# 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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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

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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.

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*. Annex H, "Guidance on risk management for *in vitro* diagnostic medical devices", was prepared by ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.



This second edition cancels and replaces the first edition (ISO 14971:2000) as well as the amendment ISO 14971:2000/Amd.1:2003.



For purposes of future IEC maintenance, Subcommittee 62A has decided that the contents of this publication will remain unchanged until the maintenance result date[1] indicated on the IEC web site under http://webstore.iec.ch in the data related to the specific publication. At this date, the publication will be

— reconfirmed,

— withdrawn,

— replaced by a revised edition or

— amended.

This corrected version of ISO 14971:2007 incorporates the following correction:

— a corrected version of Figure 1 on page 6.

1) IEC National Committees are requested to note that for this publication the maintenance result date is 2014.

# Introduction

The requirements contained in this International Standard provide manufacturers with a framework within which experience, insight and judgment are applied systematically to manage the risks associated with the use of medical devices.

This International Standard was developed specifically for medical device/system manufacturers using established principles of risk management. For other manufacturers, e.g., in other healthcare industries, this International Standard could be used as informative guidance in developing and maintaining a risk management system and process.

This International Standard deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment.

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

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



a) the probability of occurrence of harm;

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



The concepts of risk management 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. The acceptability of a risk to a stakeholder is influenced by the components listed above and by the stakeholder's perception of the risk. Each stakeholder's perception of the risk can vary greatly depending upon their cultural background, the socio-economic and educational background of the society concerned, the actual and perceived state of health of the patient, and many other factors. The way a risk is perceived also takes into account, for example, whether exposure to the hazard 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 use a medical device in the context of a particular clinical procedure requires the residual risks to be balanced against the anticipated benefits of the procedure. Such judgments should take into account the intended use, 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 judgments can 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 makes judgments relating to 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 suitability of a medical device to be placed on the market for its intended use. This International Standard specifies a process through which the manufacturer of a medical device can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of that control.

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

# Medical devices — Application of risk management to medical devices

## 1 Scope

This International Standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including *in vitro* diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

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 decision making.

This International Standard does not specify acceptable risk levels.

This International Standard does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.



## 2 Terms and definitions



For the purposes of this document, the following terms and definitions apply:

**2.1**
**accompanying document**
document accompanying a medical device and containing information for those accountable for the installation, use and maintenance of the medical device, the operator or the user, particularly regarding safety

NOTE Adapted from IEC 60601-1:2005, definition 3.4.

**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 3.3]

**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]

NOTE See Annex E for an explanation of the relationship between “hazard” and “hazardous situation”.

**2.5**
**intended use**
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

**2.6**
***in vitro* diagnostic medical device**
**IVD medical device**
medical device intended by the manufacturer for the examination of specimens derived from the human body to provide information for diagnostic, monitoring or compatibility purposes

EXAMPLES Reagents, calibrators, specimen collection and storage devices, control materials and related instruments, apparatus or articles.

NOTE 1 Can be used alone or in combination with accessories or other medical devices.

NOTE 2 Adapted from ISO 18113-1:—, definition 3.29.

**2.7**
**life-cycle**
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

**2.8**
**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 or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party



NOTE 1 Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.



NOTE 2 For a definition of labelling, see ISO 13485:2003, definition 3.6.

**2.9**
**medical device**
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

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

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

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

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary 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

NOTE 1 This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [38].

[ISO 13485:2003, definition 3.7]

NOTE 2 Products, which could be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

— aids for disabled/handicapped people,

— devices for the treatment/diagnosis of diseases and injuries in animals,

— accessories for medical devices (see Note 3),

— disinfection substances,

— devices incorporating animal and human tissues which can meet the requirements of the above definition but are subject to different controls.

NOTE 3 Accessories intended specifically by manufacturers to be used together with a "parent" medical device to enable that medical device to achieve its intended purpose, should be subject to this International Standard.

**2.10**
**objective evidence**
data supporting the existence or verity of something

NOTE Objective evidence can be obtained through observation, measurement, testing or other means.

