

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 14971 : 2012

(ISO 14971 : 2007)

(JFMDA)

Medical devices—Application of risk management to medical devices

ICS 11.040.01

Reference number : JIS T 14971 : 2012 (E)

PROTECTED BY COPYRIGHT

Date of Establishment: 2003-08-25

Date of Revision: 2012-03-01

Date of Public Notice in Official Gazette: 2012-03-01

Investigated by: Japanese Industrial Standards Committee
Standards Board

Technical Committee on Medical Equipment

JIS T 14971:2012, First English edition published in 2012-09

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

© JSA 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

PROTECTED BY COPYRIGHT

Contents

	Page
Introduction	1
1 Scope	1
2 Terms and definitions	1
3 General requirements for risk management	6
3.1 Risk management process	6
3.2 Management responsibilities	6
3.3 Qualification of personnel	7
3.4 Risk management plan	7
3.5 Risk management file	8
4 Risk analysis	9
4.1 Risk analysis process	9
4.2 Intended use and identification of characteristics related to the safety of the medical device	10
4.3 Identification of hazards	10
4.4 Estimation of the risk(s) for each hazardous situation	11
5 Risk evaluation	12
6 Risk control	12
6.1 Risk reduction	12
6.2 Risk control option analysis	12
6.3 Implementation of risk control measure(s)	13
6.4 Residual risk evaluation	13
6.5 Risk/benefit analysis	13
6.6 Risks arising from risk control measures	13
6.7 Completeness of risk control	14
7 Evaluation of overall residual risk acceptability	14
8 Risk management report	14
9 Production and post-production information	15
Annex A (informative) Rationale for requirements	16
Annex B (informative) Overview of the risk management process for medical devices	26
Annex C (informative) Questions that can be used to identify medical device characteristics that could impact on safety	28
Annex D (informative) Risk concepts applied to medical devices	35

Annex E (informative)	Examples of hazards, foreseeable sequences of events and hazardous situations	54
Annex F (informative)	Risk management plan	59
Annex G (informative)	Information on risk management techniques	61
Annex H (informative)	Guidance on risk management for <i>in vitro</i> diagnostic medical devices	65
Annex I (informative)	Guidance on risk analysis process for biological hazards	82
Annex J (informative)	Information for safety and information about residual risk	84
Bibliography		86

Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry, through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by The Japan Federation of Medical Devices Associations (JFMDA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14. Consequently **JIS T 14971:2003** has been replaced with this Standard.

This **JIS** document is protected by the Copyright Law.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public or utility model right. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public or the utility model right.

Medical devices—Application of risk management to medical devices

Introduction

This Japanese Industrial Standard has been prepared based on the second edition of **ISO 14971** published in 2007 without any modifications of technical contents.

The portions with dotted underlines are the matters not given in the corresponding International Standard.

1 Scope

This 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 Standard are applicable to all stages of the life-cycle of a medical device.

This Standard does not apply to clinical decision making.

This Standard does not specify acceptable risk levels.

This 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.

NOTE : The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 14971:2007 *Medical devices—Application of risk management to medical devices* (IDT)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

Furthermore, **JIS T 14971:2003** is applicable until 28 February 2015.

2 Terms and definitions

For the purposes of this Standard, 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 of 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.

NOTE 3 As shown in above Examples, *in vitro* diagnostic medical device includes both reagents and devices.

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 **JIS Q 13485:2005**, 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

[JIS Q 13485:2005, definition 3.7]

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

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 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.

[JIS Q 9000:2006, 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

[JIS Q 9000:2006, definition 3.4.5]

2.13 process

set of interrelated or interacting activities which transforms inputs into outputs

[JIS Q 9000:2006, definition 3.4.1]

2.14 record

document stating results achieved or providing evidence of activities performed

[JIS Q 9000:2006, 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 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 **JIS Q 9000:2006**, 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 62366:2007**, Annexes B and **D.1.3**.

