

Medical devices — Application of risk management to medical devices

The European Standard EN ISO 14971:2000, with the incorporation of A1:2003 has the status of a British Standard.

ICS 11.040.01; 11.100

National foreword

This British Standard is the official English language version of EN ISO 14971:2000, including amendment A1:2003. It is identical with ISO 14971:2000, including amendment 1:2003. It supersedes BS EN 1441:1998 which will be withdrawn 3 years after the publication of EN ISO 14971:2000

The UK participation in its preparation was entrusted to Technical Committee CH/5, Risk management of medical devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

The British Standards which implement these international or European publications may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 March 2001

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English version

Medical devices — Application of risk management to medical devices

(ISO 14971:2000 + A1:2003)
(includes amendment A1:2003)

Dispositifs médicaux — Application de la
gestion des risques aux dispositifs médicaux
(ISO 14971:2000 + A1:2003)
(inclut l'amendement A1:2003)

Medizinprodukte — Anwendung des
Risikomanagements auf Medizinprodukte
(ISO 14971:2000 + A1:2003)
(enthält Änderung A1:2003)

This European Standard was approved by CEN on 3 December 2000.
Amendment A1 was approved by CEN on 28 February 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standards may be obtained on application to the Management Centre or to any CEN member.

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A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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CEN

European Committee for Standardization
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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 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 June 2001.

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.

Endorsement notice

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

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Foreword to amendment A1

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

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Medical devices — Application of risk management to medical devices

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

Reference number
ISO 14971:2000(E)



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Contents

Page

Foreword	iv
Introduction	v
Introduction to amendment 1:2003.....	vi
1 Scope	1
2 Terms and definitions	1
3 General requirements for risk management.....	4
3.1 National or regional regulatory requirements	4
3.2 Risk management process	4
3.3 Management responsibilities	4
3.4 Qualification of personnel	5
3.5 Risk management plan	5
3.6 Risk management file	6
4 Risk analysis (Steps 1, 2 and 3 of Figure 2)	6
4.1 Risk analysis procedure	6
4.2 Intended use/intended purpose and identification of characteristics related to the safety of the medical device (Step 1)	6
4.3 Identification of known or foreseeable hazards (Step 2)	8
4.4 Estimation of the risk(s) for each hazard (Step 3)	8
5 Risk evaluation (Step 4).....	9
6 Risk control (Steps 5 to 10)	9
6.1 Risk reduction.....	9
6.2 Option analysis (Step 5)	9
6.3 Implementation of risk control measure(s) (Step 6)	9
6.4 Residual risk evaluation (Step 7).....	10
6.5 Risk/benefit analysis (Step 8)	10
6.6 Other generated hazards (Step 9).....	10
6.7 Completeness of risk evaluation (Step 10)	10
7 Overall residual risk evaluation (Step 11)	10
8 Risk management report (Step 12).....	10
9 Post-production information (Step 13)	11
Annex A (informative) Questions that can be used to identify medical device characteristics that could impact on safety	12
Annex B (informative) Guidance on risk analysis for <i>in vitro</i> diagnostic medical devices	16
Annex C (informative) Guidance on risk analysis procedure for toxicological hazards	17
Annex D (informative) Examples of possible hazards and contributing factors associated with medical devices	19
Annex E (informative) Risk concepts applied to medical devices.....	23
Annex F (informative) Information on risk analysis techniques	28
Annex G (informative) Other standards that contain information related to the elements of risk management described in this International Standard	30
Annex H (informative) Rationale for requirements	31
Bibliography.....	38

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.

Introduction to amendment 1:2003

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

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]

3 General requirements for risk management

3.1 National or regional regulatory requirements

Because of the wide variety of medical devices covered by this International Standard and the different national or regional regulatory requirements covering those devices, the requirements given in 3.3 and 3.4 apply as appropriate.

3.2 Risk management process

The manufacturer shall establish and maintain a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control. This process shall be documented and shall include the following elements:

- risk analysis;
- risk evaluation;
- risk control; and
- post-production information.

