

ISO/TR 24971:2020 (E)

Medical devices — Guidance on the application of ISO 14971

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General requirements for risk management system
4.1	Risk management process
4.2	Management responsibilities
4.2.1	Top management commitment
4.2.2	Policy for establishing criteria for risk acceptability
4.2.3	Suitability of the risk management process
4.3	Competence of personnel
4.4	Risk management plan
4.4.1	General
4.4.2	Scope of the risk management plan
4.4.3	Assignment of responsibilities and authorities
4.4.4	Requirements for review of risk management activities
4.4.5	Criteria for risk acceptability
4.4.6	Method to evaluate overall residual risk and criteria for acceptability
4.4.7	Verification activities
4.4.8	Activities related to collection and review of production and post-production information
4.5	Risk management file
5	Risk analysis
5.1	Risk analysis process
5.2	Intended use and reasonably foreseeable misuse
5.3	Identification of characteristics related to safety
5.4	Identification of hazards and hazardous situations
5.4.1	Hazards
5.4.2	Hazardous situations in general
5.4.3	Hazardous situations resulting from faults
5.4.4	Hazardous situations resulting from random faults
5.4.5	Hazardous situations resulting from systematic faults
5.4.6	Hazardous situations arising from security vulnerabilities
5.4.7	Sequences or combinations of events
5.5	Risk estimation
5.5.1	General
5.5.2	Probability
5.5.3	Risks for which probability cannot be estimated
5.5.4	Severity
5.5.5	Examples
6	Risk evaluation
7	Risk control
7.1	Risk control option analysis
7.1.1	Risk control for medical device design
7.1.2	Risk control for manufacturing processes

- 7.1.3 Standards and risk control
- 7.2 Implementation of risk control measures
- 7.3 Residual risk evaluation
- 7.4 Benefit-risk analysis
 - 7.4.1 General
 - 7.4.2 Benefit estimation
 - 7.4.3 Criteria for benefit-risk analysis
 - 7.4.4 Benefit-risk comparison
 - 7.4.5 Examples of benefit-risk analyses
- 7.5 Risks arising from risk control measures
- 7.6 Completeness of risk control
- 8 Evaluation of overall residual risk
 - 8.1 General considerations
 - 8.2 Inputs and other considerations
 - 8.3 Possible approaches
- 9 Risk management review
- 10 Production and post-production activities
 - 10.1 General
 - 10.2 Information collection
 - 10.3 Information review
 - 10.4 Actions

Annex A (informative) Identification of hazards and characteristics related to safety

- A.1 General
- A.2 Questions
 - A.2.1 What is the intended use and how is the medical device to be used?
 - A.2.2 Is the medical device intended to be implanted?
 - A.2.3 Is the medical device intended to be in contact with the patient or other persons?
 - A.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?
 - A.2.5 Is energy delivered to or extracted from the patient?
 - A.2.6 Are substances delivered to or extracted from the patient?
 - A.2.7 Are biological materials processed by the medical device for subsequent reuse, transfusion or transplantation?
 - A.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?
 - A.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user?
 - A.2.10 Does the medical device modify the patient environment?
 - A.2.11 Are measurements taken?
 - A.2.12 Is the medical device interpretative?
 - A.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?
 - A.2.14 Are there unwanted outputs of energy or substances?
 - A.2.15 Is the medical device susceptible to environmental influences?
 - A.2.16 Does the medical device influence the environment?
 - A.2.17 Does the medical device require consumables or accessories?
 - A.2.18 Is maintenance or calibration necessary?
 - A.2.19 Does the medical device contain software?
 - A.2.20 Does the medical device allow access to information?
 - A.2.21 Does the medical device store data critical to patient care?
 - A.2.22 Does the medical device have a restricted shelf life?
 - A.2.23 Are there any delayed or long-term use effects?
 - A.2.24 To what mechanical forces will the medical device be subjected?
 - A.2.25 What determines the lifetime of the medical device?
 - A.2.26 Is the medical device intended for single use?
 - A.2.27 Is safe decommissioning or disposal of the medical device necessary?
 - A.2.28 Does installation or use of the medical device require special training or special skills?
 - A.2.29 How will information for safety be provided?
 - A.2.30 Are new manufacturing processes established or introduced?
 - A.2.31 Is successful application of the medical device dependent on the usability of the user interface?

