ISO 14971 and TR 24971 Update for FDA Regulated Industries

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Background

"I'm literally bouncing with enthusiasm."

Historical Perspective

- The original ISO 14971 was released in 2000
- An update was released in 2003 with an additional informative annex containing the rationale for the requirements
- In 2007 a second edition was released with changes to informative annexes and minor changes to requirements
- In 2013 a Technical Report (informative guidance) was released as ISO TR 24971 due to requests from 2010 vote on reaffirmation of 2007

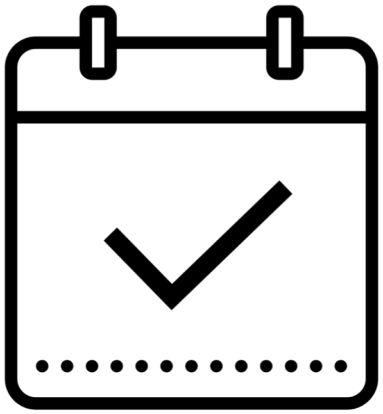
Revision Requested
How we got here...

- **In 2016 ISO charged the Technical Committee (TC 210 JWG1) responsible for ISO 14971 and ISO TR 24971 to:**
  - **Remove the Informative Annexes** from ISO 14971 to ISO TR 24971 to permit more frequent updates to guidance (3 years vs 5 years)
  - **Revise the standard** to include a Clause 2 in the requirements to add Normative References even though there are none. This requires moving all existing requirements up one Clause (e.g. present Clause 2 on Terms and definitions to Clause 3, thus resulting in 10 Requirements clauses instead of 9)
  - **Review cybersecurity risk** for inclusion in the standard
  - **Consider how ISO 31000** Guidance on risk management might be included
  - **Not change the risk management process**

Future Steps

- Complete Comments on ISO DTR 24971:20XX (April 12-14)
- Submit ISO DTR 24971:20XX to ISO for translation and publication
- (ISO FDIS 14971:20XX submitted to ISO and is in process)
- Release ISO FDIS 14971:20XX and ISO DTR 24971:20XX for final vote*
  - No technical changes may be made at FDIS, only editorial
  - Based on vote, ISO 14971:20XX and ISO TR 24971:20XX should be released in fourth quarter of 2019

*At each edition of the standard, final affirmative vote has been 100% at both ISO and IEC (this is a joint standard) and this is the only standard to achieve this record.



Current State

ISO 14971:2007
Current Requirements

1 Scope

2 Terms and definitions.

3 General requirements for risk management

- 3.1 Risk management process
- 3.2 Management responsibilities
- 3.3 Qualification of personnel
- 3.4 Risk management plan
- 3.5 Risk management file

4 Risk analysis

- 4.1 Risk analysis process
- 4.2 Intended use and identification of characteristics related to the safety of the medical device
- 4.3 Identification of hazards
- 4.4 Estimation of the risk(s) for each hazardous situation

ISO 14971:2007
Current Requirements

5 Risk evaluation
6 Risk control
- 6.1 Risk reduction
- 6.2 Risk control option analysis
- 6.3 Implementation of risk control measure(s)
- 6.4 Residual risk evaluation
- 6.5 Risk/benefit analysis
- 6.6 Risks arising from risk control measures
- 6.7 Completeness of risk control

7 Evaluation of overall residual risk acceptability
8 Risk management report
9 Production and post-production information

ISO 14971:2007
Current Informative Annexes-Not Requirements

Annex A (informative) Rationale for requirements

Annex B (informative) Overview of the risk management process for medical devices

Annex C (informative) Questions that can be used to identify medical device characteristics that could impact on safety

Annex D (informative) Risk concepts applied to medical devices

Annex E (informative) Examples of hazards, foreseeable sequences of events and hazardous situations

Annex F (informative) Risk management plan

Annex G (informative) Information on risk management techniques

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

Annex I (informative) Guidance on risk analysis process for biological hazards

Annex J (informative) Information for safety and information about residual risk

ISO TR 24971:2013
Current Guidance

Proposed Future State

ISO DIS 14971:20XX
Future Requirements

1 Scope
2 Normative references (none)
3 Terms and definitions
4 General requirements for risk management system
- 4.1 Risk management process
- 4.2 Management responsibilities
- 4.3 Competence of personnel
- 4.4 Risk management plan
- 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
- 5.5 Risk estimation