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

[**IEC 62366:2007**, definition 3.21]

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.

[JIS Q 9000:2006, 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 JIS Q 13485:2005 [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.

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.

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 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 or medium.

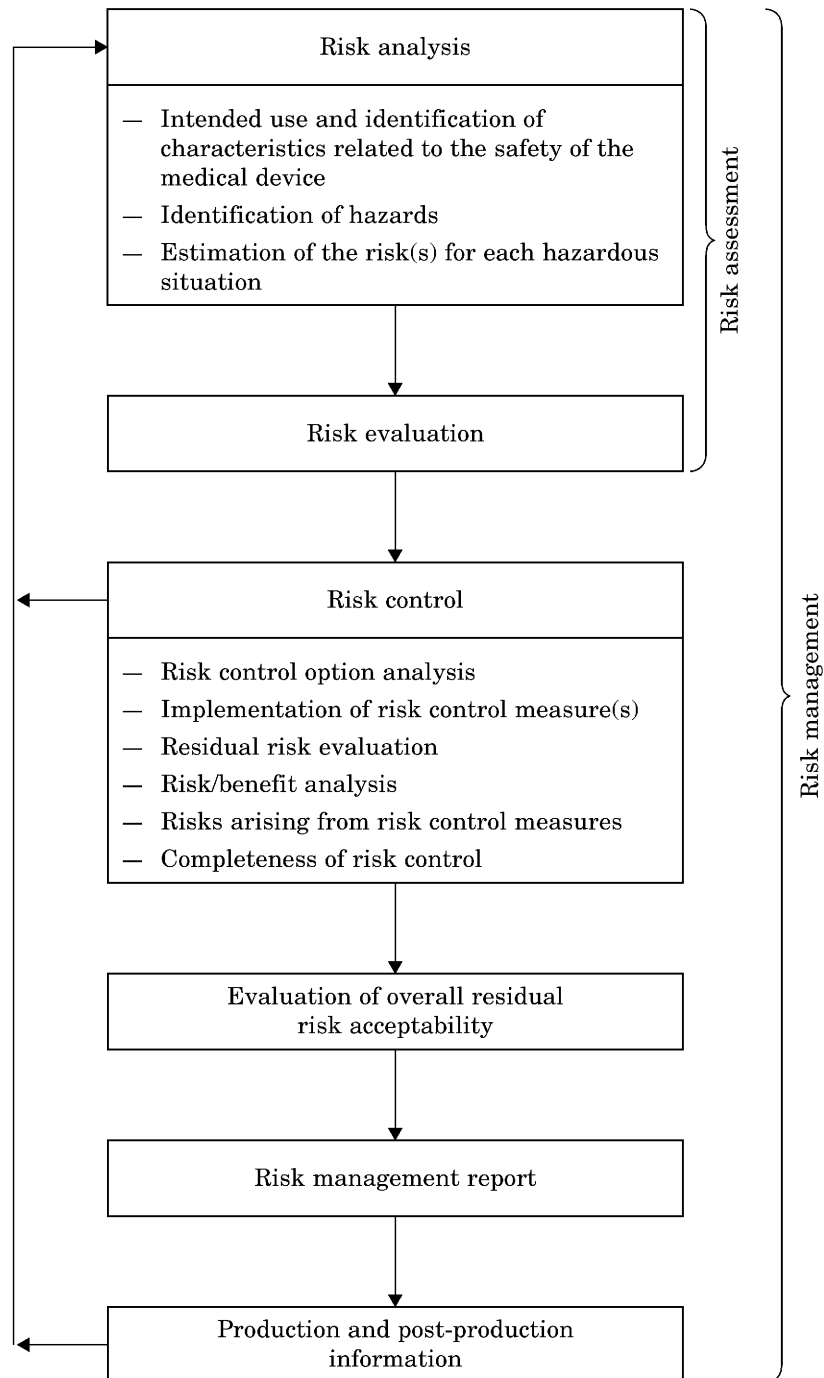


Figure 1 A schematic representation of the risk management process

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 (instructions for use, results of the evaluation, experience, etc.);
- 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 give 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.

