PD ISO/TR 24971:2013

BSI Standards Publication

Medical devices — Guidance on the application of ISO 14971

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National foreword

This Published Document is the UK implementation of ISO/TR 24971:2013.

The UK participation in its preparation was entrusted to Technical Committee CH/210/4, Risk analysis for Medical Devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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. www.iso.org/directives

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ISO/TR 24971 was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Technical Committee 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.

Introduction

Experience indicates that manufacturers have difficulty with practical implementation of some clauses of the risk management International Standard, ISO 14971:2007, *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 ISO 14971. It provides guidance for specific aspects of ISO 14971 for a wide variety of medical devices. These medical devices include active, non-active, implantable, and non-implantable medical devices and *in vitro* diagnostic medical devices.

This Technical Report is not intended to be an overall guidance document on the implementation of ISO 14971 for organizations. It supplements the guidance contained in the informative annexes of ISO 14971 related to the following areas.

— 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

This Technical Report provides some approaches that an organization can use to implement and maintain some aspects of a risk management system that conforms to ISO 14971. Alternative approaches can be used if these satisfy the requirements of ISO 14971.

When judging the applicability of the guidance in this Technical Report, one should consider the nature of the medical device(s) to which it will apply, the risks associated with the use of these medical devices, 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 of ISO 14971 when implementing risk management.

The guidance is intended to assist manufacturers and other users of the standard to:

— 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 The role of international product safety and process standards in risk management

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 is objective evidence to the contrary. Some potential sources of objective evidence to the contrary can include reports of adverse events, product recalls and complaints. The requirements of International Standards, such as engineering or analytical processes, specific output limits, warning statements, or design specifications, can be considered risk control measures established by the standards writers that are intended to address the risks of specific hazardous situations that have been identified and evaluated as needing risk control.

In many cases, the standards writers have taken on and completed elements of risk management and provided manufacturers with answers in the form of design requirements and test methods for establishing conformity. When performing risk management activities, manufacturers can take advantage of the work of the standards writers and need not repeat the analyses leading to the requirements of the standard. International standards, therefore, provide valuable information on risk acceptability that has been validated during a worldwide evaluation process, including multiple rounds of review, comment, and voting.