Module 1: Fundamentals of Medical Devices' Risk Management Standard

Learning Outcomes

After successfully completing this module, you will be able to:

- Summarize the details of the ISO 1497:2019 standard.
- State the revisions in the ISO 14971:2019 standard.
- Discuss the reasons to update the standard.
- Describe how the ISO 14971:2019 standard corresponds with other means.
- Outline the changes made in ISO 14971:2019 and ISO TR 24971.
- List the new terms and definitions which ISO added in the ISO 14971:2019 standard.
- Explain the Annexes added in the ISO 14971:2019 and ISO TR 24971 standard.

Introduction to ISO 14971

What is ISO 14971?

ISO 14971 is the international standard which specifies requirements of risk management systems for medical devices. It explains the best practices considering the entire lifecycle of medical devices.

What is the latest version of ISO 14971?

The latest version of ISO 14971 is specified as ISO 14971:2019 since it was released in 2019. Prior to this publication there were two earlier versions of ISO 14971 specified as ISO 14971:2007 and ISO 14971:2000. Also the European version of the same standard is referred as EN ISO 14971.

Does US FDA recognizes the new version of ISO 14971?

The US Food and Drug Administration (FDA) recognizes the new version of ISO 14971 along-with many other regulatory bodies throughout the world.

Does ISO 13485 require ISO 14971?

ISO 13485 mandates risk analysis and management process for

medical devices. ISO 13485 references to ISO 14971 as guidance for medical devices risk management. Learners can also learn about ISO 13485 with Alison' free course on **ISO 13485:2016 - Quality Management Systems for Medical Devices.**

What is the difference between ISO 31000 and ISO 14971?

In order to understand the difference between two international standards on risk management, please consider reading the comparison below:

ISO 31000

ISO 31000 is a general risk management standard which can be applied to any organization and to any business function.

ISO 31000 is applicable to cover the entire life of an organization; relevant to strategies, decision making, any activity, product, service, asset, project etc.

ISO 14971 is applicable to all stages of a medical device's life-cycle.

ISO 31000 is related to business risk.

ISO 31000 caters all types of risk such as risks having positive and negative consequences.

If you want to learn about ISO 31000, take Alison's free online course on **ISO 31000:2018 - Enterprise Risk Management Framework for Risk Leaders.**

ISO 14971

ISO 14971 is specific to medical devices, and is focused on managing hazards of a medical device or in-vitro medical devices.

ISO 14971 is applicable to all stages of a medical device's life-cycle.

ISO 14971 is focused on managing risks related to medical device hazards. It guides the risk management process for managing those hazards associated with medical device. It also emphasizes on risk

versus benefit analysis.

Introduction to ISO 14971

The complete name of ISO 14971 is **ISO 14971:2019 Medical Devices- Application of Risk Management to Medical Devices**.

ISO Technical Committee ISO TC/210 took part in its standardization process. The current edition of this standard is its third edition. ISO 14971:2000 and ISO 14971:2007 are the first and second editions respectively. The standard provides medical device manufacturers with a framework within which they can apply experience, insight, and judgment to manage risks associated with the use of medical devices.

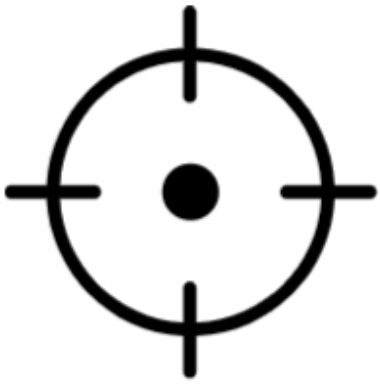
Who is ISO?

The International Organization for Standardization (ISO) is an international federation comprising national standard bodies known as ISO member bodies. These member bodies perform the task of constituting the ISO technical committee. This committee works on documentation of different international standards. Various domains such as management systems, product manufacturing, process management, or any other technical niche are encircled by these international standards.

ISO 14971 - Illustration

Scope & Exceptions of ISO 14971:2019

Standard's Scope



The requirements of ISO 14971:2019 are applicable on phases of the life cycle of a medical device such that the risks associated with medical devices, their biocompatibility, data, and systems security, electricity, moving parts, radiation, and usability are addressed thoroughly.

