New updates in ISO 14971:2019

ISO 14971:2019 Annexes compared to ISO 14971:2007 "Informative Annexes (not requirements)"

ISO 14971:2007	ISO 14971:2019
Annex A: Rationale for requirements	Annex A: Rationale for requirements
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 medical device characteristics that could impact on safety	
Annex D: Risk concepts applied to medical devices	
Annex E: Examples of hazards, foreseeable sequences of events and hazardous situations	Annex C: Fundamental risk concepts (Informative)
Annex F: Risk Management Plan	
Annex G: Information on risk management techniques	
Annex H: Guidance on risk management for in vitro diagnostic medical devices	
Annex I-Guidance on risk analysis process for biologic hazards	
Annex J: Information for safety and information about residual risk	

Specific changes between ISO 14971:2007 and ISO 14971/ TR 24971:2019

ISO 14971/TR 24971 Changes of Note:

- ISO 14971:2007-15 pages of requirements
- ISO 14971:2019-less than 17 pages
- Net-less than 2 new pages of revised requirements (Clause 10)
- ISO 14971:2007-70 pages of informative annexes
- ISO TR 24971:2013-16 pages of informative annexes
- Total 86 pages of informative annexes
- ISO 14971:2019-35 pages of informative annexes
- ISO TR 24971:2019-102 pages of informative annexes
- Total 137 pages of informative annexes
- Net-51 new pages of informative annexes

1. Scope

- The process described in this document can also be applied to products that are not necessarily medical devices in some jurisdictions and can also be used by others involved in the medical device life cycle.
- This document does not apply to:
  - Decisions on the use of a medical device in the context of any particular clinical procedure; or
  - Business risk management

The Standard

- Clause 2 is now “Normative References” as required by ISO TMB even though it states “There are no normative references in this document”
- Clauses starting with “Terms and Definitions” are now renumbered and incremented by “1”. e.g. Terms and Definitions is now Clause 3. Now 10 Clauses instead of 9 as in 2007 edition.
- New definitions for :
  - 3.2 Benefit (not defined anywhere else in standards or regulations)
  - 3.15 Reasonably foreseeable misuse (not defined elsewhere)
  - 3.28 State of the art (not defined elsewhere)
  - 3.3 harm ~~physical~~ injury or damage to the health of people, or damage to property or the environment
- Many definitions updated due to updates to sources including ISO 9000 (2015) AND ISO GUIDE 63 (2019) as well as others
- Clause 4.1 Figure 1 diagram has been changed to include “Risk management plan” and standard title changes in various steps in describing the risk management process - May need to revise your process drawings
- Clause 5.4 Risk Analysis reworded
  - The manufacturer shall identify and document known and foreseeable hazards associated with the medical device based on the intended use, reasonably foreseeable misuse and the characteristics related to safety In both normal and fault conditions. - Requires use of multiple risk analyses tools as many tools only are “fault condition” analyses-See Annex B1 paragraph 2

- Clause 7.4 retitled to Benefit-risk analysis to align with regulatory changes. 14971 only require that risks deemed to be unacceptable are analyzed; it is up to manufacturer to determine if there are regulatory requirements otherwise they must meet (Such as MDR).
    - Nearly three pages in ISO TR 24971:2019 Clause 7.4 of extensive discussion on benefit and benefit-risk analysis, including that benefit does not include economic or business advantages. (Clause 7.4.5 includes 3 specific examples of benefit-risk analysis conclusions.)
    - 7.4.2 has extensive discussion of clinical benefits
- Clause 9 retitled to Risk management review to emphasize that a review process prior to release for distribution is necessary to answer the following three questions
    - The risk management plan has been appropriately implemented;
    - The overall residual risk is acceptable; and
    - Appropriate methods are in place to collect and review information in the production and post-production phases.
- Reviewers must be identified in the Risk Management Plan (in advance of the review) and must have appropriate authority and may be necessary after device is in distribution
- Risk Management Report is a summary of review and part of Risk Management File and is different from Management Review of Risk Management process in Clause 4.2 (See ISO TR 24971 Clauses 4.2.3 & 9)
- Clause 10 retitled to Production and post-production activities. This section has been extensively revised and aligns with Clause 8 Measurement analysis and improvement in ISO 13485. Both ISO13485 and ISO 14971 developed these sections from the GHTFSG3/N18:2010 Quality management system – Medical Devices – Guidance on corrective action and preventive action and related QMS processes
- Emphasizes a need for an active process for gaining information as opposed to just waiting for complaints. Aligns with post market surveillance requirements by regulators
- Requires inclusion of risk management in post market surveillance
- Went from ½ page in 2007 to 1-1/2 pages of requirements in 2019, plus 4 pages guidance in ISO TR 24971:2019 as opposed to 1 page in ISO TR 24971:2013

The Guidance

- Added new annex, Annex F, 4-1/2 pages which covers risk management for cyber and data security and the process relationship to ISO 14971
    - Developed with members of ISO/IEC software committees
- Added new annex, Annex G, to cover components and devices that were designed without meeting ISO 14971 requirements
    - Discusses process that may be appropriate for remediating Risk Management File in 2+ pages of guidance
- Annex H for IVDs extensively revised by ISO TC 212 committee on IVDs and includes valuable information for all medical devices, not just IVDs
- It is important to understand that all information in ISO TR 24971:2019 is guidance and is NOT REQUIREMENTS
- Additionally Annexes A, B, C in ISO 14971:2019 is guidance and not requirements
- Annex A in ISO 14971:2019 is the Rationale for the requirements in the standard and should be read by anyone using the standard to improve understanding of the reason for the requirements

Differences	
ISO 14971:2007	**ISO 14971:2019**
Clause 1: Scope	Clause 1: Scope
Clause 2: Terms and Definitions	Clause 2: Normative References
Clause 3: General Requirements	Clause 3: Terms and Definitions
Clause 4: Risk Analysis	Clause 4: General Requirements for Risk Management System
Clause 5: Risk Evaluation	Clause 5: Risk Analysis
Clause 6: Risk Control	Clause 6: Risk Evaluation
Clause 7: Evalaution of Overall Residual Risk Acceptability	Clause 7: Risk Control
Clause 8: Risk Management Report	Clause 8: Evaluation of Overall Residual Risk ~~Acceptability~~
Clause 9: Production & Post-production Information	Clause 9: Risk Management Review
	Clause 10: Production and Post-production Activities

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