6.4 Residual risk evaluation

After the risk control measures are applied, any residual risk shall be evaluated using the criteria defined in the risk management plan. The results of this evaluation shall be recorded in the risk management file.

If the residual risk is not judged acceptable using these criteria, further risk control measures shall be applied (see **6.2**).

For residual risks that are judged acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documents in order to disclose those residual risks.

NOTE : Guidance on how residual risk(s) can be disclosed is provided in Annex J.

Compliance is checked by inspection of the risk management file and the accompanying documents.

6.5 Risk/benefit analysis

If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to **6.6**.

For risks that are demonstrated to be outweighed by the benefits, the manufacturer shall decide which information for safety is necessary to disclose the residual risk.

The results of this evaluation shall be recorded in the risk management file.

NOTE : See also **D.6**.

Compliance is checked by inspection of the risk management file.

6.6 Risks arising from risk control measures

The effects of the risk control measures shall be reviewed with regard to:

- a) the introduction of new hazards or hazardous situations;
- b) whether the estimated risks for previously identified hazardous situations are affected by the introduction of the risk control measures.

Any new or increased risks shall be managed in accordance with **4.4** to **6.5**.

The results of this review shall be recorded in the risk management file.

Compliance is checked by inspection of the risk management file.

6.7 Completeness of risk control

The manufacturer shall ensure that the risk(s) from all identified hazardous situations have been considered. The results of this activity shall be recorded in the risk management file.

Compliance is checked by inspection of the risk management file.

7 Evaluation of overall residual risk acceptability

After all risk control measures have been implemented and verified, the manufacturer shall decide if the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan.

NOTE 1 For guidance on overall residual risk evaluation, see **D.7**.

If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk. If this evidence supports the conclusion that the medical benefits outweigh the overall residual risk, then the overall residual risk can be judged acceptable. Otherwise, the overall residual risk remains unacceptable.

For an overall residual risk that is judged acceptable, the manufacturer shall decide which information is necessary to include in the accompanying documents in order to disclose the overall residual risk.

NOTE 2 Guidance on how residual risk(s) can be disclosed is provided in Annex J.

The results of the overall residual risk evaluation shall be recorded in the risk management file.

Compliance is checked by inspection of the risk management file and the accompanying documents.

8 Risk management report

Prior to release for commercial distribution of the medical device, the manufacturer shall carry out a review of the risk management process. This review shall at least ensure that:

- the risk management plan has been appropriately implemented;
- the overall residual risk is acceptable;
- appropriate methods are in place to obtain relevant production and post-production information.

The results of this review shall be recorded as the risk management report and included in the risk management file.

The responsibility for review should be assigned in the risk management plan to persons having the appropriate authority [see **3.4 b**].

Compliance is checked by inspection of the risk management file.

9 Production and post-production information

The manufacturer shall establish, document and maintain a system to collect and review information about the medical device or similar devices in the production and the post-production phases.

When establishing a system to collect and review information about the medical device, the manufacturer should consider among other things:

- a) the mechanisms by which information generated by the operator, the user, or those accountable for the installation, use and maintenance of the medical device is collected and processed;

or

- b) new or revised standards.

The system should also collect and review publicly available information about similar medical devices on the market.

This information shall be evaluated for possible relevance to safety, especially the following:

- if previously unrecognised hazards or hazardous situations are present or
- if the estimated risk(s) arising from a hazardous situation is/are no longer acceptable.

If any of the above conditions occur:

- 1) the impact on previously implemented risk management activities shall be evaluated and shall be fed back as an input to the risk management process and
- 2) a review of the risk management file for the medical device shall be conducted; if there is a potential that the residual risk(s) or its acceptability has changed, the impact on previously implemented risk control measures shall be evaluated.

