



ISO 14971:2019

ISO/TR 24971:20XX

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ISO 14971:2019 Risk Management for Medical Devices

- Introduction
- Terms & Definitions
- ISO 14971:2019 Overview of structure and contents
- Current status



Introduction

As a general concept, an activity 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 as stakeholders place different values on the probability and severity of harm.

**medical
practitioners**



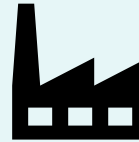
**health care
organisations**



government



industry



patients



public

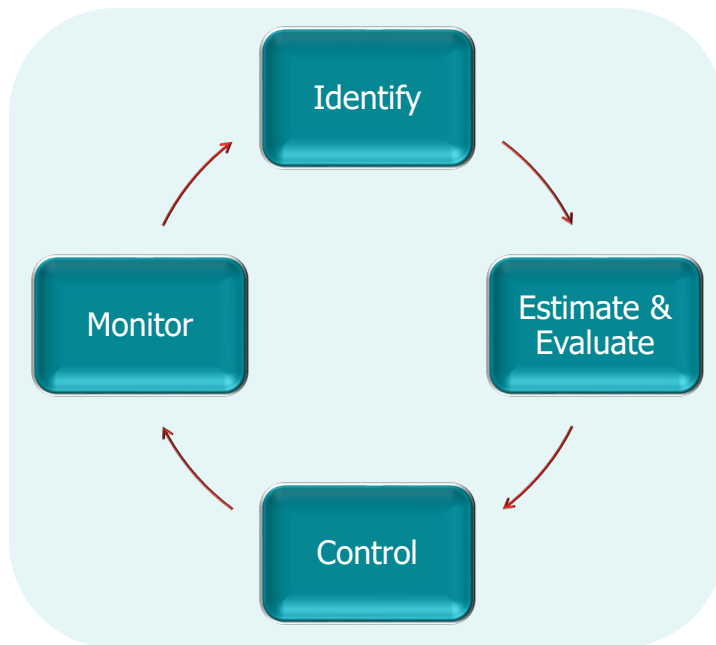


Introduction

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 acknowledged state of the art, in order to determine the suitability of a medical device to be placed on the market for its intended use.

ISO 14971 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.



Introduction

ISO IEC Directives, HLS (Annex L)
ISO31000:2018 & ISO 9000:2015

Effect of uncertainty on objectives. Note 1 to entry: An effect is a deviation from the expected. It can be positive, negative or both, and can address, create or result in opportunities and threats

Not intended for managing product related risk

Focus on *organizational risk*

ISO 14971:2019
ISO 13485:2016

Combination of the probability of occurrence of harm and the severity of that harm

Organizational risk/business risk is out of the scope of ISO 14971

Focus on *product safety risk*

Introduction

Risk management as per **ISO 14971** is:

a systematic approach to identify, assess, control and monitor all risks associated with the medical device throughout its life cycle

Initial conception, design, development

Production, distribution, installation, use, service, maintenance

Post-production (after market introduction), decommissioning, disposal

Introduction

- Fundamental understanding and process for risk management has not changed
- Multiple stakeholder perspectives exist and need to be considered
- ISO 14971 is focussed on product safety risks and not organisational or business risks



Terms & Definitions New in 2019

Risk Management: Terms & Definitions

New Definition

benefit

positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health

reasonably foreseeable misuse

use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behaviour

state of the art

developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the “generally acknowledged state of the art”.