Exclusion to Standard's Scope

The requirements of ISO 14971:2019 exempt the following from its scope:

• Decisions regarding the use of a medical device in the context of any specific clinical procedure. This is because it is not a manufacturer's concern, rather it is the concern of medical practitioners.
• Business risk management

The Reason to Update ISO 14971

Medical devices need to be managed regarding the risks they can pose. Therefore, proper risk management is necessary to be carried out during the entire life cycle of a medical device. The International Organization for Standardization has devised the standard ISO 14971 to help the companies carry out the proper risk management process for their products. Recently, few changes were brought out into ISO 14971, and its Technical Report, ISO TR 2497, and the updated version of both were released as ISO 14971:2019 and ISO/TR24971:2020, respectively.

The updated version comes up with revisions in interpretations of the primary risk management process. In addition to this, the updated version also contains a discussion on Risk Management System alongside with risk management process.

What were the Reasons to Update ISO 14971?

The reasons to update ISO 14971 are:

Difficulty in Navigation

The previous versions of ISO 14971 were hard to navigate. They also contain inefficient information regarding the safety of medical devices.

Lack of Guidance in Risk Management

Earlier versions of ISO 14971 failed to guide the medical device manufacturers regarding risk management, hence were unable to complete the standard criteria.

Use of Outdated Definitions

The predecessors of ISO 14971 contained old definitions that do not fulfill risk management requirements for the modern medical device industry.

Correspondence with Other Standards

- Apart from the reasons listed above, one of the main reasons to update ISO 14971 was to align it with the requirements of EU MDR, EU IVDR, and ISO 13485:2016

- To address the shortcomings present in the previous editions of ISO 14971, the International Standard for Standardization (ISO) and International Electrotechnical Commission (IEC) came together in 2016 to plan changes in the existing standard; the new standard was released on December 18, 2019. These updates also put their emphasis on the post-market FDA situation
- Both ISO and IEC also contributed to updating the technical report, i.e., ISO TR 24971. This technical report provides medical manufacturers with helpful guidance information.

ISO 14971:2019 Versus ISO/TR 24971:2020

ISO 14971:2019

This standard is about the **application of risk management** to medical

devices.
ISO 14971 explains terminology, principles and a **process for risk management** of medical devices.
ISO 14971 does **not mandate** the risk management to be an **integral part of QMS** based on ISO 13485.
ISO 14971 tells organization **what to do** for medical devices' risk management process.

ISO/TR 24971:2020

This guidance is about the **application of ISO 14971.**
ISO/TR 24971:2020 offers assistance on the **development, application and maintenance of a risk management system** for medical devices as per ISO 14971:2019.
ISO/TR 24971:2020 offers guidance on risk management as an integrated part of the Quality Management System based on ISO 13485.
ISO/TR 24971:2020 **how to** implement list of "To Dos" in ISO 14971:2019.

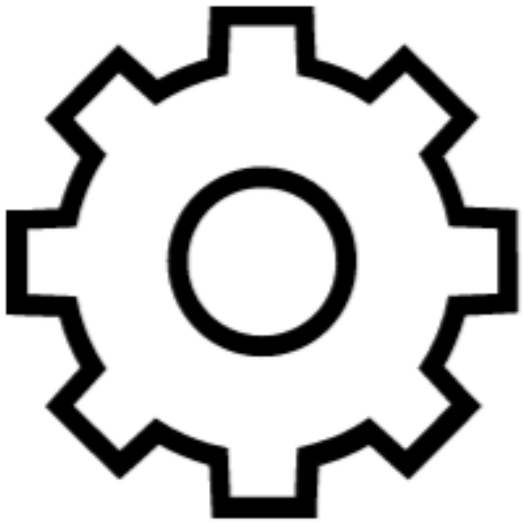
Overview of Changes

Overview of Changes Made in ISO 14971

The newly updated edition of ISO 4971:2019 contains the following changes:

- New terms and definitions
- Additional risk management guidance
- Other requirements regarding production and post-production
- A clause on normative references.