The results of this evaluation shall be recorded in the risk management file.

NOTE 1 Some aspects of post-production monitoring are the subject of some national regulations. In such cases, additional measures might be required (e.g., prospective post-production evaluations).

NOTE 2 See also **8.2** of **JIS Q 13485:2005** [8].

Compliance is checked by inspection of the risk management file and other appropriate documents.

Annex A (informative)

Rationale for requirements

A.1 General

ISO 14971 : 2007, which is the original International Standard of **JIS T 14971**, has been prepared on the following background. The **ISO/TC 210-IEC/SC 62A** Joint Working Group 1, *Application of risk management to medical devices*, developed this rationale to document its reasoning for establishing the various requirements contained in the first edition of this International Standard. During the development of this edition, this rationale was updated to take account of normative changes. Those who make future revisions to this International Standard can use this Annex, along with experience gained in the use of this International Standard, to make this International Standard more useful to manufacturers, regulatory bodies and health care providers.

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 this International Standard has been written to fill that gap. **ISO/TC 210** Working Group 4 was formed to develop the new International Standard. Almost simultaneously, drafters of the third edition of **IEC 60601-1** [23] 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**. Recognising 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. **ISO** and **IEC** also recognise each other's single-logo standards as the international standards covering their respective subjects. The dual logo signifies that the standard has been developed jointly by both communities, through the **ISO** Member Bodies and the **IEC** National Committees.

When discussions began on the international risk management standard, 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 recognised 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 original plan was to write the standard in several parts, each dealing with a specific aspect of risk management. **ISO 14971-1**, covering risk analysis, was intended as the first part of an overall risk management standard. Later, it was 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. 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.

This edition of **ISO 14971** was developed to address the need for additional guidance on its application. Minor changes were made to the normative section, such as the addition of the requirement to plan for post-production monitoring and the removal of the requirement for traceability from the risk management report. New guidance on the relationship between hazards and hazardous situations was developed and placed in Annex E (formerly Annex D). Each use of these terms in this International Standard was reviewed to ensure consistency with this guidance.

The following text gives further information on the clauses and subclauses in **ISO 14971**.

A.2 Rationale for requirements in particular clauses and subclauses

A.2.1 Scope

As explained in the introduction to **ISO 14971** which is the base of this Standard, a risk management standard applying to the design and manufacturing of all medical devices is required. IVD medical devices are specifically mentioned in the scope to avoid any misunderstanding that, due to different regulations, might be excluded from this Standard.

Risks can be introduced throughout the product life-cycle, and risks that become apparent at one point in the life-cycle can be managed by action taken at a completely different point in the life-cycle. For this reason, the standard needs to be a complete life-cycle standard. This means that the standard instructs manufacturers to apply risk management principles to a medical device from its initial conception until its ultimate decommissioning and disposal.

The scope of this Standard does not include decisions on the use of a medical device. 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 or the risks and anticipated benefits of alternative procedures. Such judgements 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 judgements can be made only by a qualified health care professional with knowledge of the state of health of an individual patient and the patient's own opinion.

Although there has been significant debate over what constitutes an acceptable level of risk, this Standard does not specify acceptability levels. Specifying a universal level for acceptable risk could be inappropriate. This decision is based upon the belief that:

- the wide variety of medical devices and situations covered by this Standard would make a universal level meaningless;
- local laws, customs, values and perception of risk are more appropriate for defining risk acceptability for a particular culture or region of the world.

Because not all countries require a quality management system for medical device manufacturers, a quality management system is not a requirement of this Standard. However, a quality management system is extremely helpful in managing risks properly. Because of this and because most medical device manufacturers do employ a quality management system, this Standard is constructed so that it can easily be incorporated into the quality management system that they use.