[ISO 9000:2005, definition 3.8.1]

**2.11**
**post-production**
part of the life-cycle of the product after the design has been completed and the medical device has been manufactured



EXAMPLES transportation, storage, installation, product use, maintenance, repair, product changes, decommissioning and disposal.



**2.12**
**procedure**
specified way to carry out an activity or a process

[ISO 9000:2005, definition 3.4.5]

**2.13**
**process**
set of interrelated or interacting activities which transforms inputs into outputs

[ISO 9000:2005, definition 3.4.1]

**2.14**
**record**
document stating results achieved or providing evidence of activities performed

[ISO 9000:2005, definition 3.7.6]

**2.15**
**residual risk**
risk remaining after risk control measures have been taken

NOTE 1 Adapted from ISO/IEC Guide 51:1999, definition 3.9.

NOTE 2 ISO/IEC Guide 51:1999, definition 3.9 uses the term "protective measures" rather than "risk control measures." However, in the context of this International Standard, "protective measures" are only one option for controlling risk as described in 6.2.

**2.16**
**risk**
combination of the probability of occurrence of harm and the severity of that harm

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

**2.17**
**risk analysis**
systematic use of available information to identify hazards and to estimate the risk

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

NOTE Risk analysis includes examination of different sequences of events that can produce hazardous situations and harm. See Annex E.

**2.18**
**risk assessment**
overall process comprising a risk analysis and a risk evaluation

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

**2.19**
**risk control**
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels



**2.20**
**risk estimation**
process used to assign values to the probability of occurrence of harm and the severity of that harm



**2.21**
**risk evaluation**
process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

**2.22**
**risk management**
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk

**2.23**
**risk management file**
set of records and other documents that are produced by risk management

**2.24**
**safety**
freedom from unacceptable risk

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

**2.25**
**severity**
measure of the possible consequences of a hazard

**2.26**
**top management**
person or group of people who direct(s) and control(s) a manufacturer at the highest level

NOTE Adapted from ISO 9000:2005, definition 3.2.7.

**2.27**
**use error**
act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user

NOTE 1 Use error includes slips, lapses and mistakes.

NOTE 2 See also IEC 62366:—, Annexes B and D.1.3.

NOTE 3 An unexpected physiological response of the patient is not by itself considered use error.

[IEC 62366:— [2)], definition 2.12]

**2.28**
**verification**
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 The term “verified” is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

— performing alternative calculations;

— comparing a new design specification with a similar proven design specification;

— undertaking tests and demonstrations;

— reviewing documents prior to issue.



[ISO 9000:2005, definition 3.8.4]



# 3 General requirements for risk management

## 3.1 Risk management process

The manufacturer shall establish, document and maintain throughout the life-cycle an ongoing process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. This process shall include the following elements:

— risk analysis;

— risk evaluation;

— risk control;

— production and post-production information.

Where a documented product realization process exists, such as that described in Clause 7 of ISO 13485:2003[8], it shall incorporate the appropriate parts of the risk management process.

NOTE 1 A documented quality management system process can be used to deal with safety in a systematic manner, in particular to enable the early identification of hazards and hazardous situations in complex medical devices and systems.

2) To be published.

NOTE 2 A schematic representation of the risk management process is shown in Figure 1. Depending on the specific life-cycle phase, individual elements of risk management can have varying emphasis. Also, risk management activities can be performed iteratively or in multiple steps as appropriate to the medical device. Annex B contains a more detailed overview of the steps in the risk management process.

Compliance is checked by inspection of appropriate documents.