Overview of Changes Made in ISO TR 24971



The updated edition of ISO TR 24971 contains the following changes:

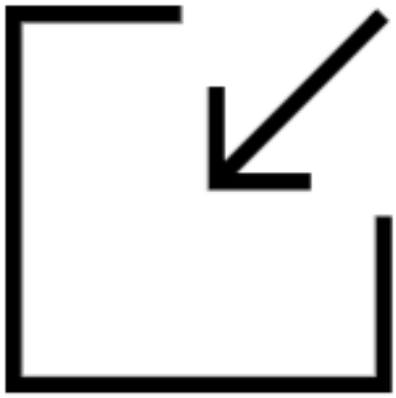
- Guidance on risk management for in-vitro diagnostic devices
- Risk management plans
- Risk concepts and techniques
- Guidance on hazard detection.

Before the 2019 update of ISO TR 24971, all of this information was present in ISO 14971. Also, the technical committee (JWG1) and ISO Technical Management Board (TMB) have decided to list all of the information annexes primarily in ISO TR 24971 instead of ISO 14971.

Major Revisions in ISO 14971:2019

The significant revisions made in ISO 14971:2019 as compared to its predecessors are as follows:

Clause on Normative References



To comply with the requirements for standardization; Clause 15 of ISO/IEC Directives, Part 2:2018, a clause on normative references has been included in the third edition. But there are no references here.

Defined Terms

Defined terms are updated and printed in italic so that readers can identify them in the body of the document. In addition, many defined terms are derived from ISO/IEC Guide 63:2019.

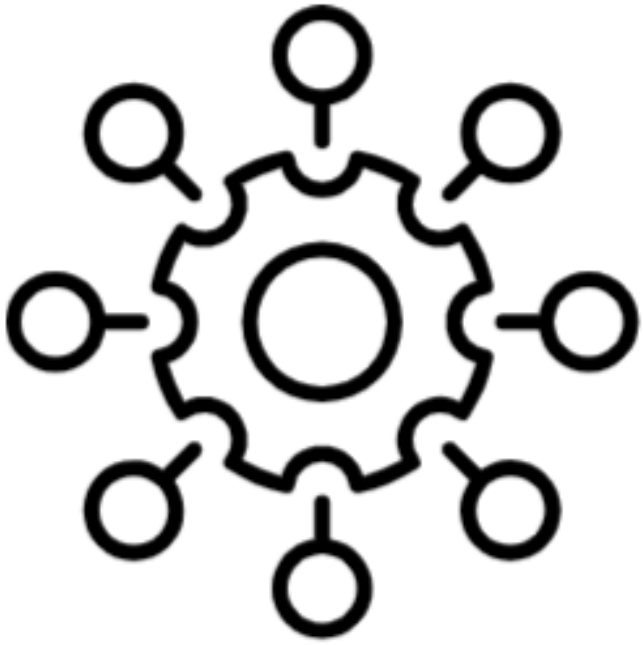
Introduction of New Terms

The terms benefit, reasonably foreseeable misuse, and state-of-the-art has been introduced and described in the third edition.

Benefit-Risk Analysis

The third edition of ISO 14971 focuses on the benefits that the use of medical devices can offer. Also, the term Benefit-Risk Analysis has been aligned with the terminology used in other regulations.

Usage of Process

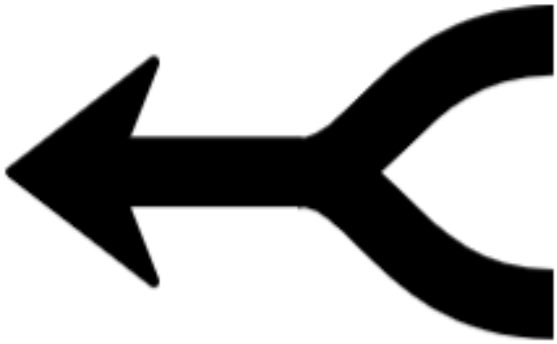


The term Process, described in the third edition of ISO 14971, can be used to manage risks associated with medical devices and those related to data and systems security.

Risk Management Plan

A risk management plan describes the method used to determine the overall residual risk and its acceptability criteria. The process can include collecting and evaluating data and other literature for the medical device and similar medical devices and other available products in the market. As a result, acceptability criteria for the overall residual risk can differ from the acceptability criteria of individual risks.

Requirements to Disclose Residual Risks



After evaluating overall residual risk and its acceptance, the requirements to disclose residual risks have been shifted and merged into one condition.

