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Risk Management Systems: Implications of ISO 14971, ISO/TR 24971 and EU MDR Updates

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Introduction

The Organization on International Standards (ISO) published its first guidance on risk management for medical devices in 1998: ISO 14971-1:1998, Medical devices – Risk management – Part 1: application of risk analysis. However, it was the publication of ISO 14971:2000, Medical devices – Application of risk management to medical devices in 2007 that was considered by the industry to be the first true edition for risk management of medical devices. The second edition of the standard (ISO 14971:2007) was published by ISO and subsequently updated by the European Union (EU) in 2009 in an effort to recognize exceptions of ISO 14971:2007, such as level of acceptable risk required by manufacturers. It was followed by an additional EU update in 2012 to harmonize the standard with the then newly-released Medical Device Directive (MDD).

It was the updates to ISO 14971 made by the EU that forced the industry to operate under two different recognized versions of ISO 14971:

- ISO 14971:2007; recognized by the United States (U.S.)
- EN ISO 14971:2009, and subsequently EN ISO 14971:2012; recognized by EU

Now, the third edition of ISO 14971 was released (December 1, 2019), and ISO 14971:2019 has once again brought the industry back to a single recognized version of risk management (Figure 1).

The companion document to ISO 14971 exists as the technical report, ISO/TR 24971, which was first published in 2013. ISO/TR 24971:2020 is expected to be available in May of 2020 and will be updated with additional guidance and information on risk management. This technical report will contain all informative annexes that were previously included within ISO 14971:2007, as well as several additional annexes to support industry risk management (Figure 2).

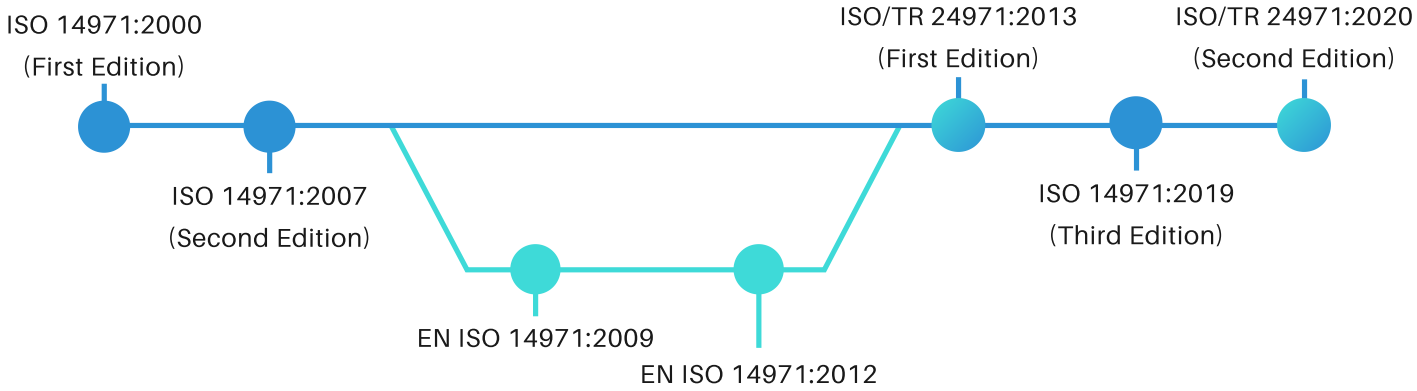

Figure 1: *Sequential Timeline of Risk Management Standard and Technical Report Editions*

Implementation Guidelines

ISO 14971:2019 was adopted without modification by the U.S. Food and Drug Administration (FDA) on December 1, 2019, and was added to the list of recognized consensus standards on December 23, 2019. The EU adopted the new standard without modification and published the EN version of the standard on December 18, 2019—conflicting national standards shall be withdrawn by June 2020. With the acceptance of ISO 14971 by both the FDA and EU, multiple versions of the Second Edition of ISO 14971 will no longer exist as a regulatory hurdle for risk management requirements and compliance.

The FDA has acknowledged a three (3) year grace period to establish compliance to ISO 14971:2019. While the EU has not officially recognized a specific grace period, NAMSA expects this to also be three (3) years for manufacturers. Grace periods will ensure that manufacturers have enough time to review the updated standard and technical report, identify gaps in compliance, implement strategies to address gaps and make updates to QMS and risk management records.

