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Medical devices — Guidance on the application of ISO 14971

Dispositifs médicaux — Recommandations relatives à l'application de l'ISO 14971

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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.

The *procedures* used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives-and-policies).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.

This second edition cancels and replaces the first edition, which has been technically revised. The main changes compared to the previous edition are as follows:

— The clauses of ISO/TR 24971:2013 and some informative annexes of ISO 14971:2007 are merged, restructured, technically revised, and supplemented with additional guidance.

— To facilitate the use of this document, the same structure and numbering of clauses and subclauses as in ISO 14971:2019 is employed. The informative annexes contain additional guidance on specific aspects of *risk management*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides guidance to assist *manufacturers* in the development, implementation and maintenance of a *risk management process* for *medical devices* that aims to meet the requirements of ISO 14971:2019, *Medical devices — Application of risk management to medical devices*. It provides guidance on the application of ISO 14971:2019 for a wide variety of *medical devices*. These *medical devices* include active, non-active, implantable, and non-implantable *medical devices*, software as *medical devices* and *in vitro diagnostic medical devices*.

The clauses and subclauses in this document have the same structure and numbering as the clauses and subclauses of ISO 14971:2019, to facilitate the use of this guidance in applying the requirements of the standard. Further division into subclauses is applied where considered useful. The informative annexes contain additional guidance on specific aspects of *risk management*. The guidance consists of the clauses of ISO/TR 24971:2013 and some of the informative annexes of ISO 14971:2007, which are merged, restructured, technically revised, and supplemented with additional guidance.

Annex H was prepared in cooperation with Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This document describes approaches that *manufacturers* can use to develop, implement and maintain a *risk management process* conforming to ISO 14971:2019. Alternative approaches can also satisfy the requirements of ISO 14971:2019.

When judging the applicability of the guidance in this document, one should consider the nature of the *medical device(s)* to which it will apply, how and by whom these *medical devices* are used, and the applicable regulatory requirements.

Medical devices — Guidance on the application of ISO 14971

1 Scope

This document provides guidance on the development, implementation and maintenance of a *risk management* system for *medical devices* according to ISO 14971:2019.

The *risk management process* can be part of a quality management system, for example one that is based on ISO 13485:2016[24], but this is not required by ISO 14971:2019. Some requirements in ISO 13485:2016 (Clause 7 on product realization and 8.2.1 on feedback during monitoring and measurement) are related to *risk management* and can be fulfilled by applying ISO 14971:2019. See also the ISO Handbook: *ISO 13485:2016 — Medical devices — A practical guide*[25].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 14971:2019, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971:2019 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

NOTE The defined terms in ISO 14971:2019 are derived as much as possible from ISO/IEC Guide 63:2019[20] which was developed specifically for the *medical device* sector.

4 General requirements for *risk management* system

4.1 *Risk management process*

ISO 14971:2019 requires that the *manufacturer* establishes, implements, documents and maintains an ongoing *risk management process* throughout the *life cycle* of the *medical device*. The required elements in this *process* and the responsibilities of *top management* are given in ISO 14971:2019 and explained in further detail in this document.

4.2 Management responsibilities

4.2.1 *Top management* commitment

Top management has the responsibility to establish and maintain an effective *risk management process*. It is important to note the emphasis on *top management* in ISO 14971:2019 *Top management* has the power to assign authorities and responsibilities, to set priorities and to provide resources within the organization. Commitment at the highest level of the organization is essential for the *risk management process* to be effective.

If the *manufacturer's* organization consists of separate entities, for example business units or divisions, then *top management* can refer to those individuals who direct and control the entity implementing the *risk management process*. Each entity can have its own *risk management process* (and its own quality management system).

4.2.2 Policy for establishing criteria for *risk* acceptability

ISO 14971:2019 requires *top management* to define and document the policy for establishing criteria for *risk* acceptability. Annex C provides detailed guidance on how to define such a policy and which elements should be included, such as applicable regulations, relevant international standards, the generally acknowledged *state of the art* and known stakeholder concerns. Annex C also explains the relation between the policy and the criteria for *risk* acceptability and how these criteria are used in *risk control* and *risk evaluation*.

The policy can allow specific criteria for each type of *medical device* (or *medical device* family). This can depend on the characteristics of the *medical device* and its *intended use* (including the intended patient population). ISO 14971:2019 requires that the policy provides guidelines on how to establish the criteria for acceptability of the overall *residual risk*.