6 Risk evaluation

ISO DIS 14971:20XX
Future Standard

7 Risk control
- 7.1 Risk control option analysis
- 7.2 Implementation of risk control measures
- 7.3 Residual risk evaluation
- 7.4 Benefit -risk analysis
- 7.5 Risks arising from risk control measures
- 7.6 Completeness of risk control

8 Evaluation of overall residual risk

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) Rationale for requirements

Annex B (informative) Risk management process for medical devices

Annex C (informative) Fundamental risk concepts

ISO DTR 24971:20XX
Future Guidance
(Numbered Clauses Directly tied to Standard Clauses)

1 Scope
2 Normative references (none)
3 Terms and definitions
4 General requirements for risk management system
- 4.1 Risk management process
- 4.2 Management responsibilities
- 4.3 Competence of personnel
- 4.4 Risk management plan
- 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
- 5.5 Risk estimation

6 Risk evaluation
7 Risk control

ISO DTR 24971:20XX
Future Guidance
(Numbered Clauses Directly tied to Requirements)

- 7.1 Risk control option analysis
- 7.2 Implementation of risk control measures
- 7.3 Residual risk evaluation
- 7.4 Benefit-risk analysis
- 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 Information collection
- 10.2 Information review
- 10.3 Actions

ISO DTR 24971:20XX

(Not tied directly to requirements)

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

- A.1 General
- A.2 Questions (informative) Risk analysis techniques

Annex B (Informative) Risk analysis techniques

- 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) Risk acceptability considerations

- C.1 Risk levels
- C.2 Risk control option analysis
- C.3 Practicability considerations
- C.4 Example

ISO DTR 24971:20XX
(Not tied directly to requirements)

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 Terminology used in security risk management
- F.2 Relation between ISO 14971 and security risks
- F.3 Relationship between health risk and security risk
- F.4 Differences between health risk and security risk
- F.5 Prioritizing confidentiality, integrity, and availability

ISO DTR 24971:20XX
(Not tied directly to requirements)

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.2 Risk analysis**
- **H.3 Risk control**
- **H.4 Benefit-Risk Analysis**
- **H.5 Disclosure of the residual risks**
- **H.6 Production and post-production activities**
- **H.7 Examples of risk scenarios for IVD medical devices**
- **H.8 Particular guidance for personal IVD medical devices using digital technology**

Where do I find Annexes Now?

Informative Annexes (not requirements)			
ISO 14971:2007	ISO 14971:201X	ISO TR 24971:2013	ISO TR 24971:201X
Annex A-Rationale for requirements	Annex A-Rationale for requirements		NOTE: Numbered clauses (1-10) in ISO 14971:201X each have informative guidance listed under the clause number in this document
Annex B-Overview of risk management process for medical devices	Annex B-Risk management process for medical devices		
Annex C-Questions that can be used to identify			Annex A-Identification of hazards and
Annex D-Risk concepts applied to medical devices			Content of this annex appears in appropriate numbered clauses of ISO TR 24971
Annex E-Examples of hazards, foreseeable sequences of events and hazardous situations,	Annex C-Fundamental risk concepts		Included in Clause 5.4-Identification of hazards and hazardous situations and Clause 5.5-Risk Estimation
Annex F-Risk management plan			Clause 4.3
Annex G-Information on risk management techniques			Annex B-Risk analysis techniques
Annex H-Guidance on risk management for in vitro diagnostic medical devices			Annex H-Guidance for in vitro diagnostic medical devices

Informative Annexes (not requirements)			
ISO 14971:2007	ISO 14971:201X	ISO TR 24971:2013	ISO TR 24971:201X
Annex I-Guidance on risk analysis process for biologic hazards			Removed-Now in ISO 10993-1
Annex J-Information for safety and information about residual risk		Clause 5-Differention of information for safety and disclosure of residual risk	Annex D-Information for safety and information on residual risk
		Clause 1-Scope	Clause 1
		Clause 2-The role of international product safety and process safety standards in risk management	Annex E-Role of international standards in risk management
		Clause 3-Developing the policy for determining the criteria for risk acceptability	Annex C-Risk acceptability considerations
		Clause 4-Production and post-production feedback loop	Clause 10
			Annex F-Guidance on risks related to (cyber) security
			Annex G-Components and devices not designed using ISO 14971

What about the EU?

FprEN ISO 14971:20XX (Informative Annexes-Not Requirements)

- Annex ZA Medical Device Directive
- Annex ZB Active Implantable Medical Devices Directive
- Annex ZC In Vitro Medical Devices Directive
- Annex ZD Medical Device Regulation
- Annex ZE In Vitro Medical Device Regulation

Questions?

Thanks for your participation