Risk Management: Terms & Definitions

Updated Definition

accompanying documentation

materials document accompanying a medical device and containing information for the operator, the user *or those accountable* for the installation, use, maintenance, *decommissioning and disposal* of the medical device, particularly regarding *safe use*

Note 1 to entry: The accompanying documentation can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: Accompanying documentation is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

harm

physical injury or damage to the health of people, or damage to property or the environment

Risk Management: Terms & Definitions

Updated Definition

in vitro diagnostic medical device

IVD medical device

~~medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including~~ **EXAMPLE** reagents, calibrators, control materials, specimen storage and collection receptacles, software, and related instruments or apparatus or *other* articles

manufacturer

~~natural or legal person with responsibility for the design and/or 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 with the intention of making the medical device available for use, under his name, whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)~~

See also *Notes 1-7*

use error

~~act or omission~~ *user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user*

See also *Notes 1-5*



ISO 14971:2019 Overview of structure and contents

ISO 14971:2019 Overview of structure and contents

EN ISO 14971:2012

- Z Annexes (informative): 13 pages
- Main body of standard: 9 clauses, 14 pages
- 10 Annexes (informative): 68 pages

ISO 14971:2019

- Main body of standard: 10 clauses, 19 pages
- 3 Annexes (informative): 30 pages

Introduction

1. Scope
2. Normative References
3. Terms and definitions
4. General requirements for risk management
 1. Risk management process
 2. Management responsibilities
 3. Qualification of personnel
 4. Risk management plan
 5. Risk management file
5. Risk analysis
 1. Risk analysis process
 2. Intended use and reasonably foreseeable misuse
 3. Identification of characteristics related to safety
 4. Identification of hazards and hazardous situations
 5. Risk estimation
6. Risk evaluation
7. Risk control
 1. Risk control option analysis
 2. Implementation of risk control measures
 3. Residual risk evaluation
 4. Benefit-risk analysis
 5. Risks arising from risk control measures
 6. Completeness of risk control
8. Evaluation of overall residual risk
9. Risk management review
10. Production and post-production activities
 1. Information collection
 2. Information review
 3. Actions

Introduction

1. Scope
2. Terms and definitions
3. General requirements for risk management
 1. Risk management process
 2. Management responsibilities
 3. Qualification of personnel
 4. Risk management plan
 5. Risk management file
4. Risk analysis
 1. Risk analysis process
 2. Intended use and identification of characteristics related to the safety of the medical device
 3. Identification of hazards
 4. Estimation of the risk(s) for each hazardous situations
5. Risk evaluation
6. Risk control
 1. Risk reduction
 2. Risk control option analysis
 3. Implementation of risk control measure(s)
 4. Residual risk evaluation
 5. Risk/benefit analysis
 6. Risks arising from risk control measures
 7. Completeness of risk control
7. Evaluation of overall residual risk **acceptability**
8. Risk management report
9. Production and post-production activities

