
Medical devices — Guidance on the application of ISO 14971

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



This document is a preview generated by EUS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements for <i>risk management system</i>	1
4.1 <i>Risk management process</i>	1
4.2 Management responsibilities	1
4.2.1 <i>Top management</i> commitment	1
4.2.2 Policy for establishing criteria for <i>risk</i> acceptability	2
4.2.3 Suitability of the <i>risk management process</i>	2
4.3 Competence of personnel	2
4.4 <i>Risk management plan</i>	3
4.4.1 General	3
4.4.2 Scope of the <i>risk management plan</i>	4
4.4.3 Assignment of responsibilities and authorities	4
4.4.4 Requirements for review of <i>risk management</i> activities	4
4.4.5 Criteria for <i>risk</i> acceptability	4
4.4.6 Method to evaluate overall <i>residual risk</i> and criteria for acceptability	5
4.4.7 <i>Verification</i> activities	5
4.4.8 Activities related to collection and review of production and <i>post-production</i> information	5
4.5 <i>Risk management file</i>	5
5 <i>Risk analysis</i>	6
5.1 <i>Risk analysis process</i>	6
5.2 <i>Intended use</i> and <i>reasonably foreseeable misuse</i>	6
5.3 Identification of characteristics related to <i>safety</i>	7
5.4 Identification of <i>hazards</i> and <i>hazardous situations</i>	7
5.4.1 <i>Hazards</i>	7
5.4.2 <i>Hazardous situations</i> in general	8
5.4.3 <i>Hazardous situations</i> resulting from faults	8
5.4.4 <i>Hazardous situations</i> resulting from random faults	8
5.4.5 <i>Hazardous situations</i> resulting from systematic faults	8
5.4.6 <i>Hazardous situations</i> arising from security vulnerabilities	9
5.4.7 Sequences or combinations of events	9
5.5 <i>Risk estimation</i>	11
5.5.1 General	11
5.5.2 Probability	12
5.5.3 <i>Risks</i> for which probability cannot be estimated	13
5.5.4 <i>Severity</i>	13
5.5.5 Examples	13
6 <i>Risk evaluation</i>	16
7 <i>Risk control</i>	16
7.1 <i>Risk control</i> option analysis	16
7.1.1 <i>Risk control</i> for <i>medical device</i> design	16
7.1.2 <i>Risk control</i> for manufacturing <i>processes</i>	18
7.1.3 Standards and <i>risk control</i>	19
7.2 Implementation of <i>risk control</i> measures	19
7.3 <i>Residual risk</i> evaluation	19
7.4 <i>Benefit-risk</i> analysis	19
7.4.1 General	19
7.4.2 <i>Benefit</i> estimation	20

7.4.3	Criteria for benefit-risk analysis	21
7.4.4	Benefit-risk comparison	21
7.4.5	Examples of benefit-risk analyses	21
7.5	Risks arising from risk control measures	22
7.6	Completeness of risk control	22
8	Evaluation of overall residual risk	22
8.1	General considerations	22
8.2	Inputs and other considerations	23
8.3	Possible approaches	24
9	Risk management review	25
10	Production and post-production activities	25
10.1	General	25
10.2	Information collection	25
10.3	Information review	27
10.4	Actions	28
Annex A (informative)	Identification of hazards and characteristics related to safety	30
Annex B (informative)	Techniques that support risk analysis	38
Annex C (informative)	Relation between the policy, criteria for risk acceptability, risk control and risk evaluation	43
Annex D (informative)	Information for safety and information on residual risk	48
Annex E (informative)	Role of international standards in risk management	51
Annex F (informative)	Guidance on risks related to security	56
Annex G (informative)	Components and devices designed without using ISO 14971	61
Annex H (informative)	Guidance for in vitro diagnostic medical devices	63
Bibliography		86

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.