To be compliant by the end of the grace period, NAMSA recommends that manufacturers first prepare a gap assessment to identify the differences between the new version of the standard and the version of the standard they currently claim compliance to. Once the differences between the versions are identified, manufacturers should then assess how this affects their QMS, risk management systems and existing risk management records.

For companies with a large catalog of legacy products, it is recommended that a quality plan be developed to prescribe the process for meeting the requirements of the new standard based on the standard gap assessment. This quality plan should aim for full compliance no later than December 1, 2022. However, manufacturers should take into consideration the date(s) of their anticipated Notified Body audits prior to December 1, 2022 as they may expect demonstration of compliance to the standard before renewing ISO 13485 or CE Mark certificates.

One important caveat to consider is the mandatory compliance date of the EU's Medical Device Regulation (MDR) (May 2020). Manufacturers currently developing devices with the plan to register under the MDR should assume the expectation of compliance to EN ISO 14971:2019 at the time of product registration.

Major Updates

The following major changes were made within ISO 14971:2019:

- Risk Management includes, within its scope, risks associated with data and systems security (such as computer systems, software subsystems integrated within a device and software as a medical device).
    - The schematic representation of the risk management process reflects the updates to the standard (see Figure 2).
- There is now a requirement that the evaluation of the overall residual risk and criteria of risk acceptability must be defined.
    - The standard clarifies criteria for acceptability of overall residual risk and that it may be different from that for individual risks.

- The standard increases the emphasis on benefits has changed all risk/benefits analysis references to benefits-risk analysis.
- Descriptions of production and post-production information collection, analysis and risk mitigation activities are clarified and details are provided on expected activities and sources of information.
  - Formal reviews of risk management plans and documentation of these reviews are now required.
  - A final evaluation and approval must be completed prior to commercial distribution.
- There are three new definitions within the standard to support risk management activities and multiple definitions have been updated (Table 1).
- ISO/TR 24971 will include updates that add more tools and information to support risk management activities; most of the informative annexes from the second edition of ISO 14971 will be moved to the updated ISO/TR 24971.