ISO 14971:2019

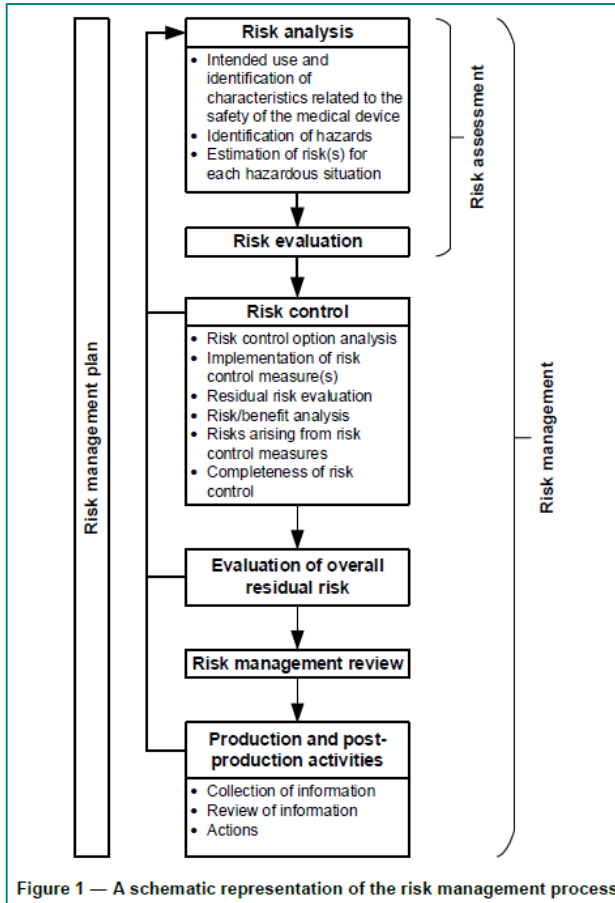


Figure 1 — A schematic representation of the risk management process

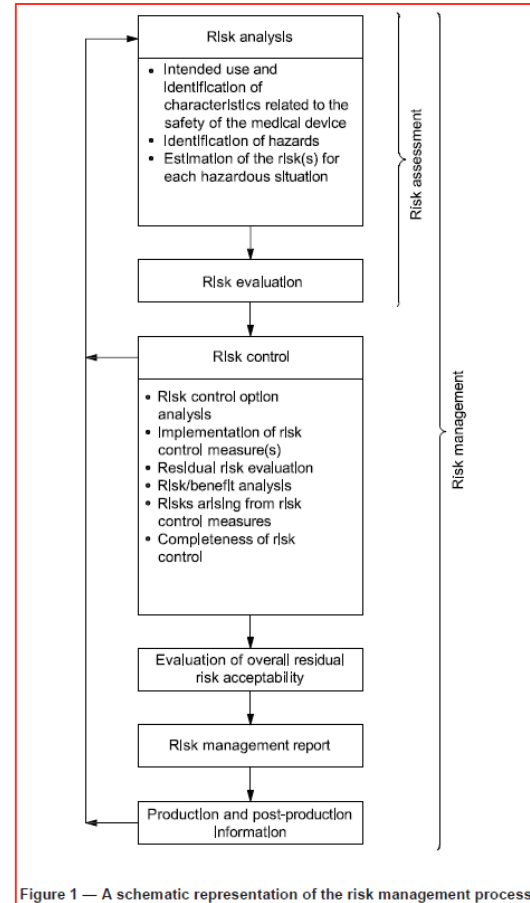


Figure 1 — A schematic representation of the risk management process

ISO 14971:2007 / EN ISO 14971:2012

ISO 14971:2019 Overview of structure and contents

ISO 14971:2019

- A. Rationale for requirements
- B. Risk management process for medical devices
- C. Fundamental risk concepts

See
ISO/TR 24971

ISO 14971:2007 / EN ISO 14971:2012

- A. Rationale for requirements
- B. Overview of the risk management process for medical devices
- C. Questions that can be used to identify medical device characteristics that could impact on safety
- D. Risk concepts applied to medical devices
- E. Examples of hazards, foreseeable sequences of events and hazardous situations
- F. Risk management plan
- G. Information on risk management techniques
- H. Guidance on risk management for in vitro diagnostic medical devices
- I. Guidance on risk analysis process for biological hazards
- J. Information for safety and information about residual risk

ISO 14971:2019 Overview of structure and contents

4.4 Risk management plan (3.4)

- 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) a method to evaluate the overall residual risk and the criteria for acceptability of the overall residual risk;
- f) verification activities; and
- g) activities related to collection and review of relevant production and post-production information.

Update to the content of Notes

ISO 14971:2019 Overview of structure and contents

4.5 Risk management file (3.5)

Update to Notes only

5.1 Risk analysis process (4.1)

Update to Notes only

5.2 Intended use and reasonably foreseeable misuse & 5.3 Identification of characteristics related to safety (4.2)

Separates the requirements into two clauses

Clause 5.2 clarifies the requirement to document reasonably foreseeable misuse (see new definition also)

Requirement generally unchanged

5.4 Identification of hazards and hazardous situations (4.3)

Adds requirement for hazardous situations to be considered and documented

Refers to Annex C

This is a clarification in the standard

ISO 14971:2019 Overview of structure and contents

5.5 Risk estimation (4.4)

Clarification of the text

Update to Notes

Requirement generally unchanged

6 Risk evaluation (5)

Clarification of the text

Update to Notes

Requirement generally unchanged

7.1 Risk control option analysis (6.2)

Clause 6.1 has been deleted

Clarification of the text

Update to Notes

Requirement generally unchanged

ISO 14971:2019 Overview of structure and contents

7.2 Implementation of risk control measures (6.3)

Update to Notes

Requirement unchanged

7.3 Residual risk evaluation (6.4)

Deletion of disclosure of residual risk statement and Note

Requirement generally unchanged

7.4 Benefit-risk analysis (6.5)

Update to Notes

Requirement unchanged

7.5 Risks arising from risk control measures (6.6)

Requirement unchanged

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7.6 Completeness of risk control (6.7)

