SLOVENSKI STANDARD
SIST EN ISO 14971:2001/A1:2003

01-september-2003

Medicinski pripomoļ ki - Uporaba obvladovanja tveganja pri medicinskih pripomoļ kih ï Dopolnilo 1: Osnovna naļ ela za zahteve (ISO 14971:2000/AM1:2003)

Medical devices - Application of risk management to medical devices - Amendment 1: Rationale for requirements (ISO 14971:2000/AM1:2003)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte - Änderung 1: Begründung der Anforderungen (ISO 14971:2000/Amd.1:2003)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux - Amendement 1: Justification des exigences (ISO 14971:2000/AM1:2003)

Ta slovenski standard je istoveten z: **EN ISO 14971:2000/A1:2003**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 14971:2001/A1:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14971:2000/A1

March 2003

ICS 11.040.01

English version

Medical devices - Application of risk management to medical devices - Amendment 1: Rationale for requirements (ISO 14971:2000/AM1:2003)

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This amendment A1 modifies the European Standard EN ISO 14971:2000; it was approved by CEN on 28 February 2003 and by CENELEC on 18 March 2003.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN or CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN or CENELEC member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Ref. No. EN ISO 14971:2000/A1:2003 E

CORRECTED 2003-07-23

Foreword

This document (EN ISO 14971:2000/A1:2003) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with CMC and CENELEC.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2003, and conflicting national standards shall be withdrawn at the latest by September 2003.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14971:2000/A1:2003 has been approved by CEN and CENELEC as EN ISO 14971:2000/A1:2003 without any modifications.

INTERNATIONAL STANDARD

ISO 14971

First edition
2000-12-15

AMENDMENT 1
2003-03-01

Medical devices — Application of risk management to medical devices

AMENDMENT 1: Rationale for requirements

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

AMENDEMENT 1: Justification des exigences

Reference number
ISO 14971:2000/Amd.1:2003(E)

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Published in Switzerland

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 2.

The main task of technical committees is to prepare International Standards. 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.

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.

Amendment 1 to ISO 14971:2000 was prepared 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*.

At the time of publication of ISO 14971:2000, it was anticipated that maintenance of the standard would be required within a few years. IEC/SC 62A has already anticipated that a revision may be needed in about 2005. In anticipation of the maintenance process, ISO/TC 210-IEC/SC 62A Joint Working Group 1, *Application of risk management to medical devices*, developed this Amendment to document its reasoning for establishing the various requirements contained in ISO 14971. Those who make future revisions to the standard can use this Amendment, along with experience gained in the use of the standard, to make the standard more useful to manufacturers, regulatory bodies, and health care providers.

The material in this Amendment is purely informative. It does not alter in any way the requirements of ISO 14971 or modify any of the other informative material.

Introduction

A standard for the application of risk management to medical devices became important largely because of the increasing recognition by regulators that the manufacturer should apply risk management to medical devices. No medical device risk management standard existed, and ISO 14971 was written to fill that gap. ISO/TC 210 Working Group 4 was formed to develop the new standard. Almost simultaneously, drafters of the third edition of IEC 60601-1 planned to have risk management included in the standard then under development. They saw the need for a separate risk management activity and formed Working Group 15 of IEC/SC 62A. Recognizing that the efforts of these two working groups overlapped, IEC and ISO formed the Joint Working Group 1 (JWG 1) on Risk Management combining the membership of both working groups. This collaboration resulted in the publication of ISO 14971 with both an ISO and an IEC logo. The dual logo signifies that both ISO and IEC recognize ISO 14971 as the International Standard covering the application of risk management to medical devices.

When JWG 1 started its discussions on the international risk management standard, there was no satisfactory standard in place to address risk management for medical devices. Crucial features of risk management needed to be addressed such as the process of risk evaluation, as well as the balancing of risks and benefits for medical devices. Manufacturers, regulatory bodies, and health care providers had recognized that "absolute safety" in medical devices was not achievable. In addition, the risks that derive from the increasing diversity of medical devices and their applications cannot be completely addressed through product safety standards. The recognition of these facts and the consequent need to manage risks from medical devices throughout their life cycle led to the decision to develop ISO 14971.

The JWG 1's original plan was to write ISO 14971 in several parts, each dealing with a specific aspect of risk management. ISO 14971-1:1998, covering risk analysis, was intended as the first part of an overall risk management standard. Later, the JWG 1 decided that it was better to develop a single document that would include all aspects of risk management. The main reason for this was that it was apparent that risk management would be mandated by several regulatory regimes in the world, including Europe. It was therefore no longer useful or necessary to have a separate standard on risk analysis available. Also, making one risk management standard instead of having several parts would much better show the coherence between the several aspects of risk management.

In this Amendment, the numbering parallels the numbering of the clauses and subclauses of ISO 14971:2000.

Medical devices — Application of risk management to medical devices

AMENDMENT 1: Rationale for requirements

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Add the following annex before the Bibliography.

Annex H
(informative)

Rationale for requirements

H.1 Rationale for Clause 1, Scope

As explained in the Introduction, a risk management standard applying to all medical devices is required. Risks exist throughout the product life cycle, and risks that become apparent at one point in the life cycle may be managed by action taken at a completely different point in the life cycle. For this reason, this International Standard is intended to be a complete life cycle standard. This means that it instructs manufacturers to apply risk management principles to a medical device from its initial conception until its ultimate decommissioning and disposal.

This International Standard is not intended to be applicable to clinical decision making. The decision to embark upon a clinical procedure utilizing a medical device requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgements should take into account the intended use/intended purpose, performance, and risks associated with the medical device as well as the risks and benefits associated with the clinical procedure or the circumstances of use. Some of these judgements may be made only by a qualified health care professional with knowledge of the state of health of an individual patient and the patient's own opinion.

Although there has been significant debate over what constitutes an acceptable level of risk, this International Standard does not specify acceptability levels. Specifying a single level for acceptable risk would be inappropriate because

— the wide variety of devices and situations covered by this International Standard would make a single level meaningless, and

— local laws, customs, and values are more appropriate for defining risk acceptability for a particular culture or region of the world.

Because not all countries require a quality system for medical device manufacturers, a quality system is not required in this International Standard. However, a quality system is extremely helpful in managing risks properly. Because of this and because most medical device manufacturers do employ a quality system, this International Standard is constructed so that it can easily be incorporated into the quality system that they use. The relationship with ISO 13485:1996 is shown in Table G.2 in Annex G.