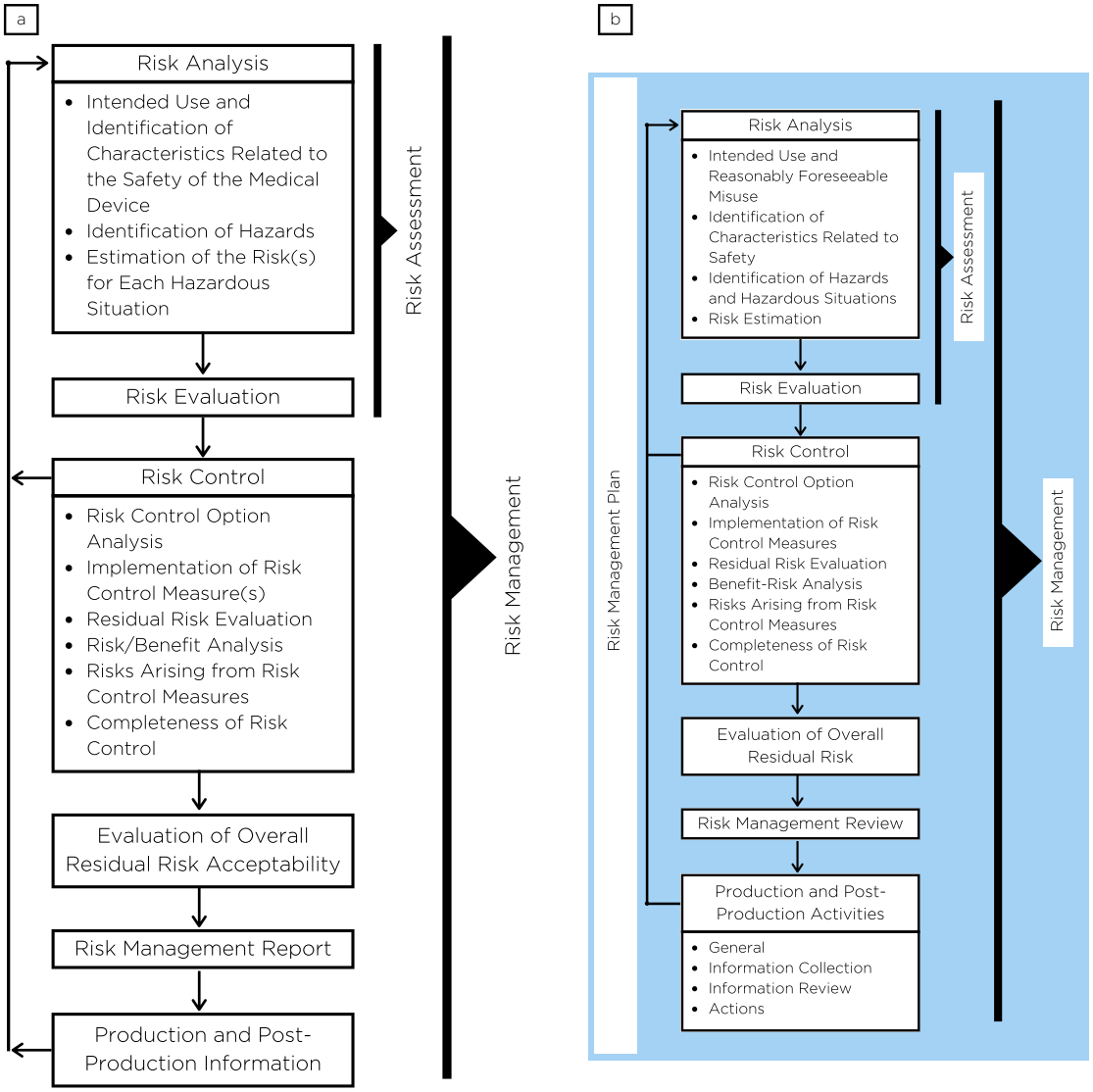

Figure 2: *Schematic Representations of the Risk Management System; (a) ISO 14971:2007 (b) ISO 14971:2019 on left)*

Implications of the Updates

1. Inclusion of Data and Security Systems

It is important to recognize that ISO 14971:2019 is the central process for assessing and documenting risks associated with medical devices. However, it does not mean that the use of other standards or guidance documents on risk management of a specific risk factor, such as cybersecurity, are precluded.

Manufacturers must review current risk management plans and benefits-risk analyses to ensure that the clinical benefits of devices are clearly identified.

Similar to how ISO 10933-1 is utilized to assess specific biocompatibility risks, processes such as the National Institute of Standards and Technology (NIST) cybersecurity framework can be used to assess the specific risks associated with cybersecurity. Moving forward, risks identified, assessed and reduced (if possible) through processes like the NIST cybersecurity framework process, or other data and security systems risk mitigation processes, should be referenced or documented in the risk management report. Additionally, all risk-related records should be stored or referenced within the risk management file.

2. Schematic Representation of Risk

Many manufactures have used the standard's schematic representation of risk figure found in ISO 14971 and have either duplicated it in their quality system procedures or developed their own schematic with similar details (Figure 2). These schematics should be reviewed to determine whether updates are necessary. For example, the new schematic in ISO 14971 emphasizes how all risk analysis steps are part of the risk management plan. The step of the risk management report is changed under the risk management review, of which the risk management report should be an output.

3. Individual Residual Risks and Overall Residual Risk

Manufacturers should review risk management records, such as Failure Modes Effects Analysis (FMEAs), to ensure that all residual risks are assessed relative to the clinical benefits of the intended use of the device being evaluated. Furthermore, a detailed benefits-risk analysis should be properly developed and cite studies/reports of clinical benefits of the device compared to the overall residual risk.

For each identified hazardous situation where the risk cannot be reduced to acceptable levels (based on a company's risk acceptance policy), the benefits of the medical device should be compared to individual residual risk to determine whether that risk is acceptable. Documents such as FMEAs, and similar risk evaluation tools, must be reviewed and verified so that all individual risks are properly assessed. There should be clear traceability to the benefits of the risk analysis of any individual residual risks. Furthermore, individual residual risks are to be properly communicated to the user, typically through precautions, warnings and contraindications in the information for use documentation.

In previous versions of ISO 14971, the criteria for risk acceptability was defined as either:

- ALARP: "as low as reasonably practicable," which was recognized in ISO 14971:2007
- AFAP: "as far as possible," which was recognized by the European version of the Standard, EN ISO 14971:2012

ISO 14971:2019 states that manufacturers are responsible for defining criteria for risk acceptability, which provides manufacturers some level of flexibility in establishing risk management requirements. However, manufacturers must assure that the criteria for risk acceptability meets specific global regulatory requirements (Table 3).