Risk Management Report

The Risk Management Plan demands a review of the medical device before its commercial distribution. The results of this review ought to be documented in the risk management report.

Production & Post-Production Requirements

The third edition contains restructured requirements regarding production and post-production activities. In addition, detailed information is given regarding the collection of the information. The clause also lists the actions taken after reviewing the collected data and determining its relevance to safety.

Information Annexes

In the third edition of ISO 14971, more information and rationale for the requirements have been given in Annex A. The information covering correspondence between the clauses of the second edition with the third is provided in Annex B.

Major Updates in ISO 14971

Risk Management Plan

The revised version contains the Risk Management Plan. The standard also shows variations at different steps while describing the risk management plan. A medical device manufacturer may need to revise his process drawings accordingly with the standard in this regard.

Risk Analysis (Clause-5.4)

Clause 5.4 on Risk Analysis has been made more precise and specific.

The revised passage says:

“The manufacturer shall identify and the 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.”

Now the approach on risk analysis won't be limited to fault condition analysis only. Rather, due to the addition of the paragraph above, there will be other factors to consider within the risk management process.

Benefit-Risk Analysis (Clause-7.4)

Clause 7.4 has been renamed Benefit-Risk Analysis. The standard requires only those risks to have a Benefit-Risk Analysis, which are declared as unacceptable.

Production & Post-Production Activities (Clause-10)

Clause 10 of ISO 14971:2019 has been renamed as Production and post-production activities, and this clause now aligns with clause 8 of ISO 13485, which is on Measurement Analysis and Improvement. this clause comes with the following changes in the revised version of ISO 14971:

1. Instead of waiting for complaints, clause 10 now focuses on having an active process for collecting information.

2. Regarding production and post-production information, clause 10 provides guidelines on:
• Establishing a system for collection of production and post-production information
• Reviewing information collected on production and post-production
• The correct action which needs to be taken
• How the correct action should be taken.

3. This clause now requires risk management in post-market surveillance.

Details of Changes Made in ISO TR 24971

The addition regarding changes made in ISO TR 24971 in its 2019 version consists mainly of the addition of new Annexes. These annexes are listed below:

Risk Concepts (Annex-D)

This Annex refers to Risk Concepts Applied for Medical Devices. This clause has been deleted from ISO 14971. Instead, it is now redistributed throughout ISO TR 24971 as a numbered clause.

Risk Management for Cyber-security (Annex-F)

Annex F is the newly added Annex. It is four pages long and addresses risk management regarding cyber and data security along with the cyber-security process about ISO 14971.

Risk Management File (Annex-G)

This annex is beneficial for the companies that are willing to update their risk management system to comply with the requirements of the edited version of ISO 14971.

In-Vitro Diagnostic (IVD) Devices (Annex-H)

This new annex does not only contain information on IVD devices; instead, it contains information on all medical devices.

Addition of New Terms & Definitions in ISO 14971

The sub-clauses of clause 3 of the ISO 14971:2019 contains new definitions for these terms

Benefit (Clause-3.2)

The term Benefit is defined as, ***"Positive impact or desired outcome of the use of a medical device in the health of an individual, or a positive impact on patient management or public health."***

Harm (Clause-3.3)

The term Harm is defined as ***“physical injury or damage to the health of people, or damage to property or the environment.”***

Reasonably Foreseeable Misuse (Clause-3.15)

The term Reasonably Foreseeable Misuse is defined as, ***“Use of a product or system in a way not intended by the manufacturer, but which can result from readily predictable human behavior.”***

State of the Art (Clause-3.28)

The term State-of-the-Art is defined as, ***"Developed state of technical capability at a given time as regards products, processes, and services, based on the relevant consolidated findings of science, technology, and experience."***

Other Definitions in ISO 14971

Many defined terms in ISO 14971:2019 are derived from ISO/IEC Guide 63:2019.

Accompanying Documentation

Accompanying Documentation is defined in Clause 3.1 as '***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.'***

Some important notes are:

• The accompanying documentation can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.
• Accompanying documentation is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

Intended Use or Purpose

Intended Use or Purpose is defined in Clause 3.6 as '***use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer.'***

In Vitro Diagnostic Medical Device

IVD medical device is defined in Clause 3.7 as '***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 .***'

Life Cycle

Life Cycle is defined in Clause 3.8 as'***series of all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.'***

Other Definitions in ISO 14971

Manufacturer

Manufacturer is defined in Clause 3.9 as '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 persons.'