Requirement unchanged

8 Evaluation of overall residual risk (7)

Addition of disclosure of residual risk statement

Clarification of the text

Update to Notes

Requirement generally unchanged

9 Risk management review (8)

Addition of requirement: The manufacturer shall determine when subsequent reviews of the execution of the risk management plan need to be performed and when the risk management report needs to be updated

Requirement generally unchanged

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10 Production and post-production activities (9)

Separated into three sub-clauses

10.1 Information collection

Clarifies the requirement and sources of information
Note on state of the art

10.2 Information review

Clarifies the requirement to review for possible relevance to safety and adds third bullet point for changes in general state of the art

10.3 Actions

Separates the actions into *particular medical device* and *risk process*
Adds consideration of devices on the market
Clarifies the requirement

ISO 14971:2019 Overview of structure and contents

Annex A

Generally updated but remains similar in intent and content, specific to 2019 version

Annex B

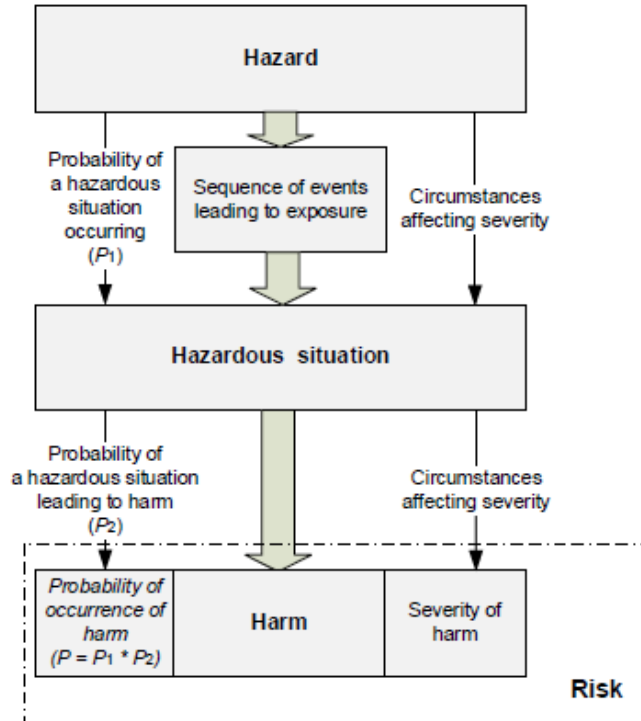
Provides a detailed correspondence between ISO 14971:2007 and ISO 14971:2019
Updated graphic reflecting the amendments to 2019

Annex C

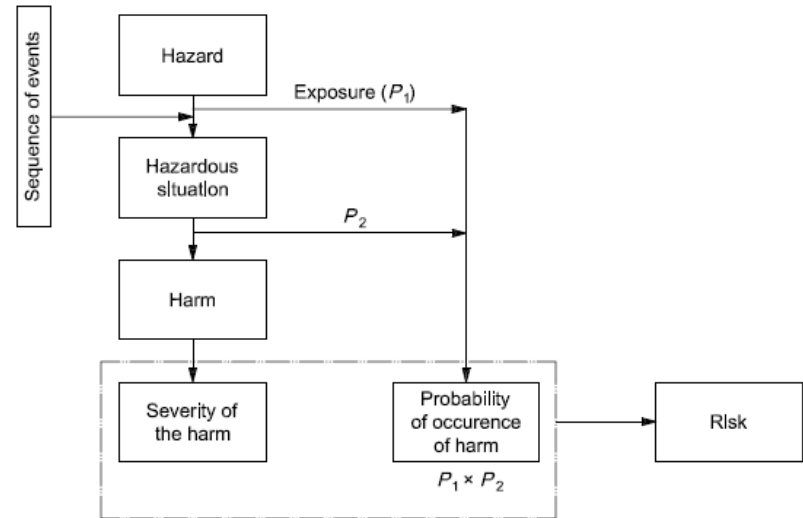
Describes some fundamental risk concepts on hazards, hazardous situations (similar to Annex E)
Updated graphic describing the relationship of hazard, sequence of events, hazardous situation and harm (previously in Annex E.1). The concept itself is not changed
Examples of hazards in Table C.1 updated compared to Table E.1
Examples of events and circumstances in Table C.2 updated compared to Table E.2
Examples of Relationship between hazards, foreseeable sequences of events, hazardous situations and the harm that can occur in Table C.3 updated compared to Table E.3