4. Benefits-Risk Analyses

Manufacturers must review current risk management plans and benefits-risk analyses to ensure that the clinical benefits of devices are clearly identified. The re-emphasis of benefits by adding a definition, changing the terminology from risk/benefits analysis to benefits-risk analysis and referencing the documentation of benefits in more standard locations links risk management to expected device benefits to the evaluation of the overall/residual risks.

The benefits-risk analysis of overall residual risk should be a robust document that addresses clinical benefits of evaluated medical device(s) by referencing either clinical study reports, literature on state-of-the-art, clinical evidence reports or other similar sources of clinical information. The evidence supporting both the benefits and overall residual risks must use quantitative information when possible and avoid vague language.

To meet MDR requirements, manufacturers must also ensure that the benefit-risk analysis is properly documented within technical files.

5. Production and Post-Production Information

It is recommended that manufacturers confirm that all production and post-production activities prescribed within ISO 14971:2019 are properly adopted within their QMS. While manufacturers should already have a process for collecting production and post-production information, they should review these processes to show a clear link between this information and risk management activities. The production and post-production information collection system must verify collection of data from all sources identified in ISO 14971:2019, if applicable.

6. Risk Management Review

The planning and reviewing of risk management plans/reports should be formalized and fully integrated within design controls and include a clear process demonstrating that risk management plans are reviewed and agreed upon prior to implementation. The risk management report is then considered the final output of the risk management review and must contain information demonstrating full execution; it should also be evaluated for effectiveness of risk mitigation activities prior to commercial release.

7. Definitions

While three (3) new definitions were added to ISO 14971:2019 (benefits, reasonably foreseeable misuse and state-of-the-art), many other definitions were modified. Manufacturers should review each definition to verify that updates to definitions do not alter the scope of how manufacturers apply these definitions. For example, the definition of harm was updated to remove the word "physical" from the types of injuries or damage to the health of people. Manufacturers, therefore, must verify that other types of harm such as psychological harm, for example, are factored into assessments.

The definition of a manufacturer has also been slightly modified and should be reviewed. Specifically, the added notes regarding this definition are useful in determining what constitutes a manufacturer. Table 1 provides a list of all definitions (with notes) that were either added or modified.

8. ISO/TR 24971:2020

ISO/TR 24971:2020 is planned to be published in May 2020. There are significant updates expected in the second edition of ISO/TR 24971:2020; manufacturers should to plan to have immediate access to this new document. The new iteration of this technical report will contain all of the useful tools that were previously informative annexes in ISO 14971:2007 and EN ISO 14971:2012. ISO/TR 24971:2020 will add annexes that provide insight on how security is related to risk management and how to manage devices that were developed without ISO 14971. It will also provide information on the risks associated with in vitro diagnostic medical devices. Table 2 contains a list of the Annexes that were updated or added to ISO 14971:2019 and are expected to be added to ISO/TR 24971:2020.

9. EN ISO 14971:2019 and the EU's Medical Device Regulation (MDR) 2017/745

EN ISO 14971:2019, the EU-recognized version of the standard, was updated with the intent to integrate well with the EU MDR. For example, both EN ISO 14971:2019 and the MDR have increased descriptions of production and post-production information collection and analysis activities related to risk management; both documents are consistent in requirements for such activities.

There are, nevertheless, some differences between the two risk management requirements. The main difference is related to the level of acceptable risk adopted by manufacturers. While EN ISO 14971:2019 was written with the flexibility to mold risk acceptance into respective manufacturer markets, the EU MDR clearly states that identified risks must continue to be reduced as far as possible. This is consistent with the language in the previous European version of the standard (EN ISO 14971:2012). Therefore, to market medical devices in the EU, manufacturers should continue to reduce all risks as far as possible to remain compliant with EU regulations.

The updates to EN ISO 14971:2019 align well with the published risk management requirements of the EU MDR (2017/745 Annex I). Alignment with the EU MDR also means that any QMS activities required for EN ISO 14971:2019 compliance must be completed by May 2020 for manufacturers distributing devices within the EU. In Table 3, a breakdown of the EN ISO 14971:2019 clauses have been aligned with the sections of the MDR that relate to risk management, and more specifically, Annex I.