Some important notes under this definition are:

• 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.
• The manufacturer's responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.
• "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.

Medical Device

Medical Device is defined in Clause 3.1 as '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 purposes 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.'

Learn about medical devices, start this course online on Alison: **ISO 13485:2016 - Quality Management Systems for Medical Devices**

Objective Evidence

Objective Evidence is defined in Clause 3.11 as 'data supporting the existence or verity of something.' Objective evidence can be acquired with observations, measurements, tests or by other means.

Post-Production

Post-Production is defined in Clause 3.12 as 'part of the life cycle of the medical device after the design has been completed and the medical device has been manufactured.'

Procedure

Procedure is defined in Clause 3.13 as 'specified way to carry out an activity or a process.'

Process

Process is defined in Clause 3.14 as 'set of interrelated or interacting activities that use inputs to deliver an intended result.'

Residual Risk

Residual Risk is defined in Clause 3.17 as 'risks remaining after risk control measures have been implemented.'

Risk

Risk is defined in Clause 3.18 as 'combination of the probability of occurrence of harm and the severity of that harm.

Risk Analysis

Risk Analysis is defined in Clause 3.19 as 'systematic use of available information to identify hazards and to estimate the risk.'

Risk Assessment

Risk Assessment is defined in Clause 3.2 as 'overall process comprising a risk analysis and a risk evaluation.'

Risk Control

Risk Control is defined in Clause 3.21 as 'process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels.'

Risk Estimation

Risk Estimation is defined in Clause 3.22 as 'process used to assign values to the probability of occurrence of harm and the severity of that harm.'

Risk Evaluation

Risk Evaluation is defined in Clause 3.23 as 'process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk.'

Risk Management

Risk Management is defined in Clause 3.24 as 'systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.'

Risk Management File

Risk Management File is defined in Clause 3.25 as 'set of records and

other documents that are produced by risk management.'

Safety

Safety is defined in Clause 3.26 as 'freedom from unacceptable risk.'

Severity

Severity is defined in Clause 3.27 as 'measure of the possible consequences of a hazard.'

Top Management

Top Management is defined in Clause 3.29 as 'person or group of people who directs and controls a manufacturer at the highest level.'

Use Error

Use Error is defined in Clause 3.3 as '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.'

In Vitro Diagnostic Medical Device

Verification is defined in Clause 3.31 as 'confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.'

Lesson Summary

- The complete name of ISO 14971:2019 is ISO 14971:2019 Medical Devices-Application of Risk Management to Medical Devices.
- The requirements of ISO 14971:2019 are applicable on phases of the life cycle of a medical device such that the risks associated with medical devices, their biocompatibility, data, and systems security, electricity, moving parts, radiation, and usability are addressed thoroughly.
- **The requirements of ISO 14971:2019 exempt the following from its scope:**
  • Decisions regarding the use of a medical device in the context of any specific clinical procedure;
  • Business risk management.
- The third edition of ISO 14971 focuses on the benefits of the use of medical devices. Also, the term Benefit-Risk Analysis has been aligned with the terminology used in other regulations.
- **Usage of Process**

The term Process, described in the third edition of ISO 14971, can be used to manage risks associated with medical devices and those related to data and systems security.

- **Risk Management Plan**
  A risk management plan describes the method to determine the overall residual risk and its acceptability criteria.

- **Requirements to Disclose Residual Risks**
  After evaluating overall residual risk and its acceptance, the requirements to disclose residual risks have been shifted and merged into one single requirement.

- **Risk Management Report**
  The Risk Management Plan demands a review of the medical device before its commercial distribution. The results of this review ought to be documented in the risk management report.

- **Production & Post-Production Requirements**
  The third edition contains restructured requirements regarding production and post-production activities. In addition, detailed information is given regarding the collection of the information. The clause also lists the actions to be taken after reviewing the collected data and determining its relevance to safety.

- **Information Annexes**
  In the third edition of ISO 14971, more information and rationale for the requirements have been given in Annex A. The data covering correspondence between the clauses of the second edition with the third is provided in Annex B.

