

SVENSK STANDARD

SS-EN ISO 14971:2012

**Medicintekniska produkter – Tillämpning av ett system för riskhantering för medicintekniska produkter
(ISO 14971:2007, Corrected version 2007-10-01)**

Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)



sis Svenska
Institutet för
Standarder

Språk: engelska/English

Utgåva: 4

This preview is downloaded from www.sis.se. Buy the entire standard via <https://www.sis.se/std-87165>

Den här standarden kan hjälpa dig att effektivisera och kvalitetssäkra ditt arbete. SIS har fler tjänster att erbjuda dig för att underlätta tillämpningen av standarder i din verksamhet.

SIS Abonnemang

Snabb och enkel åtkomst till gällande standard med SIS Abonnemang, en prenumerationstjänst genom vilken din organisation får tillgång till all världens standarder, senaste uppdateringarna och där hela din organisation kan ta del av innehållet i prenumerationen.

Utbildning, event och publikationer

Vi erbjuder även utbildningar, rådgivning och event kring våra mest sålda standarder och frågor kopplade till utveckling av standarder. Vi ger också ut handböcker som underlättar ditt arbete med att använda en specifik standard.

Vill du delta i ett standardiseringsprojekt?

Genom att delta som expert i någon av SIS 300 tekniska kommittéer inom CEN (europeisk standardisering) och/eller ISO (internationell standardisering) har du möjlighet att påverka standardiseringsarbetet i frågor som är viktiga för din organisation. Välkommen att kontakta SIS för att få veta mer!

Kontakt

Skriv till kundservice@sis.se, besök sis.se eller ring 08 - 555 523 10

© Copyright/Upphovsrätten till denna produkt tillhör Svenska institutet för standarder, Stockholm, Sverige. Upphovsrätten och användningen av denna produkt regleras i slutanvändarlicensen som återfinns på sis.se/slutanvandarlicens och som du automatiskt blir bunden av när du använder produkten. För ordlista och förkortningar se sis.se/ordlista.

© Copyright Svenska institutet för standarder, Stockholm, Sweden. All rights reserved. The copyright and use of this product is governed by the end-user licence agreement which you automatically will be bound to when using the product. You will find the licence at sis.se/enduserlicenseagreement.

Upplysningar om sakinnehållet i standarden lämnas av Svenska institutet för standarder, telefon 08 - 555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Standarden är framtagen av kommittén Medicintekniska kvalitetssystem, SIS/TK 355.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

Europastandarden EN ISO 14971:2012 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14971:2012.

Denna standard ersätter SS-EN ISO 14971:2009, utgåva 3.

The European Standard EN ISO 14971:2012 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14971:2012.

This standard supersedes the Swedish Standard SS-EN ISO 14971:2009, edition 3.

EUROPEAN STANDARD

EN ISO 14971

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2012

ICS 11.040.01

Supersedes EN ISO 14971:2009

English version

Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2007, Version corrigée de 2007-10-01)

Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2007, korrigierte Fassung 2007-10-01)

This European Standard was approved by CEN on 16 May 2012.

CEN and CENELEC 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 standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



**CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels**

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Terms and definitions	1
3 General requirements for risk management	5
3.1 Risk management process	5
3.2 Management responsibilities	7
3.3 Qualification of personnel	7
3.4 Risk management plan	7
3.5 Risk management file	8
4 Risk analysis	8
4.1 Risk analysis process	8
4.2 Intended use and identification of characteristics related to the safety of the medical device	9
4.3 Identification of hazards	9
4.4 Estimation of the risk(s) for each hazardous situation	9
5 Risk evaluation	10
6 Risk control	11
6.1 Risk reduction	11
6.2 Risk control option analysis	11
6.3 Implementation of risk control measure(s)	11
6.4 Residual risk evaluation	12
6.5 Risk/benefit analysis	12
6.6 Risks arising from risk control measures	12
6.7 Completeness of risk control	12
7 Evaluation of overall residual risk acceptability	13
8 Risk management report	13
9 Production and post-production information	13
Annex A (informative) Rationale for requirements	15
Annex B (informative) Overview of the risk management process for medical devices	23
Annex C (informative) Questions that can be used to identify medical device characteristics that could impact on safety	25
Annex D (informative) Risk concepts applied to medical devices	32
Annex E (informative) Examples of hazards, foreseeable sequences of events and hazardous situations	49
Annex F (informative) Risk management plan	54
Annex G (informative) Information on risk management techniques	56
Annex H (informative) Guidance on risk management for <i>in vitro</i> diagnostic medical devices	60
Annex I (informative) Guidance on risk analysis process for biological hazards	76
Annex J (informative) Information for safety and information about residual risk	78
Annex ZA (informative) Relationship between this European Standard and Requirements of EU Directive 93/42/EEC on Medical Devices	80
Annex ZB (informative) Relationship between this European Standard and Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices	85
Annex ZC (informative) Relationship between this European Standard and Requirements of EU Directive 98/79/EC on In Vitro Diagnostic Medical Devices	89
Bibliography	93