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ISO 14971:2019



ISO 14971:2007 / EN ISO 14971:2012



NOTE P_1 is the probability of a hazardous situation occurring.
 P_2 is the probability of a hazardous situation leading to harm.

ISO 24971:20XX

Many of the concepts from ISO14971:2019 are explained in further detail in ISO/TR 24971:20XX

Annexes from ISO 14971:2007 are incorporated into ISO/TR 24971:20XX

| ISO 14971:2007 / 2012 | ISO/TR 24971:20XX |
|-----------------------|-------------------|
| Annex A | ISO 14971:2019 |
| Annex B | ISO 14971:2019 |
| Annex C | Annex A |
| Annex D | Clause 5, 6, 7 |
| Annex F | Clause 4 |
| Annex G | Annex B |
| Annex H | Annex H |
| Annex I | - |
| Annex J | Annex D |
| - | Annex C |
| - | Annex E |
| - | Annex F |
| - | Annex G |

ISO 14971:2019 Overview of structure and contents

- New: Clause 2 on normative references (per ISO/IEC Directives) (there are no references)
- New: Definition for benefit, reasonably foreseeable misuse, state of the art
- Change: Alignment of terms with GHTF (IMDRF), ISO 13485:2016, ISO/IEC Guide 63:2019
- Change: Emphasis on benefits and benefit-risk balance
- Change: Corrections of editorial errors and inaccuracies in all clauses
- Change: Clarification of requirements for evaluation of overall residual risk
- Change: Clarification of requirements for production and post-production activities
- Change: Additional guidance in ISO/TR 24971:2019, incorporates informative annexes of ISO 14971:2007

The overall process remains unchanged
The 2019 revision clarifies, explains and elaborates

Current Status – ISO 14971:2019



Target
Publication
in Q4 2019

- ISO 14971:2019 was reviewed by the EU HAS consultant for harmonisation
- A negative assessment was returned
- ISO 14971:2019 decoupled from Vienna Agreement and will be published without Annex Zs
- Gap analysis between EN ISO 14971:2012, ISO 14971:2019 and the MDD/MDR to ensure compliance with the state of the art
- For MDR, no harmonised version, therefore ISO 14971:2019 represents the state of the art
- There is no plan to harmonise 2007 version to MDR
- A formal standards harmonisation request has not yet been issued by the EUC
- The draft standards harmonisation request prioritises ISO 14971

The **Vienna Agreement** signed between CEN and ISO in 1991 recognizes the primacy of international **standards** and aims at **standards** to be recognized simultaneously at international and **European** level by means of improved exchange of information and mutual representation at meetings.

Current Status – ISO/TR 24971:20XX

- Committee has completed commenting period
- Pending publication of Final Draft
- Public consultation to proceed
- Estimated publication date is not yet available



Summary

- ISO 14971:2019 expected in Q4 2019
- Overall process remains unchanged
- The revision clarifies, explains and elaborates
- ISO/TR 24971 in process
- Provides guidance on concepts in ISO 14971:2019
- Incorporates Annexes from ISO 14971:2007