- **The Reason to Update ISO 14971**
  Medical devices need to be managed regarding the risks they can pose. Therefore, proper risk management is necessary to be carried out during the entire life cycle of a medical device. The International Organization for Standardization has devised the standard ISO 14971 to help the companies carry out the proper risk management process for their products.

- The previous versions of ISO 14971 were hard to navigate. They also contain inefficient information regarding the safety of medical devices.

- Earlier versions of ISO 14971 failed to guide the medical device manufacturers regarding risk management, hence were unable to

complete the standard criteria.

- The predecessors of ISO 14971 contained old definitions that do not fulfill risk management requirements for the modern medical device industry.

- **Correspondence with Other Standards**
  To address the shortcomings present in the previous editions of ISO 14971, the International Standard for Standardization (ISO) and International Electrotechnical Commission (IEC) came together in 2016 to plan changes in the existing standard; the new standard was released on December 18, 2019. These updates also put their emphasis on the post-market FDA situation.

- **Overview of Changes Made in ISO 14971**
  • New terms and definitions
  • Additional risk management guidance
  • Other requirements regarding production and post-production
  • A clause on normative references.

- **Overview of Changes Made in ISO TR 24971**
  • Guidance on risk management for in-vitro diagnostic devices
  • Risk management plans
  • Risk concepts and techniques
  • Guidance on hazard detection.

Details of Changes Made in ISO 14971

- Clause 2 of ISO 14971:2019 is entirely new. It deals with Normative References, which is the requirement of the ISO Technical Management Board. ISO 14971's clause 2 states that there are "no normative references."

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  In the 2019 version of ISO 14971, clauses have been renumbered and incremented by 1 from this clause on wards.

Lesson Summary

- **Addition of New Terms & Definitions**
  Benefit (Clause-3.2)
  Harm (Clause-3.3)
  Reasonably Foreseeable Misuse (Clause-3.15)
  State of the Art (Clause-3.28)

- **Risk Management Plan**

The revised version contains the Risk Management Plan in Figure 1 of clause 4.1. The standard also shows variations at different steps while describing the risk management plan. A medical device manufacturer may need to revise his process drawings accordingly with the standard in this regard.

- **Risk Analysis (Clause-5.4)**
- Clause 5.4 on Risk Analysis has been made more precise and specific. The revised passage says:
- "The manufacturer shall identify and document the 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."
- Because many tools are only fault condition analysis, this section now requires the use of multiple risk analysis tools.

- **Benefit-Risk Analysis (Clause-7.4)**
  Clause 7.4 has been renamed Benefit-Risk Analysis. The risks declared as unacceptable; the standard requires only those risks to have a Benefit-Risk Analysis.

- **Production & Post-Production Activities (Clause-10)**
  Instead of waiting for complaints, clause 10 now focuses on having an active process for collecting information, and it also requires risk management in post-market surveillance.

Details of Annexes Added in ISO 14971:2019

- **Rationale for Requirements (Annex-A)**
- Annex-A helps in clarifying the reasons for having requirements in ISO 14971:2019.
- **Risk Management Process (Annex-B)**
- Previously, this annex contained a flowchart that gave an overview of the risk management process. In the revised version, Annex B includes Risk Management Process for Medical Devices and a table of correspondence between the standard's versions of 2007 to 2020.
- **Examples of Hazards, Foreseeable Sequences, Events, and Hazardous Situations (Annex-C)**
- This Annex was previously part of Annex E of ISO TR 24971. Now, it has been moved to ISO 14971:2019 and contains information on examples of Hazards, Foreseeable Sequences, Events, and

Hazardous Situations.

Details of Changes Made in ISO TR 24971

The addition of changes made in ISO TR 24971 in its 2019 version consists mainly of new Annexes. These annexes are listed below:

- **Risk Concepts (Annex-D)**
- This Annex refers to Risk Concepts Applied for Medical Devices. This clause has been deleted from ISO 14971. Instead, it is now redistributed throughout ISO TR 24971 as a numbered clause.
- **Risk Management for Cyber-security (Annex-F)**
  Annex F is the newly added Annex. It is four pages long and addresses risk management regarding cyber and data security along with the cyber-security process about ISO 14971.
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