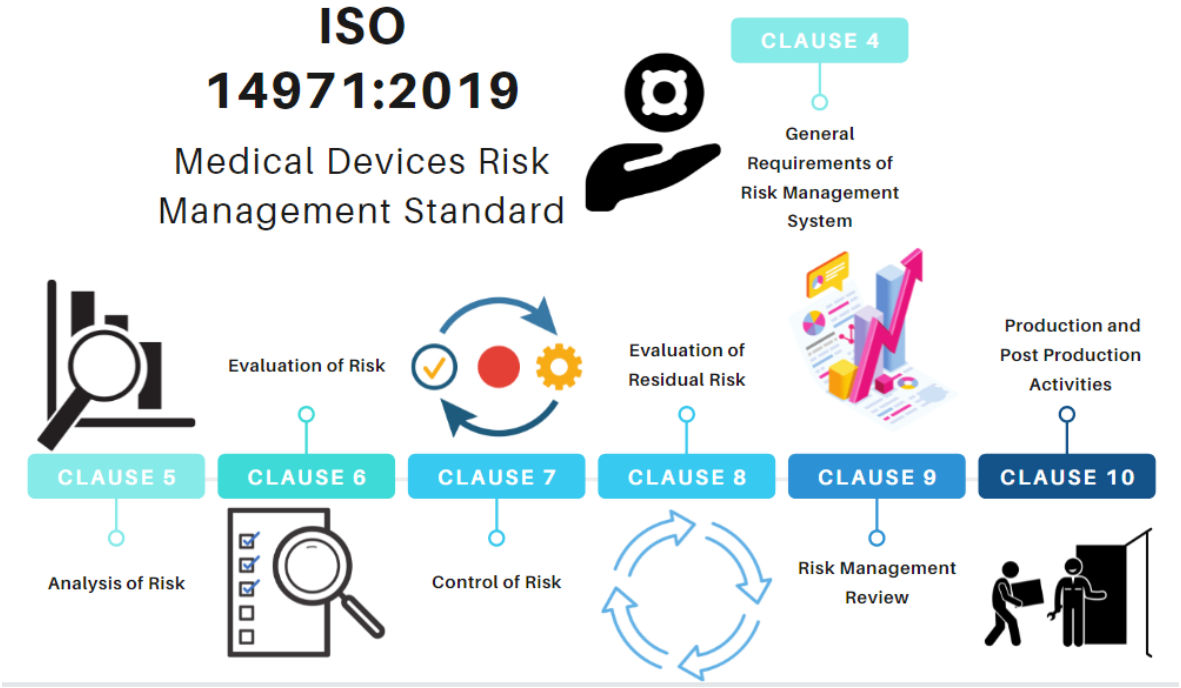
Module 2: Essentials of ISO 14971 & ISO TR 24971

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

- Discuss the composition of the ISO 14971 standard.
- Outline the changes in the ISO 14971 standard.
- List the specific changes made in the revised version of the ISO 14971 standard.
- Summarize the annexes, transitions, and clauses in the technical report of the ISO 14971 standard.
- List the risk management process steps in the ISO 14971:2019 standard.
- Discuss the sub-categories of risk management process steps.
- Explain the impact of ISO 14971:2019 in Europe.

ISO 14971:2019 - Illustration



ISO 14971:2019

The two most important aspects of ISO 14971 are risk management process and benefit risk analysis.

Risk Management Process

Clause 4.1 of the revised standard includes the Risk Management steps within its process. The steps needs to be incorporated in a complete plan which incorporates risk analysis, risk evaluation, risk control, evaluation of overall risk, risk management review and production, post production activities.

Benefit-Risk Analysis

Clause 7.4 has been renamed as Benefit-Risk Analysis. According to ISO 14971:2019, the Benefit-Risk Analysis will be required only for those unacceptable risks. The manufacturers should determine if there are any regulatory requirements to consider to conduct a Benefit-Risk Analysis.