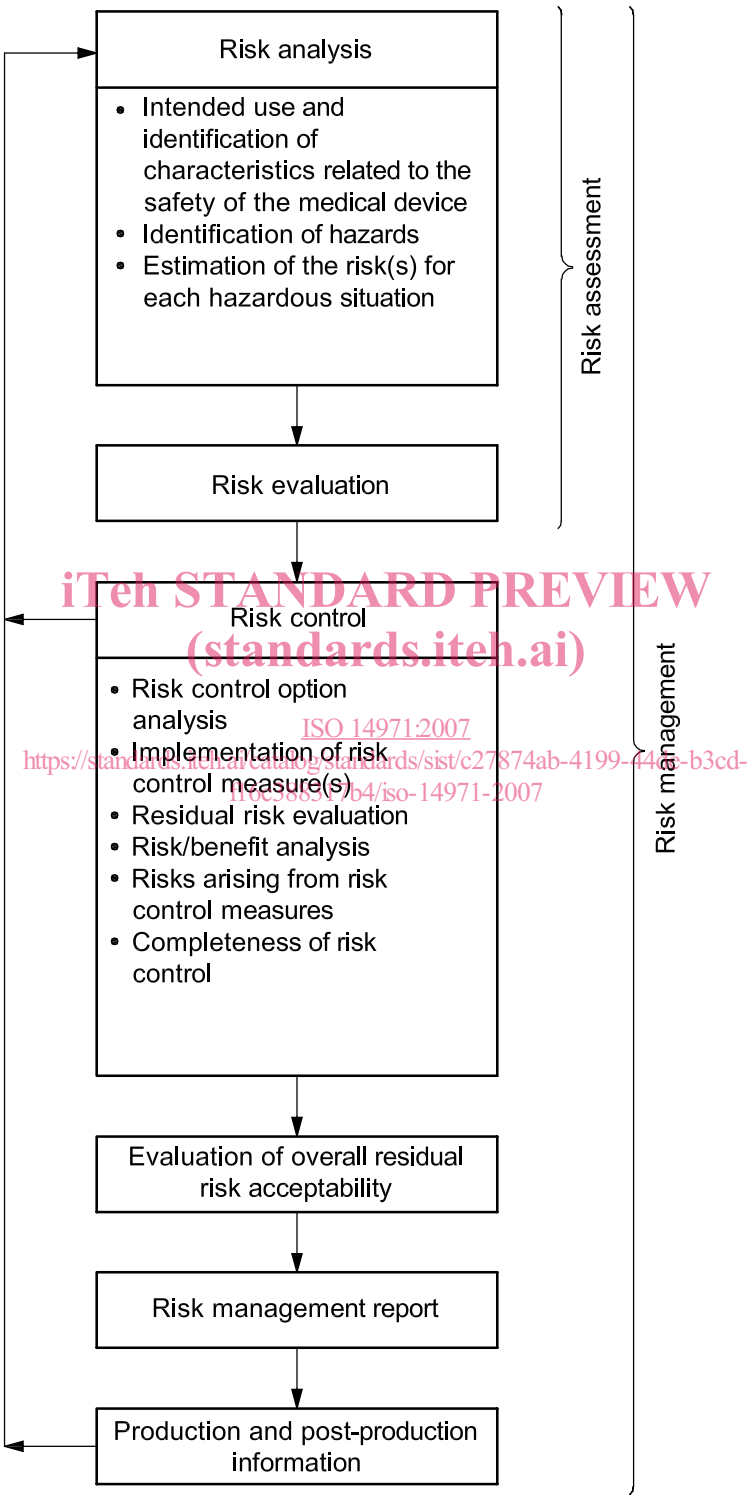




**Figure 1 — A schematic representation of the risk management process**

### 3.2 Management responsibilities

Top management shall provide evidence of its commitment to the risk management process by:

— ensuring the provision of adequate resources

and

— ensuring the assignment of qualified personnel (see 3.3) for risk management.

Top management shall:

— define and document the policy for determining criteria for risk acceptability; this policy shall ensure that criteria are based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns;

— review the suitability of the risk management process at planned intervals to ensure continuing effectiveness of the risk management process and document any decisions and actions taken; if the manufacturer has a quality management system in place, this review may be part of the quality management system review.

NOTE The documents can be incorporated within the documents produced by the manufacturer's quality management system and these documents can be referenced in the risk management file.

Compliance is checked by inspection of the appropriate documents.



### 3.3 Qualification of personnel

Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them. These shall include, where appropriate, knowledge and experience of the particular medical device (or similar medical devices) and its use, the technologies involved or risk management techniques. Appropriate qualification records shall be maintained.



NOTE Risk management tasks can be performed by representatives of several functions, each contributing their specialist knowledge.

Compliance is checked by inspection of the appropriate records.

