SLOVENSKI STANDARD
SIST EN ISO 14971:2001

01-november-2001

Nadomeġļa:
SIST EN 1441:2000

Medicinski pripomoļki - Uporaba obvladovanja tveganja pri medicinskih pripomoļkih (ISO 14971:2000)

Medical devices - Application of risk management to medical devices (ISO 14971:2000)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2000)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2000)

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English version

Medical devices - Application of risk management to medical devices (ISO 14971:2000)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2000)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2000)

This European Standard was approved by CEN on 3 December 2000, and by CENELEC on 2 May 2001.

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

CEN/CENELEC members are the national standards bodies and national electrotechnical committees, respectively, of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

The text of the International Standard ISO 14971:2000 has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with IEC/SC 62A, CEN Management Centre (CMC) and CENELEC.

This European Standard supersedes EN 1441:1997, for which the date of withdrawal is extended. National implementations of EN 1441:1997 shall be withdrawn at the latest by March 2004.

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of an identical text or by endorsement, at the latest by June 2001, and conflicting national standards shall be withdrawn at the latest by March 2004.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A to G are informative.

Endorsement notice

The text of the International Standard ISO 14971:2000 was approved by CEN/CENELEC as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 14971

First edition
2000-12-15

Medical devices — Application of risk management to medical devices

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

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

In the field of risk management for medical devices, Technical Committee ISO/TC 210 and IEC/SC 62A have established a joint working group, JWG 1, *Application of risk management to medical devices*.

International Standard ISO 14971 was prepared by 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.*

Requirements concerning the risk analysis component of the risk management process were developed first and published as ISO 14971-1:1998, with the intention that the requirements for risk evaluation, risk control and post-production information evaluation could be covered in additional part(s), but all the requirements have now been incorporated into this International Standard.

This first edition of ISO 14971 cancels and replaces ISO 14971-1:1998.

For purposes of future IEC maintenance, Subcommittee 62A has decided that this publication remains valid until 2004. At this date, Subcommittee 62A, in consultation with ISO/TC 210, will decide whether the publication will be

— reconfirmed,

— withdrawn,

— replaced by a revised edition, or

— amended.

Annexes A to G of this International Standard are for information only.

Introduction

This International Standard should be regarded as a framework for effective management by the manufacturer of the risks associated with the use of medical devices. The requirements that it contains provide a framework within which experience, insight and judgement are applied systematically to manage these risks.

As a general concept, activities in which an individual, organization or government is involved can expose those or other stakeholders to hazards which may cause loss or damage of something they value. Risk management is a complex subject because each stakeholder places a different value on the probability of harm occurring and on the detriment that might be suffered on exposure to a hazard.

It is accepted that the concept of risk has two components:

a) the probability of the occurrence of harm, that is, how often the harm may occur;

b) the consequences of that harm, that is, how severe it might be.

The acceptability of a risk to a stakeholder is influenced by these components and by the stakeholder's perception of the risk.

These concepts are particularly important in relation to medical devices because of the variety of stakeholders including medical practitioners, the organizations providing health care, governments, industry, patients and members of the public.

All stakeholders need to understand that the use of a medical device entails some degree of risk. Factors affecting each stakeholder's perception of the risks include the socio-economic and educational background of the society concerned and the actual and perceived state of health of the patient. The way a risk is perceived also takes into account, for example, whether exposure to the risk seems to be involuntary, avoidable, from a man-made source, due to negligence, arising from a poorly understood cause, or directed at a vulnerable group within society. 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 medical practitioner with knowledge of the state of health of an individual patient or the patient's own opinion.

As one of the stakeholders, the manufacturer should make judgements relating to the safety of a medical device, including the acceptability of risks, taking into account the generally accepted state of the art, in order to determine the probable suitability of a medical device to be placed on the market for its intended use/intended purpose. This International Standard specifies a procedure by which the manufacturer of a medical device can identify hazards associated with a medical device and its accessories, estimate and evaluate the risks associated with those hazards, control those risks and monitor the effectiveness of that control.

For any particular medical device, other International Standards may require the application of specific methods for controlling risk.

Medical devices — Application of risk management to medical devices

1 Scope

This International Standard specifies a procedure by which a manufacturer can identify the hazards associated with medical devices and their accessories, including *in vitro* diagnostic medical devices, estimate and evaluate the risks, control these risks and monitor the effectiveness of the control.

The requirements of this International Standard are applicable to all stages of the life cycle of a medical device.

This International Standard does not apply to clinical judgements relating to the use of a medical device.

It does not specify acceptable risk levels.

This International Standard does not require that the manufacturer has a formal quality system in place. However, risk management can be an integral part of a quality system (see, for example, Table G.1).

2 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

2.1
accompanying document
document accompanying a medical device, or an accessory, and containing important information for the user, operator, installer or assembler of the medical device particularly regarding safety

NOTE Based on IEC 60601-1:1988, definition 2.1.4.

2.2
harm
physical injury or damage to the health of people, or damage to property or the environment

[ISO/IEC Guide 51:1999, definition 3.1]

2.3
hazard
potential source of harm

[ISO/IEC Guide 51:1999, definition 3.5]

2.4
hazardous situation
circumstance in which people, property or the environment are exposed to one or more hazard(s)

[ISO/IEC Guide 51:1999, definition 3.6]

2.5
intended use/intended purpose
use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer

2.6
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market and/or put into service, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

2.7
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[ISO 13485:1996, definition 3.1]

2.8
objective evidence
information which can be proven true, based on facts obtained through observation, measurement, test or other means

[ISO 8402:1994, definition 2.19]

2.9
procedure
specific way to perform an activity

[ISO 8402:1994, definition 1.3]

2.10
process
set of inter-related resources and activities which transform inputs into outputs

[ISO 8402:1994, definition 1.2]

2.11
record
document which furnishes objective evidence of activities performed or results achieved

[ISO 8402:1994, definition 3.15]

2.12
residual risk
risk remaining after protective measures have been taken

[ISO/IEC Guide 51:1999, definition 3.9]

2.13
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51:1999, definition 3.2]

2.14
risk analysis
systematic use of available information to identify hazards and to estimate the risk

[ISO/IEC Guide 51:1999, definition 3.10]

2.15
risk assessment
overall process comprising a risk analysis and a risk evaluation

[ISO/IEC Guide 51:1999, definition 3.12]

2.16
risk control
process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

2.17
risk evaluation
judgement, on the basis of risk analysis, of whether a risk which is acceptable has been achieved in a given context based on the current values of society

NOTE Based on ISO/IEC Guide 51: 1999, definitions 3.11 and 3.7.

2.18
risk management
systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk

2.19
risk management file
set of records and other documents, not necessarily contiguous, that are produced by a risk management process

2.20
safety
freedom from unacceptable risk

[ISO/IEC Guide 51:1999, definition 3.1]

2.21
severity
measure of the possible consequences of a hazard

2.22
verification
confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

NOTE In design and development, verification concerns the process of examining the result of a given activity to determine conformity with the stated requirement for that activity.

[ISO 8402:1994, definition 2.17]