4.2.3 Suitability of the *risk management process*

ISO 14971:2019 requires *top management* to review the suitability of the *risk management process* at planned intervals. The review of the suitability is a high-level review of the *risk management process* and can include reviewing the following aspects, for example:

— the effectiveness of the implemented *risk management procedures*;

— the adequacy of the criteria for *risk* acceptability, which can imply the need for an adaptation of the criteria for *risk* acceptability for specific *medical devices*; and

— the effectiveness of the feedback loop of the production and *post-production* information (see 10.4).

4.3 Competence of personnel

Ensuring the assignment of competent personnel is a responsibility of *top management*. Examples of the personnel that can be involved in specific *risk management* tasks and the relevant knowledge and experience supporting effective completion of the associated tasks are given in Table 1.

Some *risk management* activities can be performed by external consultants or specialists. The required competence should be documented as well as the *objective evidence* of the fulfilment of these requirements.

Table 1 — Examples of competent personnel and relevant knowledge and experience

Personnel or function	Knowledge and experience
Risk management owner	*Medical device risk management process*
Engineer or scientist	*Medical device* technologies, design and operating principles
Operations	Manufacturing *processes*
Supply-chain management	Sources of material and services, including outsourced *processes*
Medical or clinical expert	Clinical evaluation methodologies and requirements Use in medical practice, including *benefits*, *hazardous situations* and possible *harm*

Table 1 *(continued)*

Personnel or function	Knowledge and experience
Regulatory affairs	Regulatory requirements pertaining to *safety* and *risk management* in countries/regions where the *medical device* is intended to be marketed
Quality assurance	Quality management systems and quality practices
Packaging, storage, handling and distribution	*Hazards* and *risk control* measures in relation to packaging, storage, handling and distribution
Service engineer, biomedical engineer or medical physicist	*Hazards* and *risk control* measures in relation to installation, maintenance, repair, calibration, service and support *processes* and practices
Post-production	Customer complaints and adverse event reporting, post-market surveillance
Information services	Data mining *processes*, methodologies for literature search
All individuals involved in the review and approval of the *records*	Expertise in the functional area for which they are reviewing and approving

Consider the need to include the following topics in the education of *risk management* experts:

— management of a *risk management* program for *medical devices*;

— ethics, *safety*, security and liability;

— concepts of *risk, risk* acceptability and *benefit-risk* analysis;

— probability and statistics for *risk management* and reliability;

— *risk management* and reliability in design and development;

— relevant standards and regulations;

— *risk estimation* including methods to determine the *severity* and probability of occurrence of *harm*;

— *risk assessment* methodology;

— methods for *risk control*;

— methods for verifying the effectiveness of *risk control* measures;

— methods for analysing production and *post-production* information.

4.4 *Risk management* plan

4.4.1 General

The *risk management* plan describes the scope of the *risk management* activities, the responsibilities and authorities of those involved, the criteria for *risk* acceptability, the production and *post-production* information to be collected and reviewed for the *medical device*, and all *risk management* activities that are carried out during the entire product *life cycle*. The *risk management* plan can be a separate document, or it can be integrated with other documentation, e.g. quality management system documentation. It

can be self-contained or it can reference other documents, such as planning of clinical, biological or usability evaluations or planning of *post-production* activities.

The *risk management* plan is a "living document" that will be reviewed and updated throughout the *life cycle* of the *medical device* as new information becomes available. The information should be collected on a continuous basis, even after the last *medical device* is sold and placed on the market. ISO 14971:2019 requires that changes to the *risk management* plan be recorded in the *risk management file*.

The extent of planned activities and the level of detail of the *risk management* plan should be commensurate with the level of *risk* associated with the *medical device*. The requirements in ISO 14971:2019 are the minimum requirements for a *risk management* plan. *Manufacturers* can include other items such as time-schedule, *risk analysis* tools, or a rationale for the choice of specific *risk* acceptability criteria.

4.4.2 Scope of the *risk management* plan

The scope identifies and describes the *medical device* and the *life cycle* phases for which each element of the plan is applicable.

Some of the elements of the *risk management* plan can apply to the product realization *process* (design, development and production of the *medical device*). Other elements can apply to the production and *post-production* phase (such as installation, use, maintenance, decommissioning and disposal of the *medical device*).