Foreword

The text of ISO 14971:2007, Corrected version 2007-10-01, has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14971:2012 by Technical Committee CEN-CLC/TC 3 “Quality management and corresponding general aspects for medical devices”, the Secretariat of which is held by NEN.

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 January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

This document supersedes EN ISO 14971:2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document 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 Directives 93/42/EEC on Medical Devices, 90/385/EEC on Active Implantable Medical Devices and 98/79/EC on In Vitro Diagnostic Devices.

For relationship with EU Directives, see informative Annexes ZA, ZB and ZC, which are an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14971:2007, Corrected version 2007-10-01, has been approved by CEN as an EN ISO 14971:2012 without any modification.

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.

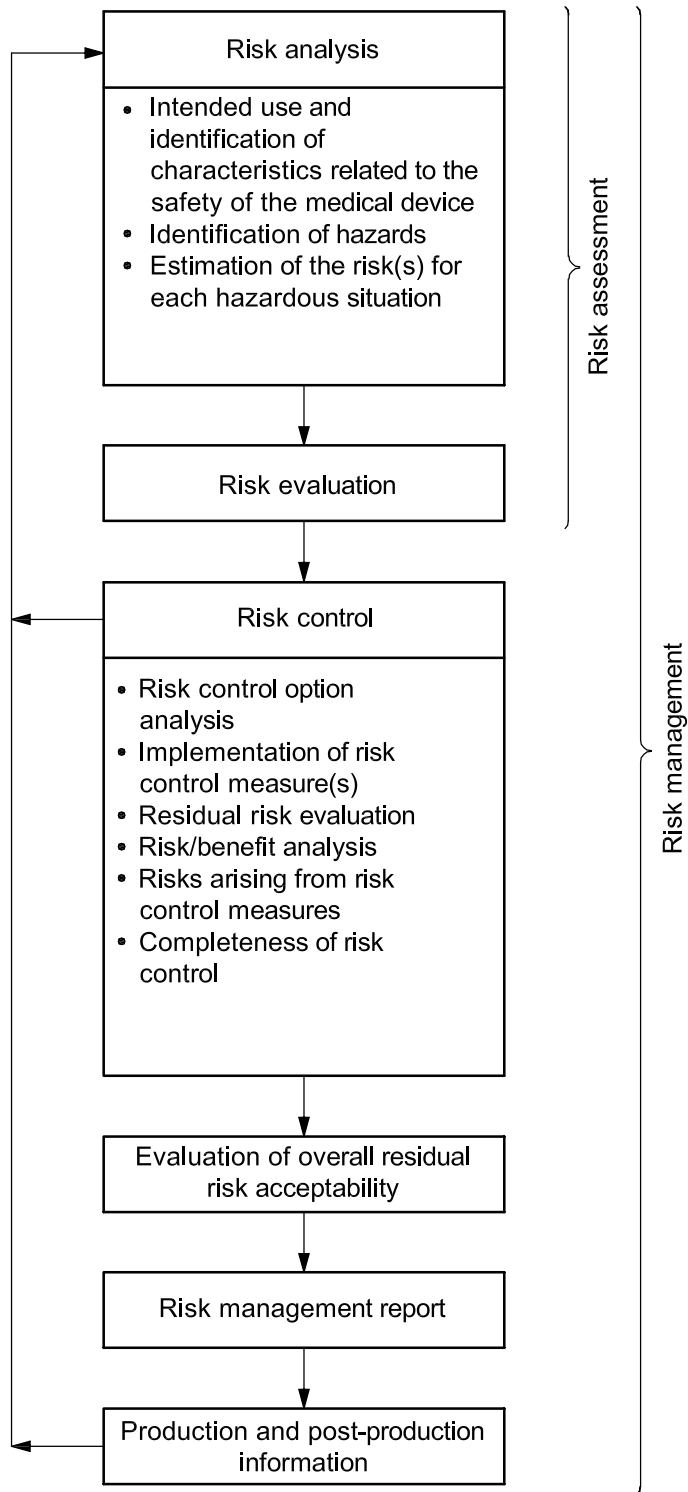


Figure 1 — A schematic representation of the risk management process

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.