- A.2.31.1 Can the user interface design features contribute to use error?
- A.2.31.2 Is the medical device used in an environment where distractions can cause use error?
- A.2.31.3 Does the medical device have connecting parts or accessories?
- A.2.31.4 Does the medical device have a control interface?
- A.2.31.5 Does the medical device display information?
- A.2.31.6 Is the medical device controlled by a menu?
- A.2.31.7 Is the successful use of the medical device dependent on a user's knowledge, skills and abilities?
- A.2.31.8 Will the medical device be used by persons with specific needs?
- A.2.31.9 Can the user interface be used to initiate unauthorised actions?
- A.2.32 Does the medical device include an alarm system?
- A.2.33 In what ways might the medical device be misused (deliberately or not)?
- A.2.34 Is the medical device intended to be mobile or portable?
- A.2.35 Does the use of the medical device depend on essential performance?
- A.2.36 Does the medical device have a degree of autonomy?
- A.2.37 Does the medical device produce an output that is used as an input in determining clinical action?

Annex B (informative) Techniques that support risk analysis

- B.1 General
- B.2 Preliminary Hazard Analysis (PHA)
- B.3 Fault Tree Analysis (FTA)
- B.4 Event Tree Analysis (ETA)
- B.5 Failure Mode and Effects Analysis (FMEA)
- B.6 Hazard and Operability Study (HAZOP)
- B.7 Hazard Analysis and Critical Control Point (HACCP)

Annex C (informative) Relation between the policy, criteria for risk acceptability, risk control and risk evaluation

- C.1 General
- C.2 Policy for establishing criteria for risk acceptability
- C.3 Criteria for risk acceptability
- C.4 Risk control
- C.5 Risk evaluation
- C.6 Examples

Annex D (informative) Information for safety and information on residual risk

- D.1 General
- D.2 Information for safety
- D.3 Disclosure of residual risk

Annex E (informative) Role of international standards in risk management

- E.1 General
- E.2 Use of international product safety standards in risk management
- E.3 International process standards and ISO 14971

Annex F (informative) Guidance on risks related to security

- F.1 General
- F.2 Terminology used in security risk management
- F.3 Relation between ISO 14971 and security
- F.4 Characteristics of security risk management
- F.5 Prioritizing confidentiality, integrity, and availability

Annex G (informative) Components and devices designed without using ISO 14971

- G.1 General
- G.2 Risk management plan
- G.3 Risk management file

Annex H (informative) Guidance for in vitro diagnostic medical devices

- H.1 General
- H.1.1 Risk management for IVD medical devices
- H.1.2 Context for IVD risk management
- H.2 Risk analysis
- H.2.1 Intended use and reasonably foreseeable misuse

H.2.1.1	Analytical and clinical use
H.2.1.2	Device description
H.2.1.3	Analytical use
H.2.1.4	Clinical use
H.2.2	Characteristics related to patient safety
H.2.2.1	General considerations
H.2.2.2	Performance characteristics related to patient safety
H.2.2.3	Reliability characteristics related to patient safety
H.2.2.4	Digital information technology characteristics related to patient safety
H.2.3	Known and foreseeable hazards to patients
H.2.3.1	Identification of hazards
H.2.3.2	Identification of hazards from fault conditions
H.2.3.3	Identification of hazards from normal use
H.2.3.4	Identification of hazards from use errors
H.2.3.5	Identification of hazards from reasonably foreseeable misuse
H.2.4	Identification of potential harms
H.2.5	Identification of hazardous situations
H.2.6	Identification of foreseeable sequences of events
H.2.6.1	General considerations
H.2.6.2	Description of the sequence of events
H.2.7	Estimation of the probability of occurrence of harm
H.2.7.1	General considerations
H.2.7.2	Particular guidance for using the “P1 x P2” approach
H.2.7.3	Guidance for estimating the probability of occurrence of harm
H.3	Risk control
H.3.1	General
H.3.2	Inherently safe design and manufacture
H.3.3	Protective measures in the IVD medical device or manufacturing process
H.3.4	Information for safety
H.3.5	Role of standards and analytical performance criteria
H.3.6	User education and training
H.4	Benefit-risk analysis
H.5	Disclosure of the residual risks
H.5.1	General considerations
H.5.2	Performance specifications
H.5.3	Limitations of the IVD medical device
H.5.4	Generally recognized limitations of use
H.6	Production and post-production activities
H.6.1	General considerations
H.6.2	Monitoring analytical performance
H.6.3	Monitoring clinical performance
H.7	Examples of risk scenarios for IVD medical devices
H.7.1	General
H.7.2	Automated medical laboratory analyser: incorrect examination result
H.7.3	Personal (self-testing) device: incorrect classification of glycaemic status
H.7.4	Portable IVD medical device for the point of care: critical result delayed

Page count: 87