Conclusion

While the overall processes related to medical device risk management remain unchanged, the scope of risk management has expanded to include data and security, as well as more clarity on production and post-production activities.

Moving forward, manufacturers will be required to clearly define intended clinical benefits of medical device(s) and properly evaluate them for both individual and overall residual risks after completion of mitigation activities. Manufacturers must also ensure that documentation of the conclusions of risk management activities are recorded within the completed risk management reports.

Manufacturers should review each definition to verify that updates to definitions do not alter the scope of how manufacturers apply these definitions.

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Helping medical device Sponsors improve healthcare since 1967, NAMSA is the only 100% medical device-focused, full continuum Contract Research Organization (CRO) in the world. Driven by our global regulatory expertise and in-depth therapeutic knowledge, NAMSA is dedicated to accelerating medical device product development, offering only the most proven solutions to move clients' products through the development lifecycle efficiently and cost-effectively. From medical device testing; regulatory, reimbursement and quality consulting; and clinical research services, we are the industry's premier, trusted partner for successful development and commercialization outcomes.

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About the Author

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Rich Granquist has been in the medical device industry for nearly 15 years with a dedicated focus on global quality assurance and EU regulatory affairs. For the last six years, Rich has served as a Senior Quality Systems Consultant for NAMSA's Clinical and Consulting Teams. Mr. Granquist has a certification in Biomedical Auditing with a specialized focus and deep-rooted expertise on risk management, complaint and CAPA investigations, sterilization validation, preclinical testing and technical file management. Most recently, he has provided expertise on the impact of the EU Medical Device Regulation (MDR) on quality systems, product development and risk management. Rich is a member of the AAMI Quality Management Working Group 04 for the Application of Risk Management to Medical Devices.

Table 1: **New or Updated Definitions Under ISO 14971:2019**

Section	Updated Definition
3.1	**Accompanying Documentation** Materials accompanying a medical device and containing information for 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.
3.2 (NEW)	**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 Note 1 to entry: Benefits can include positive impact on clinical outcome, the patient's quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or positive impact on public health.
3.3	**Harm** Injury or damage to the health of people, or damage to property or the environment.
3.6	**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. Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the intended use.
3.7	**In Vitro Diagnostic Medical Device** *IVD Medical Device* 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 reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

Section	Updated Definition
3.9	**Manufacturer** Natural or legal person with responsibility for the design and/or manufacture of a medical device 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). Note 1 to entry: The natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction. Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions. Note 3 to entry: "Design and/or manufacture" may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose. Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device. Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device. Note 6 to entry: An authorised representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer. Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

Section	Updated Definition
3.10	**Medical Device** Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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 medical 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 by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Note 1 to entry: Products which can be considered to be medical devices in some jurisdictions but not in others include: • disinfection substances; • aids for persons with disabilities; • devices incorporating animal and/or human tissues; • devices for in vitro fertilization or assisted reproduction technologies.
3.14	**Process** Set of interrelated or interacting activities that use inputs to deliver an intended result. Note 1 to entry: Whether the "intended result" of a process is called output, product or service depends on the context of the reference. Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes. Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.
3.15 (NEW)	**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 behavior. Note 1 to entry: Readily predictable human behavior includes the behavior of all types of users, e.g. lay and professional users. Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

Section	Updated Definition
3.16	**Record** Document stating results achieved or providing evidence of activities performed. Note 1 to entry: Records can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action. Note 2 to entry: Generally records need not be under revision control.
3.28 (NEW)	**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”.
3.30	**Use Error** 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. Note 1 to entry: Use error includes the inability of the user to complete a task. Note 2 to entry: Use errors can result from a mismatch between the characteristics of the user, user interface, task, or use environment. Note 3 to entry: Users might be aware or unaware that a use error has occurred. Note 4 to entry: An unexpected physiological response of the patient is not by itself considered use error. Note 5 to entry: A malfunction of a medical device that causes an unexpected result is not considered a use error.
3.31	**Verification** Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents. Note 2 to entry: The activities carried out for verification are sometimes called a qualification process. Note 3 to entry: The word “verified” is used to designate the corresponding status.