NOTE 1 To identify hazardous situations not previously recognised, systematic methods covering the specific situation can be used (see Annex G).

NOTE 2 Examples of hazardous situations are provided in H.2.4.5 and E.4.

NOTE 3 Hazardous situations can arise from slips, lapses and mistakes.

For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data. For hazardous situations for which the probability of the occurrence of harm cannot be estimated, the possible consequences shall be listed for use in risk evaluation and risk control. The results of these activities shall be recorded in the risk management file.

Any system used for qualitative or quantitative categorization of probability of occurrence of harm or severity of harm shall be recorded in the risk management file.

NOTE 4 Risk estimation incorporates an analysis of the probability of occurrence and the consequences. Depending on the application, only certain elements of the risk estimation process might need to be considered. For example, in some instances it will not be necessary to go beyond an initial hazard and consequence analysis. See also D.3.

NOTE 5 Risk estimation can be quantitative or qualitative. Methods of risk estimation, including those resulting from systematic faults, are described in Annex D. Annex H gives information useful for estimating risks for *in vitro* diagnostic medical devices.

NOTE 6 Information or data for estimating risks can be obtained, for example, from:

- a) published standards;
- b) scientific technical data;
- c) field data from similar medical devices already in use, including published reported incidents;
- d) usability tests employing typical users;
- e) clinical evidence;
- f) results of appropriate investigations;
- g) expert opinion;
- h) external quality assessment schemes.

Compliance is checked by inspection of the risk management file.

5 Risk evaluation

For each identified hazardous situation, the manufacturer shall decide, using the criteria defined in the risk management plan, if risk reduction is required. If risk reduction is not required, the requirements given in 6.2 to 6.6 do not apply for this hazardous situation (i.e., proceed to 6.7). The results of this risk evaluation shall be recorded in the risk management file.

NOTE 1 Guidance for deciding on risk acceptability is given in D.4.

NOTE 2 Application of relevant standards, as part of the medical device design criteria, might constitute risk control activities, thus meeting the requirements given in 6.3 to 6.6.

Compliance is checked by inspection of the risk management file.

6 Risk control

6.1 Risk reduction

When risk reduction is required, risk control activities, as described in 6.2 to 6.7, shall be performed.

6.2 Risk control option analysis

The manufacturer shall identify risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level.

The manufacturer shall use one or more of the following risk control options in the priority order listed:

- a) inherent safety by design;
- b) protective measures in the medical device itself or in the manufacturing process;
- c) information for safety.

NOTE 1 If implementing option b) or c), manufacturers can follow a process where reasonably practicable risk control measures are considered and the option providing the appropriate reduction in risk is chosen before determining whether the risk is acceptable.

NOTE 2 Risk control measures can reduce the severity of the harm or reduce the probability of occurrence of the harm, or both.

NOTE 3 Many standards address inherent safety, protective measures, and information for safety for medical devices. In addition, many other medical device standards have integrated elements of the risk management process (e.g. electromagnetic compatibility, usability, biocompatibility). Relevant standards should be applied as part of the risk control option analysis.

NOTE 4 For risks for which the probability of occurrence of harm cannot be estimated, see D.3.2.3.

NOTE 5 Guidance on information for safety is provided in Annex J.

The risk control measures selected shall be recorded in the risk management file.

If, during risk control option analysis, the manufacturer determines that required risk reduction is not practicable, the manufacturer shall conduct a risk/benefit analysis of the residual risk (proceed to 6.5).

Compliance is checked by inspection of the risk management file.

6.3 Implementation of risk control measure(s)

The manufacturer shall implement the risk control measure(s) selected in 6.2.

Implementation of each risk control measure shall be verified. This verification shall be recorded in the risk management file.

The effectiveness of the risk control measure(s) shall be verified and the results shall be recorded in the risk management file.

NOTE The verification of effectiveness can include validation activities.

Compliance is checked by inspection of the risk management file.