. They may also identify changes required to increase reliability and safety. The application of risk analysis techniques are described in ISO 14971-1 (see Bibliography).

Design-related documents and records should form part of a file as described in row A of annex B.

4.4.2 Design and development planning

The generic guidance given in 4.4.2 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

Design and development planning can ensure that the design process is appropriately managed and that design objectives are met. The method chosen and the detail will vary depending on the complexity of the project and the level of risk associated with the medical device.

Generally, the design plan includes the specific quality practices, assessment methodology, documentation requirements, record keeping, resources and the sequence of activities relevant to a particular design or design category and the timing and content of design review. The plan should reference applicable codes, standards, regulatory requirements, specifications and acceptance criteria. Design activities should be specified to the level of detail necessary for carrying out the design process in a manner that permits the generation of objective evidence that the design activity has been completed. Design plans do not have to be elaborate. They may be as simple as a flow chart showing steps to be taken and who is responsible for taking them. If appropriate, applicable codes, standards, regulatory requirements, specifications and acceptance criteria can be considered for inclusion in the plan.

The decision process in deciding whether a clinical investigation and/or literature search as part of the clinical evaluation is necessary should be addressed (see note in 4.4.8 of ISO 13485:1996).

4.4.3 Organizational and technical interfaces

The generic guidance given in 4.4.3 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

For medical devices, the design process typically involves more than just design personnel. Other internal groups may also play a role. These include, but are not limited to, Marketing and Sales, Production, Testing, Purchasing, Quality Assurance, Clinical Affairs, and Regulatory Affairs. In addition, groups external to the device manufacturer may also be involved.

Operational procedures may be required to ensure that information from all levels of the organization, as required, is available to participants in the design activity. Failure to exercise the interfaces at all levels, when appropriate, can result in the organization's inability to use them when necessary.

4.4.4 Design input

The generic guidance given in 4.4.4 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

The design inputs should be specified to the level necessary to permit the design activity to be carried out effectively and to provide a consistent basis for design decisions, design verifications and design validation.

Examples of design inputs that should be defined, reviewed, approved and recorded by the supplier, include:

— intended clinical use;

— customer requirements, e.g. intended device performance (indications for use) and limits;

— performance requirements, e.g. during normal use, storage, handling and maintenance;

— specifications for various forms of labelling, e.g. instructions for use and servicing;

— environmental, safety and regulatory requirements;

— ergonomics and other human factors;

— other relevant standards;

— systems elements when a medical device is specified for use in combination with another device, e.g. other equipment or accessory. In this case the design input should completely define the interface requirement.

In defining the design inputs, the supplier should consider foreseeable use and misuse of the product and any related needs for specific labelling and customer/user training.

The design input document(s) should be regarded as a living document(s) and updated and reissued as necessary upon completion of design reviews. A record should be kept of all “agreed to” changes to the design input as it evolves during the design process.

The design transfer process should flow more smoothly if, during the design input stage, consideration is given to eventual production (producibility, parts/materials availability, production equipment needs, operator training etc.) and possible conformity assessment requirements (procedures, methods, equipment).

4.4.5 Design output

The generic guidance given in 4.4.5 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

Design outputs can also include specifications for:

— raw materials;

— component parts;

— sub-assemblies;

— finished devices;

— product and process software;

— quality assurance procedures, including acceptance criteria;

— manufacturing and inspection procedures;

— packaging and labelling;

— identification and traceability procedures;

— installation and servicing procedures and materials.

As part of, or in addition to, the design output documents, it is common practice to maintain a record/file to demonstrate that each design was developed and verified in accordance with the approved design plan.

The transfer of a design to production should occur after review and approval of specifications and procedures. The adequacy of specifications, methods and procedures can be demonstrated through process validation, including the testing of finished product under actual or simulated use conditions.

4.4.6 Design review

The generic guidance given in 4.4.6 of ISO 9000-2:1997 applies.

Additional guidance for all medical devices

In order to assure objectivity, it is advisable to involve one or more individuals, not having direct responsibility for the design activity in question, in the design review. This broader involvement also enables the reviewers to take into account all aspects of the supplier’s interest, e.g. manufacturing, marketing, design, after-sales servicing and support, and the likely medical effectiveness of the design. For medical devices, design reviews should also consider the following.

— Has a risk analysis been carried out to ensure that safety considerations are covered?

— Is the labelling adequate?

— Will the design reasonably accomplish the medical use intended ?

— Is the packaging adequate, particularly for sterile devices?

— Is the sterilization process adequate?

— Is the device compatible with the sterilization method?

At the completion of significant phases of the design process, design output documents should be reviewed and approved by designated functions prior to release for subsequent implementation; this is often accomplished through design review.

The records of design reviews should identify those involved and the decisions reached.

4.4.7 Design verification

The generic guidance given in 4.4.7 of ISO 9000-2:1997 applies.

<u>Additional guidance for all medical devices</u>

Once the design is translated into a tangible form, its safety, performance and reliability should be verified for conformance to the design inputs. Such verifications include:

— review of engineering specifications and drawings;

— physical and chemical laboratory testing (bench testing);

— *in vitro* testing;

— *in vivo* testing;

— packaging and labelling review (see 4.15.4).

4.4.8 Design validation

The generic guidance given in 4.4.8 of ISO 9000-2:1997 applies.

<u>Additional guidance for all medical devices</u>

Design validation goes beyond the technical issues of verifying that the design output meets the design input, and is intended to ensure that the medical device meets user needs and the intended use. This involves consideration of the knowledge and capabilities of the intended user, the operating instructions, compatibility with other systems, and any restriction on the use of the product.

The medical device units employed for validations should be produced under the conditions specified as “final” for the product, e.g. initial production units. The validation should be conducted under actual or simulated use conditions; this can involve clinical investigations.

4.4.9 Design changes

The generic guidance given in 4.4.9 of ISO 9000-2:1997 applies.

<u>Additional guidance for all medical devices</u>

Whether or not the device is currently on the market, the following considerations, among others, should be addressed before permitting a change to an approved design.

— Will the product still conform to the agreed-to product requirements?

— Will the product still conform to the agreed-to product specifications?

— Will the intended use be affected?

— Will different components of the product or system be affected by the change?

— Will there be a need for further interface design; i.e. physical contact with other components in a product or system?

— Will the change create problems in manufacture, installation or use?

— Will the design still be verifiable?

— Will the change affect the regulatory status of the product?