### 3.4 Risk management plan

Risk management activities shall be planned. Therefore, for the particular medical device being considered, the manufacturer shall establish and document 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 at least the following:

a) the scope of the planned risk management activities, identifying and describing the medical device and the life-cycle phases for which each element of the plan is applicable;

b) assignment of responsibilities and authorities;

c) requirements for review of risk management activities;

d) criteria for risk acceptability, based on the manufacturer's policy for determining acceptable risk, including criteria for accepting risks when the probability of occurrence of harm cannot be estimated;

e) verification activities;

f) activities related to collection and review of relevant production and post-production information.

NOTE 1 Refer to Annex F for guidance on developing a risk management plan.

NOTE 2 Not all parts of the plan need to be created at the same time. The plan or parts of it can be developed over time.

NOTE 3 The criteria for risk acceptability are essential for the ultimate effectiveness of the risk management process. For each risk management plan the manufacturer should choose appropriate risk acceptability criteria.

Options could include, among others:

— indicating in a matrix, such as Figures D.4 and D.5, which combinations of probability of harm and severity of harm are acceptable or unacceptable;

— further subdividing the matrix (e.g., negligible, acceptable with risk minimization) and requiring that risks first be made as low as reasonably practicable before determining that they are acceptable (see D.8).

Whichever option is chosen, it should be determined according to the manufacturer's policy for determining criteria for risk acceptability and thus be based upon applicable national or regional regulations and relevant International Standards, and take into account available information such as the generally accepted state of the art and known stakeholder concerns (see 3.2). Refer to D.4 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.



### 3.5 Risk management file



For the particular medical device being considered, the manufacturer shall establish and maintain a risk management file. In addition to the requirements of other clauses of this International Standard, the risk management file shall provide traceability for each identified hazard to:

— the risk analysis;

— the risk evaluation;

— the implementation and verification of the risk control measures;

— the assessment of the acceptability of any residual risk(s).

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. The risk management file need not physically contain all the records and other documents; 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.

NOTE 2 The risk management file can be in any form or type of medium.

## 4 Risk analysis

### 4.1 Risk analysis process

Risk analysis shall be performed for the particular medical device as described in 4.2 to 4.4. The implementation of the planned risk analysis activities and the results of the risk analysis shall be recorded in the risk management file.

 

NOTE 1 If a risk analysis, or other relevant information, is available for a similar medical device, that analysis or information can be used as a starting point for the new analysis. The degree of relevance depends on the differences between the devices and whether these introduce new hazards or significant differences in outputs, characteristics, performance or results. The extent of use of an existing analysis is also based on a systematic evaluation of the effects the changes have on the development of hazardous situations.

NOTE 2 Some risk analysis techniques are described in Annex G.

NOTE 3 Additional guidance on risk analysis techniques for *in vitro* diagnostic medical devices is given in Annex H.

NOTE 4 Additional guidance on risk analysis techniques for toxicological hazards is given in Annex I.

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 that was analysed;

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

c) scope and date of the risk analysis.

NOTE 5 The scope of the risk analysis can be very broad (as for the development of a new device with which a manufacturer has little or no experience) or the scope can be limited (as for analysing the impact of a change to an existing device for which much information already exists in the manufacturer's files).

Compliance is checked by inspection of the risk management file.



## 4.2 Intended use and identification of characteristics related to the safety of the medical device

For the particular medical device being considered, the manufacturer shall document the intended use and reasonably foreseeable misuse. The manufacturer shall identify and document those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits. This documentation shall be maintained in the risk management file.



NOTE 1 In this context, misuse is intended to mean incorrect or improper use of the medical device.

NOTE 2 Annex C contains questions such as those relating to use that can serve as a useful guide in identifying medical device characteristics that could have an impact on safety.

Compliance is checked by inspection of the risk management file.

## 4.3 Identification of hazards

The manufacturer shall compile documentation on known and foreseeable hazards associated with the medical device in both normal and fault conditions.

This documentation shall be maintained in the risk management file.

NOTE The examples of possible hazards in E.2 and H.2.4 can be used as guidance by the manufacturer to initiate hazard identification.

Compliance is checked by inspection of the risk management file.

## 4.4 Estimation of the risk(s) for each hazardous situation

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation shall be considered and the resulting hazardous situation(s) shall be recorded.