A.2.2 Terms and definitions

To avoid inventing a host of new and possibly unfamiliar terms, this Standard is intentionally built upon the wealth of risk management information both in standards and in the literature. Existing definitions have been used wherever possible. The primary sources for the definitions are:

- ISO/IEC Guide 51:1999 *Safety aspects—Guidelines for the inclusion in standards*
- JIS Q 9000:2006 *Quality management systems—Fundamentals and vocabulary*
- JIS Q 13485:2005 *Medical devices—Quality management systems—Requirements for regulatory purposes*

Some of these definitions have a slightly different meaning in this Standard. For example, JWG 1 intended the definition of “harm” (2.2) to include unreasonable psychological stress or unwanted pregnancy as part of “damage to the health of people.” It was known that risk management would be made mandatory, either explicitly or implicitly, in many countries and regions of the world. An attempt was therefore made to use definitions that would be widely acceptable in a regulatory sense. For example, the term, “manufacturer” (2.8), while based on the medical device directive in the EU, is consistent with the definition used in the United States. The term, “medical device” (2.9), was taken from the definition developed by the Global Harmonization Task Force (GHTF). See bibliographic reference [38].

The definition of the term, “intended use” (2.5) combines the definition of “intended use” as used in the United States and “intended purpose,” which is the term in the European Union. These terms have essentially the same definition. It was intended that, when considering the intended use of a medical device, the manufacturer take account of the intended users of the product.

Seven other terms are not based on definitions in other standards. These are “life-cycle” (2.7), “post-production” (2.11), “risk control” (2.19), “risk evaluation” (2.21), “risk estimation” (2.20), “risk management” (2.22), and “risk management file” (2.23). The definition of “life-cycle” was necessary to make it clear that the term as used in this Standard covers all aspects of the existence of a medical device. A definition of “post-production” was added to emphasise that the entire life-cycle of the medical device is important for risk management. The definition for “risk control” was provided to be consistent with the definitions of “risk analysis” given by **ISO/IEC Guide 51** [2]. In the first edition, the definition of risk evaluation used the term “current values of society”. In this edition, this reference has been removed for two reasons: one is that the definition of the term should not contain a requirement, and the other is that “current values of society” is an imprecise term. The removal of the term from the definition is compensated for by the fact that the concept is already in the introduction and by providing additional normative requirements for the risk management policy and by guidance on risk acceptability. The definition for “risk management” emphasises the use of a systematic approach and the need for management oversight. The concept of a “risk management file” was originally expressed in **IEC 60601-1-4** [24], but the definition was changed because the definition refers to quality records, which need not exist for compliance with **ISO 14971**.

The definition of “top management” (2.26) uses the definition from **JIS Q 9000: 2006** [4]. It applies to the person or group at the highest level in an organization.

A.2.3 General requirements for risk management

A.2.3.1 Risk management process

Subclause **3.1** requires the manufacturer to establish a risk management process as part of the design of a medical device. This is required so that the manufacturer can systematically ensure that the required elements are in the process. Risk analysis, risk evaluation and risk control are commonly recognised as essential parts of risk management. In addition to these elements, this Standard emphasises that the risk management process does not end with the design and production (including, as relevant, sterilization, packaging, and labelling) of a medical device, but continues on into the post-production phase. Therefore, the gathering of post-production information was identified as a required part of the risk management process. Furthermore, it was felt that when a manufacturer employs a quality management system, the risk management process should be fully integrated into that quality management system.

Although risk management activities are highly individual to the medical device being evaluated, there are basic elements that need to be included in the risk management process. This clause addresses that need. This clause also recognises that there can be some differences in regulatory approach to applying risk management to medical devices.

Subclauses **3.2** and **3.3** closely follow some requirements of quality management system standards. In some countries a quality management system is always required to market a device (unless the device is specifically exempted). In other countries manufacturers can choose whether to apply a quality management system. However, the requirements of subclauses **3.2** and **3.3** are always needed for an effective risk management process, whether or not the manufacturer operates all the other elements of a quality management system.

