TECHNICAL REPORT

ISO/TR 24971

Redline version compares Second edition to First edition

Medical devices — Guidance on the application of ISO 14971

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

Reference number
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Text example 1 — Text has been added (in green)

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1.x ... — If there are changes in a clause/subclause, the corresponding clause/subclause number is highlighted in yellow in the Table of contents

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This marked-up version highlights the main changes in this edition of the document compared with the previous edition. It does not focus on details (e.g. changes in punctuation).

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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~~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.

~~ISO/TR 24971~~This document was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and ~~Technical Committee~~Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*. ~~The draft was circulated for voting to the national bodies of both ISO and IEC.~~

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

Experience indicates thatThis document provides guidance to assist *manufacturers* have difficulty with practical implementation of some clauses of the in the development, implementation and maintenance of a *risk management* *International Standard, process* for *medical devices* that aims to meet the requirements of ISO 14971:2007*2019*, *Medical devices — Application of risk management to medical devices*. This Technical Report provides guidance to assist in the development, implementation and maintenance of risk management for medical devices that aim to meet the requirements of It provides guidance on the application of ISO 14971:2019. It provides guidance for specific aspects of for ISO 14971 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*.

This Technical Report is not intended to be an overall guidance document on the implementationThe clauses and subclauses in this document have the same structure and numbering as the clauses and subclauses of ISO 14971:2019 for organizations. It supplements the guidance contained in the informative annexes, 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 14971/TR 24971:2013 related to the following areasand some of the informative annexes of ISO 14971:2007, which are merged, restructured, technically revised, and supplemented with additional guidance.

— Guidance on the role of international product safety and process standards in risk management

— Guidance on developing the policy for determining the criteria for risk acceptability

— Guidance on how the production and post-production feedback loop can work

— Guidance on the differentiation of information for safety as a risk control measure and disclosure of residual risk

— Guidance on the evaluation of overall residual risk

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

This Technical Report provides some document describes approaches that *manufacturers* an organization can use to develop, implement and maintain some aspects of a *risk management process* system that conformsconforming to ISO 14971:2019. Alternative approaches can be used if thesealso satisfy the requirements of ISO 14971:2019.

When judging the applicability of the guidance in this Technical Reportdocument, one should consider the nature of the *medical device(s)* to which it will apply, the risks associated with the use ofhow 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 ~~Technical Report provides guidance in addressing specific areas~~document provides guidance on the development, implementation and maintenance of ~~ISO 14971 when implementing risk management~~a *risk management* system for *medical devices* according to ISO 14971:2019.

The *risk management process*~~guidance is intended~~ 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*~~assist manufacturers and other users of~~ and ~~the standard to~~can be fulfilled by applying ISO 14971:2019. See also the ISO Handbook: *ISO 13485:2016 — Medical devices — A practical guide*[25].

~~— understand the role of international product safety and process standards in risk management;~~

~~— develop the policy for determining the criteria for risk acceptability;~~

~~— incorporate production and post-production feedback loop into risk management;~~

~~— differentiate between “information for safety” and “disclosure of residual risk”; and~~

~~— evaluate overall residual risk.~~

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*

~~2~~3 ~~The role of international product safety and process standards in risk management~~Terms and definitions

~~2.1 Overview~~

~~International product safety and process standards play a significant role in risk management as described by ISO 14971. In principle, these standards are developed using a type of risk management that can include identifying hazards and hazardous situations, estimating risks, evaluating risks, and specifying risk control measures. More information on a process for developing medical device standards using a type of risk management can be found in documents such as ISO/IEC Guide 51 and ISO/IEC Guide 63. International product safety and process standards are developed by experts in the field and represent the generally accepted state of the art (see D.4 of ISO 14971:2007).~~

~~These standards can have an important role in risk management. When performing risk management, the manufacturer first needs to consider the medical device being designed, its intended use and the hazards/hazardous situations related to it. Manufacturers can, if they choose, identify standard(s) that contain specific requirements that help manage the risks related to those hazards/hazardous situations.~~

~~For medical devices that satisfy the requirements and compliance criteria of these standards, the residual risks related to those hazards/hazardous situations can be considered acceptable unless there~~