INTERNATIONAL STANDARD

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Medical devices — Application of risk management to medical devices

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

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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]

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.

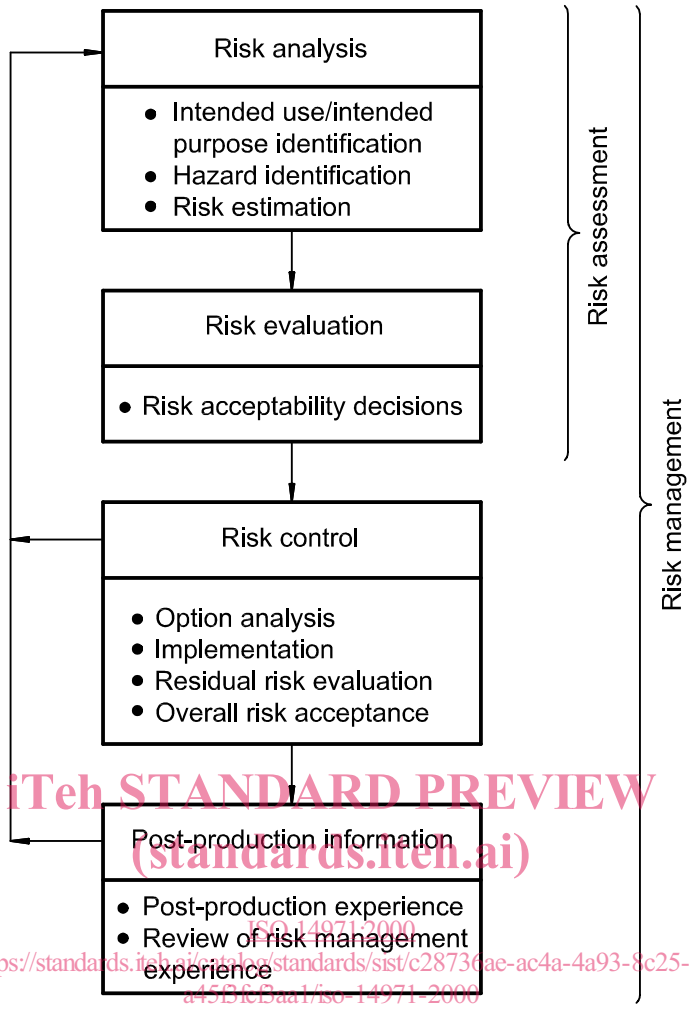

Figure 1 — Schematic representation of the risk management process

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:

a) the scope of the plan, identifying and describing the medical device and the life cycle phases for which the plan is applicable;

b) a verification plan;

c) allocation of responsibilities;

d) requirements for review of risk management activities; and

e) criteria for risk acceptability.

NOTE The criteria for risk acceptability will do much to determine the ultimate effectiveness of the risk management process. Refer to annex E for guidance on establishing such criteria.

If the plan changes during the life cycle of the medical device, a record of the changes shall be maintained in the risk management file.

Compliance is checked by inspection of the risk management file.

3.6 Risk management file

For the particular medical device or accessory being considered, the results of all risk management activities shall be recorded and maintained in the risk management file.

NOTE 1 The records and other documents that make up the risk management file can form part of other documents and files required, for example, by a manufacturer's quality management system.

NOTE 2 The risk management file need not physically contain all the documents relating to this International Standard. However, it should contain at least references or pointers to all required documentation. The manufacturer should be able to assemble the information referenced in the risk management file in a timely fashion.

4 Risk analysis (Steps 1, 2 and 3 of Figure 2)

4.1 Risk analysis procedure

Risk analysis, as described in 4.2 to 4.4, shall be performed and the conduct and results of the risk analysis shall be recorded in the risk management file.

NOTE If a risk analysis is available for a similar medical device, it may be used as a reference provided it can be demonstrated that the processes are similar or that the changes that have been made will not introduce significant differences in results. This should be based on a systematic evaluation of the changes and the ways they can influence the various hazards present.

In addition to the records required in 4.2 to 4.4, the documentation of the conduct and results of the risk analysis shall include at least the following:

a) a description and identification of the medical device or accessory that was analysed;

b) identification of the person(s) and organization which carried out the risk analysis;

c) date of the analysis.

Compliance is checked by inspection of the risk management file.

4.2 Intended use/intended purpose and identification of characteristics related to the safety of the medical device (Step 1)

For the particular medical device or accessory being considered, the manufacturer shall describe the intended use/intended purpose and any reasonably foreseeable misuse. The manufacturer shall list all those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits (see Note 1). These records shall be maintained in the risk management file.