Table 2: **Annexes in ISO/TR 24971**

ISO 14971:2007/2012 ISO/TR 24971:2013 Annex	**Original Title**	**New Title**	**ISO 14971:2019/ ISO/TR 24971:2020 Annex**
Annex A	Rational for requirements	Rational for requirements	ISO 14971:2019 Annex A
Annex B	Overview of the risk management process for medical devices	Risk management process for medical devices	ISO 14971:2019 Annex B
Annex C	Questions that can be used to identify medical device characteristics that could impact on safety	Identification of hazards and characteristics related to safety	ISO/TR 24971:2019 Annex A
Annex D	Risk concepts applied to medical devices	Information incorporated into ISO/TR 24971	ISO/TR 24971:2019 Clause 5.5 Risk estimation
Annex E	Examples of hazards, foreseeable sequences of events and hazardous situations	Guidance on risks related to security	ISO/TR 24971:2019 Annex F
Annex F	Risk management plan	Information incorporated into ISO/TR 24971	ISO/TR 24971:2019 Clause 4.4 Risk Management Plan
Annex G	Information on risk management techniques	Techniques that support risk analysis	ISO/TR 24971:2019 Annex B
Annex H	Guidance on risk management for in vitro diagnostic medical devices	Guidance for in vitro diagnostic medical devices	ISO/TR 24971:2019 Annex H
Annex I	Guidance on risk analysis process for biological hazards	Retired	n/a
Annex J	Information for safety an information on residual risk	Information for safety an information on residual risk	ISO/TR 24971:2019 Annex D

ISO 14971:2007/2012 ISO/TR 24971:2013 Annex	Original Title	New Title	ISO 14971:2019/ ISO/TR 24971:2020 Annex
n/a	NEW Annex	Relation between the policy, criteria for risk acceptability, risk control and risk evaluation	ISO/TR 24971:2019 Annex C
n/a	NEW Annex	Role of international standards in risk management	ISO/TR 24971:2019 Annex E
n/a	NEW Annex	Components and devices designed without using ISO 14971	

Table 3: Correspondence Between Risk Management Requirements in (EN) ISO 14971:2019 Clauses and Regulation (EU) 2017/745 (MDR)

Risk Management Element	(EN) ISO 14971:2019	Regulation (EU) 2017/745 (MDR)
General Requirements for Risk Management System	4	
Risk Management Process	4.1	Annex I 3
Management Responsibilities	4.2	Article 10 9
Competence of Personnel	4.3	
Risk Management Plan	4.4	Annex I 3(a)
Risk Management File	4.5	
Risk Analysis	5	
Risk Analysis Process	5.1	Annex 1 3
Intended Use and Reasonably Foreseeable Misuse	5.2	Annex 1 3(c)
Identification of Characteristics Related to Safety	5.3	Annex I 3(b)
Identification of Hazards and Hazardous Situations	5.4	Annex I 3(b) Annex I 10 Annex I 11.1 Annex I 14.2 Annex I 15 Annex I 16 Annex I 17 Annex I 18 Annex I 19 Annex I 20 Annex I 21 Annex I 22
Risk Estimation	5.5	Annex I 3(c)
Risk Evaluation	6	Annex I 3(c)
Risk Controls	7	
Risk Control Option Analysis	7.1	Annex I 3(d) Annex I 4 (a)(b) Annex I 5 (a)(b)
Implementation of Risk Control Measures	7.2	Annex I 3(d)

Table 3: Correspondence Between Risk Management Requirements in (EN) ISO 14971:2019 Clauses and Regulation (EU) 2017/745 (MDR)

Risk Management Element	**(EN) ISO 14971:2019**	**Regulation (EU) 2017/745 (MDR)**
Residual Risk Evaluation	7.3	Annex I 4(a) Annex I 10 Annex I 11.1 Annex I 14.2 Annex I 15 Annex I 16 Annex I 17 Annex I 18 Annex I 19 Annex I 20 Annex I 21 Annex I 22
Benefit-Risk Analysis	7.4	Annex I 8 Annex II 5(a)(b)
Risks Arising from Risk Control Measures	7.5	
Completeness of Risk Control	7.6	
Evaluation of Overall Residual Risk	8	Annex I 8 Annex II 5(a)(b)
Risk Management Review	9	
Production and Post-Production Activities	10	
General	10.1	
Information Collection	10.2	Annex I 3(e) Annex III 1(b)
Information Review	10.3	Annex I 3(e) Annex III 1(b)
Action	10.4	Annex I 3(f)

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