Proactive Processes in Medical Device Risk Management Process

Need for Active Process

Instead of relying on complaints only, this standard stresses the need for an active process to collect information. This standard will help in showing correspondence to the post-market surveillance requirements set by the regulators. This standard provides guidelines on establishing a system that will help gather information regarding production, post-production, and other information relevant to this clause.

Advantages of Revision

It also helps in reviewing this collected information as well as the execution of the corrective action afterward. This standard text on post market activities is three times lengthier in the 2019 version as compared to its 2007 predecessor. This is because it requires risk management to be included in post-market surveillance.

Risk Analysis - Clause 5

What is Risk Analysis?

Risk analysis is conducted on each medical device, and foreseeable hazards are recognized. Risk is estimated for each hazardous situation. Functionalities that can likely influence the safety of the medical device are also noted. Risk analysis should also include a combination of hazardous events that can generate a hazardous situation. Likely foreseeable combinations of such events should also be assessed.

Updates in Clause 5

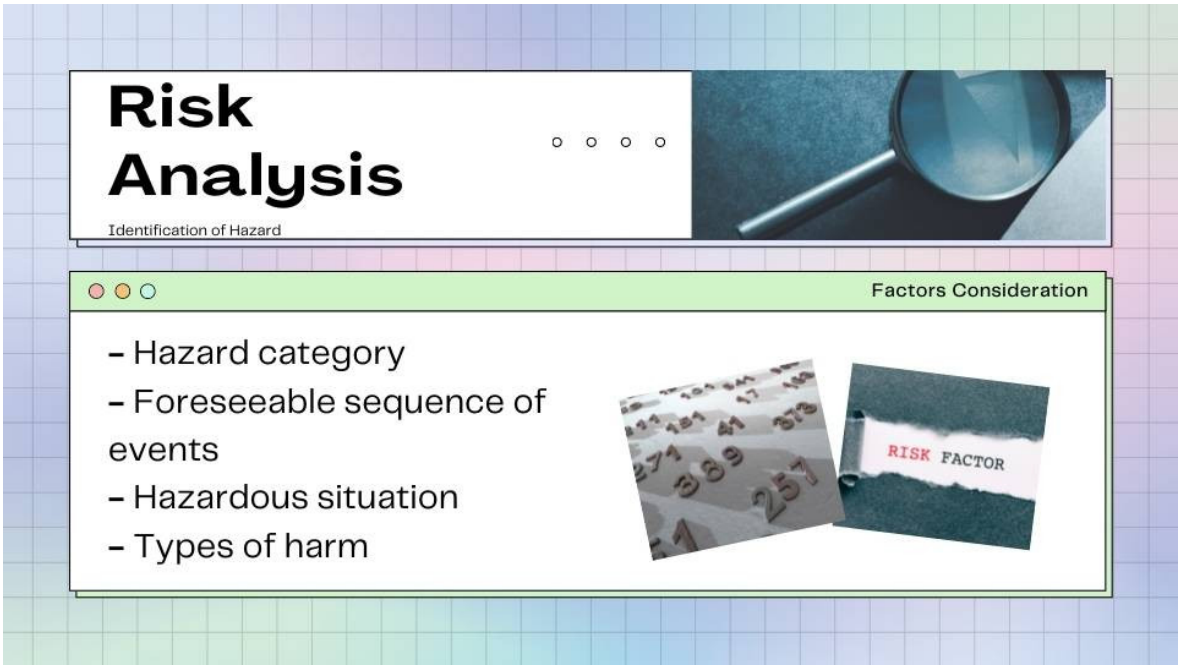
The ISO 14971:2019 categorically incorporates two important changes:

- IT security threat in the medical device will also be reflected in the scope of risk management. So the risk analysis should also consider it.
- The risk analysis will now incorporate likely foreseeable misuse of the medical device. Such as use of the device without reading IFUs i.e. instruction for use.