Where a documented product design/development process exists, it shall incorporate the appropriate parts of the risk management process.

NOTE 1 A documented product design/development process can be used to deal with safety in a systematic manner, in particular to enable the early identification of hazards in complex systems and environments.

NOTE 2 A schematic representation of the risk management process is shown in Figure 1.

NOTE 3 See the bibliography.

Compliance is checked by inspection of the risk management file.

3.3 Management responsibilities

The manufacturer shall

- a) define the policy for determining acceptable risk, taking into account relevant International Standards, and national or regional regulations,
- b) ensure the provision of adequate resources,
- c) ensure the assignment of trained personnel (see 3.4) for management, performance of work and assessment activities, and
- d) review the results of risk management activities at defined intervals to ensure continuing suitability and the effectiveness of the risk management process.

The above shall be documented in the risk management file.

Compliance is checked by inspection of the risk management file.

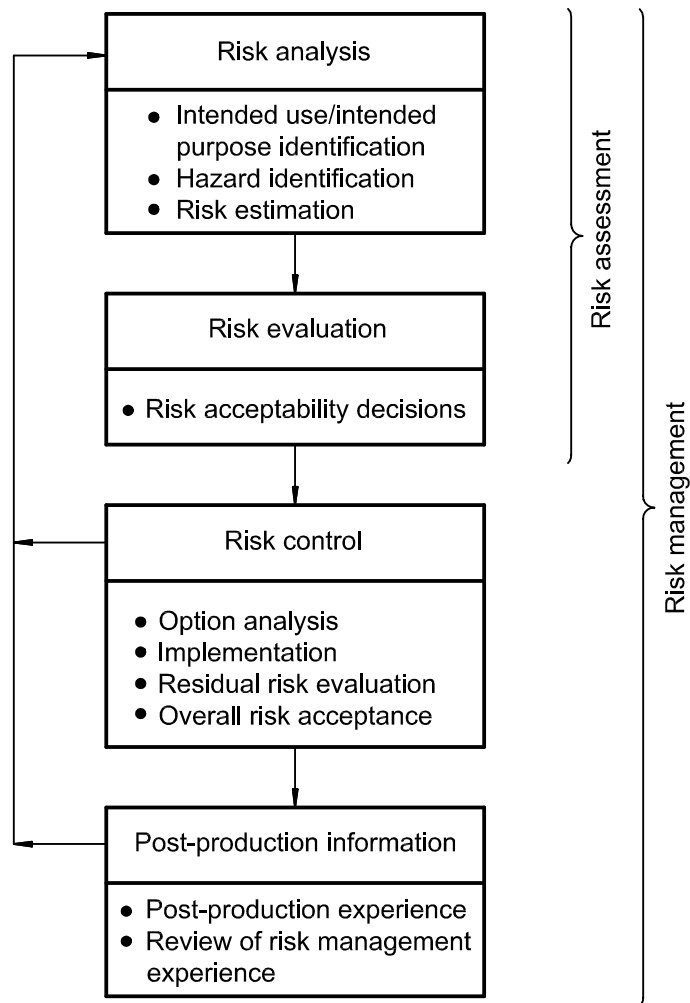


Figure 1 — Schematic representation of the risk management process

3.4 Qualification of personnel

The manufacturer shall ensure that those performing risk management tasks include persons with knowledge and experience appropriate to the tasks assigned to them. This shall include, where appropriate, knowledge and experience of the medical device and its use and risk management techniques. Records of the appropriate qualifications shall be maintained.

Compliance is checked by inspection of the appropriate records.

3.5 Risk management plan

For the particular medical device or accessory being considered, the manufacturer shall prepare a risk management plan in accordance with the risk management process. The risk management plan shall be part of the risk management file.

This plan shall include the following:

- the scope of the plan, identifying and describing the medical device and the life cycle phases for which the plan is applicable;
- a verification plan;
- allocation of responsibilities;