A.2.3.2 Management responsibilities

The commitment of top management is critical for an effective risk management process. These individuals should take responsibility for overall guidance of the risk management process and this subclause is intended to emphasise their role. In particular:

- a) in the absence of adequate resources, risk management activities would be less effective, even if complying, to the letter, with the other requirements of this Standard;
- b) risk management is a specialized discipline and requires the involvement of individuals trained in risk management techniques (see **A.2.3.3**);
- c) because this Standard does not define acceptable risk levels, top management is required to establish a policy on how acceptable risks will be determined;
- d) risk management is an evolving process and periodic review of the risk management activities is needed to ascertain whether they are being carried out correctly, to rectify any weaknesses, to implement improvements, and to adapt to changes.

A.2.3.3 Qualification of personnel

It is most important to get people with the expertise necessary to perform risk management tasks. The risk management process requires people with expertise in areas such as:

- how the medical device is constructed;
- how the medical device works;
- how the medical device is produced;
- how the medical device is actually used;
- how to apply the risk management process.

In general, this will require several representatives from various functions or disciplines, each contributing their specialist knowledge. The balance and relation between individuals performing risk management tasks should be considered.

Records of the appropriate qualifications are required to provide objective evidence. In order to avoid duplication and because of confidentiality and data protection considerations, this Standard does not require these records to be kept in the risk management file.

A.2.3.4 Risk management plan

A risk management plan is required because:

- a) an organized approach is essential for good risk management;
- b) the plan provides the roadmap for risk management;
- c) the plan encourages objectivity and helps prevent essential elements being forgotten.

The elements **a)** to **f)** (subclause **3.4**) are required for the following reasons.

- There are two distinct elements in the scope of the plan. The first identifies the intended medical device, the other identifies the phase of the life-cycle covered by each element in the plan. By defining the scope, the manufacturer establishes the baseline on which all the risk management activities are built.
- Allocation of responsibilities and authorities are needed to ensure that no responsibility is omitted.
- Review of activities such as risk management is included as a generally recognised responsibility of management.
- The criteria for risk acceptability are fundamental to risk management and should be decided upon before risk analysis begins. This helps make the process in clause **5** to be objective.
- Verification is an essential activity and is required by **6.3**. Planning this activity helps ensure that essential resources are available when required. If verification is not planned, important parts of the verification could be neglected.
- Device specific methods for obtaining production and post-production information need to be established so that there is a formal and appropriate way to feed back production and post-production information into the risk management process.

The requirement to keep a record of changes is to facilitate audit and review of the risk management process for a particular medical device.

A.2.3.5 Risk management file

This Standard uses this term to signify where the manufacturer can locate or find the locations of all the records and other documents applicable to risk management. This facilitates the risk management process and enables more efficient auditing to this Standard. Traceability is necessary to demonstrate that the risk management process has been applied to each identified hazard.

Completeness is very important in risk management. An incomplete task can mean that an identified hazard is not controlled and harm to someone can be the consequence. The problem can result from incompleteness at any stage of risk management, e.g. unidentified hazards, risks not assessed, unspecified risk control measures, risk control measures not implemented or risk control measures that prove ineffective. Traceability is needed to establish completeness of the risk management process.

A.2.4 Risk analysis

A.2.4.1 Risk analysis process

The second paragraph describes how to deal with the availability of a risk analysis for a similar medical device. The note informs users of this Standard that when adequate information already exists it can and should be applied to save time, effort and other resources. Users of this Standard need to be careful, however, to assess systematically the previous work for applicability to the current risk analysis.

Note that details required by **a)**, **b)**, and **c)** of **4.1** form the basic minimum data set for ensuring traceability and are important for management reviews and for subsequent audits. The requirement in **c)** also helps clarify what is in the scope of the analysis and verifies completeness.