NOTE 1 Annex A contains questions that can serve as a useful guide in drawing up such a list.

NOTE 2 Additional guidance on risk analysis techniques for *in vitro* diagnostic medical devices is given in annex B.

NOTE 3 Additional guidance on risk analysis techniques for toxicological hazards is given in annex C.

Compliance is checked by inspection of the risk management file.

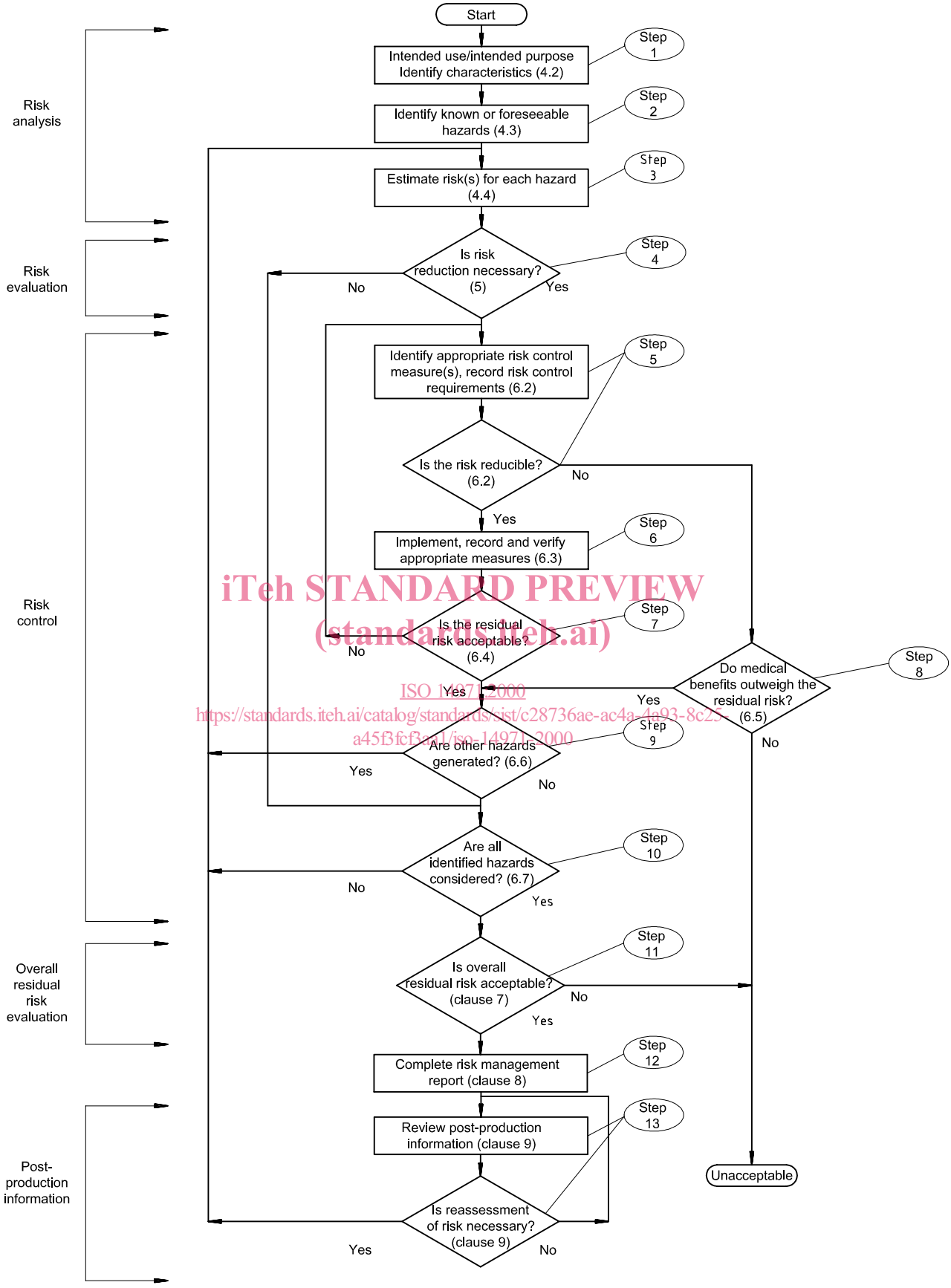

Figure 2 — Overview of risk management activities as applied to medical devices