4.4.3 Assignment of responsibilities and authorities

The *risk management* plan identifies the personnel or functions with responsibility for the execution of specific activities related to *risk management* (see Table 1). In addition, the *risk management* plan identifies the individuals with appropriate authority to review and approve *risk management* decisions and actions. This can entail assignment of personnel familiar with the unique characteristics of the *medical device* (or *medical device* family) and their possible relevance to *safety*. This assignment can be included in a resource allocation matrix defined for the specific *life cycle* phase and the activities covered in the scope of the plan.

4.4.4 Requirements for review of *risk management* activities

The *risk management* plan details how and when the *risk management* activities will be reviewed for a specific *medical device* (or *medical device* family). This should include the review method, the responsible individuals or functions, who is required to participate in the review, and how the review results are managed. The results of the review of planned *risk management* activities will be consolidated in the *risk management* report (see Clause 9). The requirements for the review of *risk management* activities can be part of other quality system review requirements, such as design and development review (see ISO 13485[24]).

4.4.5 Criteria for *risk* acceptability

Criteria for *risk* acceptability are established according to the *manufacturer's* policy for determining acceptable *risk*. This includes criteria for situations where the probability of occurrence of *harm* cannot be estimated, in which case the criteria for *risk* acceptability can be based on the *severity* of *harm* alone. The criteria can be common for categories of similar *medical devices* (or *medical device* families).

It is important to establish the criteria for *risk* acceptability before starting the *risk assessment*. Otherwise, the results of the *risk assessment* could influence the decision when establishing the criteria.

See Annex C for further guidance and examples of criteria that are derived from the policy and applied in *risk evaluation*.

4.4.6 Method to evaluate overall *residual risk* and criteria for acceptability

The method to evaluate the overall *residual risk* and the criteria for its acceptability are derived from the *manufacturer's* policy for establishing criteria for *risk* acceptability. ISO 14971:2019 requires that the method and the criteria be stated in the *risk management* plan for the particular *medical device* under development. Some inputs for and considerations on the evaluation of overall *residual risk* are listed in Clause 8.

4.4.7 *Verification* activities

The *risk management* plan specifies how the two *verification* activities required per 7.2 of ISO 14971:2019 are carried out. The *risk management* plan can detail the *verification* activities explicitly or by reference to other plans.

Verification of implementation of *risk control* measures can be part of design review, approval of specifications, design and development *verification* in a quality management system, or other *verification* activities in a quality management system.

Verification of the effectiveness of *risk control* measures can be part of design and development *verification* in a quality management system. It can require the collection of clinical data, usability studies, etc., as part of design and development validation in a quality management system.

4.4.8 Activities related to collection and review of production and *post-production* information

ISO 14971:2019 requires the *manufacturer* to establish a system to actively collect and review information about the *medical device* in the production and *post-production* phases and to review this information for relevance to *safety*. Thus, it is important that the *risk management* plan includes the activities necessary to establish this system. *Manufacturers* should understand that the information to be collected can be voluminous and comes from many disparate sources. Consequently, robust *processes* should be used to analyse the information and to identify trends that could otherwise go undiscovered, so that appropriate conclusions and actions can be taken. Statistical techniques should be considered to assist in the processing of the collected data.

The system to actively collect and review information includes monitoring and receiving feedback such as complaints and adverse event reports. In addition, the system should include active solicitation of feedback from users and collection of other relevant information. The *manufacturer* should consider the extent of these activities and determine which activities are appropriate for the particular *medical device*.

For example, limited monitoring might be sufficient for *medical devices* with a long history of use and well understood *risks*. For *medical devices* involving novel treatments (for example new *intended uses*) or innovative technologies and possibly with less understood *risks*, more elaborate monitoring including post-market clinical follow-up (PMCF) studies could be warranted to understand the issues that can arise in the actual use of the *medical device*. Further guidance is provided in Clause 10.

The method for collecting production and *post-production* information can be part of established quality management system *processes* (see for example 8.2 of ISO 13485:2016[24]). While a reference to an existing *procedure* can be sufficient in some cases, any requirements specific to the *medical device* under consideration should be documented in the *risk management* plan. Details of the monitoring activities and any planned PMCF studies should also be specified in the *risk management* plan.

The frequency of review of the collected information should be commensurate with the *risk* and can also depend on the number of *medical devices* on the market, the number of incidents reported and the *severity* of *harm* reported. The collection and review should continue during the expected lifetime of the *medical device*.

4.5 *Risk management file*

ISO 14971:2019 requires the *manufacturer* to establish and maintain a *risk management file*, which contains *records* and other documents created during *risk management* activities for the *medical device*