A.2.4.2 Intended use and identification of characteristics related to the safety of the medical device

This step forces the manufacturer to think about all the characteristics that could affect safety of the medical device. The manufacturer should also consider the intended user(s) of the medical device, e.g., whether a lay user or a trained medical professional will use the medical device. This analysis should consider that medical devices can also be used in situations other than those intended by the manufacturer and in situations other than those foreseen when a medical device is first conceived. Medical devices are frequently used in situations other than those intended by the manufacturer and in situations other than those foreseen when a medical device is first conceived. It is important that the manufacturer tries to look into the future to see the hazards due to potential uses of their medical device.

Annex C is intended to be helpful in describing the characteristics of the medical device and the environments in which it is used. It cannot be emphasised too strongly that this list is not exhaustive. Every manufacturer should be creative in determining the relevant safety characteristics for the medical device under investigation. The list in Annex C was originally taken from **ISO 14971-1** with some additions made as a result of comments on drafts of that standard. The list ought to stimulate thinking

of “where can things go wrong.” Annex H on *in vitro* diagnostic medical devices has been developed by **ISO/TC 212**, *Clinical laboratory testing and in vitro diagnostic test systems*, for use in this Standard. Annex I on toxicological hazards has been taken from Annex B of **ISO 14971-1** with only minor changes.

A.2.4.3 Identification of hazards

This step requires that the manufacturer be systematic in the identification of anticipated hazards in both normal and fault conditions. The identification should be based upon the safety characteristics identified in **4.2**.

A.2.4.4 Estimation of the risk(s) for each hazardous situation

A risk can only be assessed and managed once a hazardous situation has been identified. Documenting the reasonably foreseeable sequences of events that can transform a hazard into a hazardous situation allows this to be done systematically.

Annex E is provided to help manufacturers identify hazards and hazardous situations by listing typical hazards and giving examples to demonstrate the relationships between hazards, foreseeable sequences of events, hazardous situations and associated possible harm. This is especially important when there is a sequence of events that can lead to a hazardous situation and maybe in the end to harm. The manufacturer should recognise and identify these sequences of events in order to address risk properly (see figure E.1).

The list as given in Annex E is non-exhaustive and is not intended as a checklist, but rather to stimulate creative thinking.

This is the final step of risk analysis. The difficulty of this step is that estimation of risk is different for every hazardous situation that is under investigation as well as for every medical device. Therefore, this subclause was written generically. Because hazards can occur both when the medical device functions normally and when it malfunctions, one should look closely at both situations. In practice, both components of risk, probability and consequence, should be analysed separately. When a manufacturer uses a systematic way of categorizing the severity levels or probability of occurrence of harm, the categorization scheme should be defined and recorded in the risk management file. This enables the manufacturer to treat equivalent risks consistently and serves as evidence that the manufacturer has done so.

Some hazardous situations occur because of systematic faults or sequences of events. There is no consensus on how to calculate the probability of a systematic fault. Where the probability of occurrence of harm cannot be calculated, hazards still have to be addressed and listing resulting hazardous situations separately allows the manufacturer to focus on reducing the risks due to these hazardous situations.

Frequently, good quantitative data are not readily available. The suggestion that estimation of risk should be done only in a quantitative way has therefore been avoided.

Annex D has been provided as helpful guidance on risk analysis. The information originates from several sources, including **IEC 60300-3-9** [21]. This Standard recognised the usefulness of **IEC 60300-3-9** [21] and extended it to apply to all medical devices and all phases of the risk management process. Although risk charts and risk matrices are used extensively in Annex D as examples, this Standard does not require their use.

A.2.5 Risk evaluation

Decisions have to be made about the acceptability of risk. Manufacturers can use the recently estimated risks and evaluate them using the criteria for risk acceptability defined in the risk management plan. They can screen the risks to determine which ones need to be reduced. Clause 5 was carefully worded to allow the user of this Standard to avoid unnecessary work.

A.2.6 Risk control

A.2.6.1 Risk reduction

It is intended that steps 6.2 to 6.7 make up a logical sequence of stages. This systematic approach is important since it ensures that relevant information is available when required.

A.2.6.2 Risk control option analysis

Often there will be more than one way to reduce a risk. There are three mechanisms listed:

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

These are all standard risk reduction measures and are derived from **ISO/IEC Guide 51** [2]. The priority order listed is important. This principle is found in several places, including **IEC/TR 60513** [22] and local or regional regulations (e.g. the European Medical Device Directive [34]). If practicable, the medical device should be designed to be inherently safe. If this is not practicable, then protective measures such as barriers or alarms are appropriate. The least preferred protective measure is a written warning or contra-indication.

It is recognised that one possible result of the risk control option analysis could be that there is no practicable way of reducing the risk to acceptable levels according to the pre-established criteria for risk acceptability. For example, it could be impractical to design a life-supporting medical device with such an acceptable residual risk. In this case, a risk/benefit analysis can be carried out as described in 6.5 to determine whether the benefit of the medical device, to the patient, outweighs the residual risk. This option is included at this point in the standard to make sure that every effort was first made to reduce risks to the pre-established acceptable levels.

A.2.6.3 Implementation of risk control measures

Two distinct verifications are included. The first verification is required to make sure that the risk control measure has been implemented in the final design. The second verification is required to ensure that the measure as implemented actually reduces the risk. In some instances, a validation study can be used for verifying the effectiveness of the risk control measure.

A.2.6.4 Residual risk evaluation

A check was introduced here to determine whether the implemented measures have made the risk acceptable. If the risk is not less than the criteria established in the

risk management plan, manufacturers are instructed to assess additional risk control measures. This iterative procedure should be continued until the risk is reduced to within the acceptable levels established in the risk management plan.

The user should be provided with relevant information on residual risks so that the user can make informed decisions. However, it is the manufacturer's decision as to what and how much information on residual risk should be provided. This requirement is consistent with the approach taken in many countries and regions.

A.2.6.5 Risk/benefit analysis

There will be some occasions where the risk of a medical device is greater than the manufacturer's criteria for acceptable risk. This subclause enables the manufacturer to provide a high-risk medical device for which they have done a careful evaluation and can show that the benefit of the medical device outweighs the risk. It is important for users to be informed of significant residual risks and resulting benefits so that informed decisions can be made. See Annex J.

A.2.6.6 Risks arising from risk control measures

This subclause recognises that risk control measures alone or in combination might introduce a new and sometimes quite different hazard and that measures introduced to reduce one risk might increase another risk.

A.2.6.7 Completeness of risk control

At this stage, the risk of all the hazards should have been evaluated. This check was introduced to ensure that no hazards were left out in the intricacies of a complex risk analysis.

A.2.7 Evaluation of overall residual risk acceptability

During the process defined by clauses 4 to 6, manufacturers identify hazards, evaluate the risks, and implement risk control measures in their design one at a time. This is the point where the manufacturer has to step back, consider the combined impact of the individual residual risks, and make a decision as to whether to proceed with the medical device. It is possible that the overall residual risk can exceed the manufacturer's criteria for acceptable risk, even though individual residual risks do not. This is particularly true for complex systems and medical devices with a large number of risks. Even if the overall residual risk exceeds the criteria in the risk management plan, the manufacturer has an opportunity to do an overall risk/benefit evaluation to determine whether a high-risk, but highly beneficial, medical device should be marketed. It is important for users to be informed of significant overall residual risks. Thus, manufacturers are instructed to include pertinent information in the accompanying documents.

A.2.8 Risk management report

The risk management report is a crucial part of the risk management file. It is intended to be a summary of the review of the final results of the risk management process. The report serves as the high level document that provides evidence that the manufacturer has ensured that the risk management plan has been satisfactorily fulfilled and results confirm that the required objective has been achieved. The first edition