Example

When a heel stick is utilized to gather blood from infants for testing, the blood is warmed with a chemical pack. The sudden rupturing of this chemical pack is a foreseeable effect of the characteristics of the chemical pack, and the hazardous event is a combination of the heel stick used for collecting the sample (likely a negligible hazard) and the chemical pad used to ease the process of sampling. The risk management file is updated accordingly based on all analysis results.

Factors - Illustration



What is Risk Evaluation?

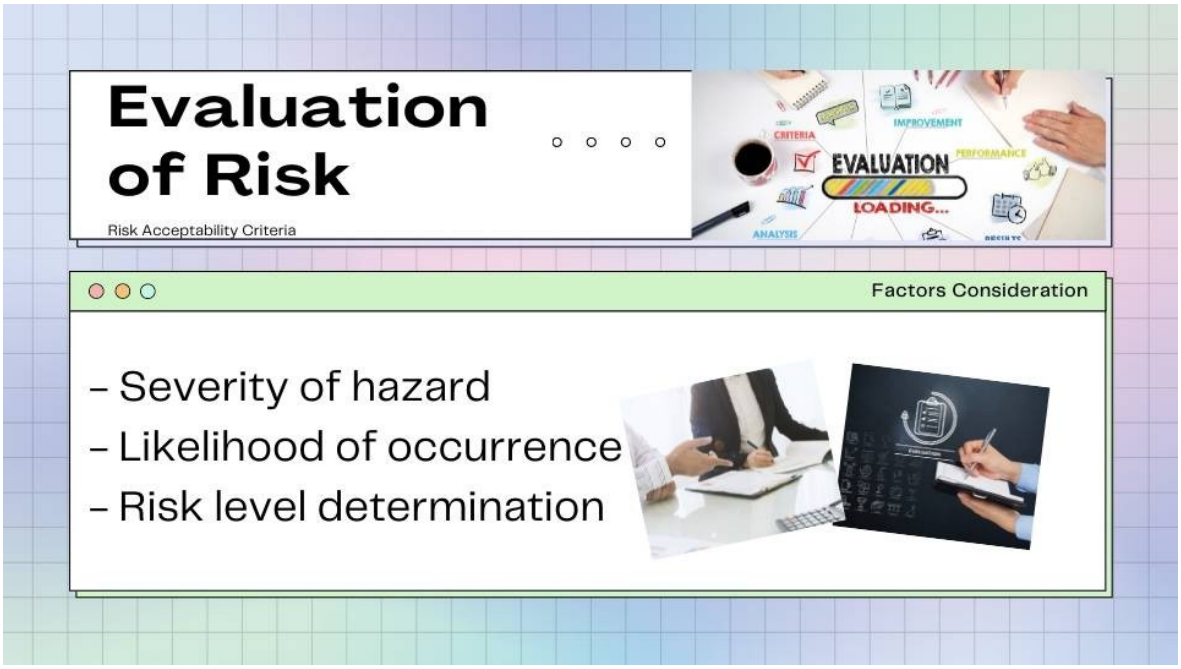
Each hazardous situation is further evaluated, and then the organization's risk acceptability criteria are employed to verify whether risk mitigation techniques are needed for listed hazards or not. The outcomes of risk evaluation are also reported in the risk management file.

Risk Evaluation Calculation

Risk evaluation is normally done by multiplying the severity of the hazard by the likelihood of its occurrence.

Risk Evaluation = Likelihood x Severity of Hazard

Factors - Illustration



Risk Control - Clause 7

What is Risk Control?

Risk control is a risk mitigation process in which unacceptable risk is mitigated through controls.

What can go wrong?

At times, controls enforced to mitigate a risk add different risk hazard. The effectiveness of the control is measured by reevaluation of residual risk, i.e., remaining risk after the control is implemented. Therefore these controls are ineffective unless and until, the new risks are within acceptable range or controlled within acceptable limits.

Factors to Select a Control

A risk control is selected based on the following factors:

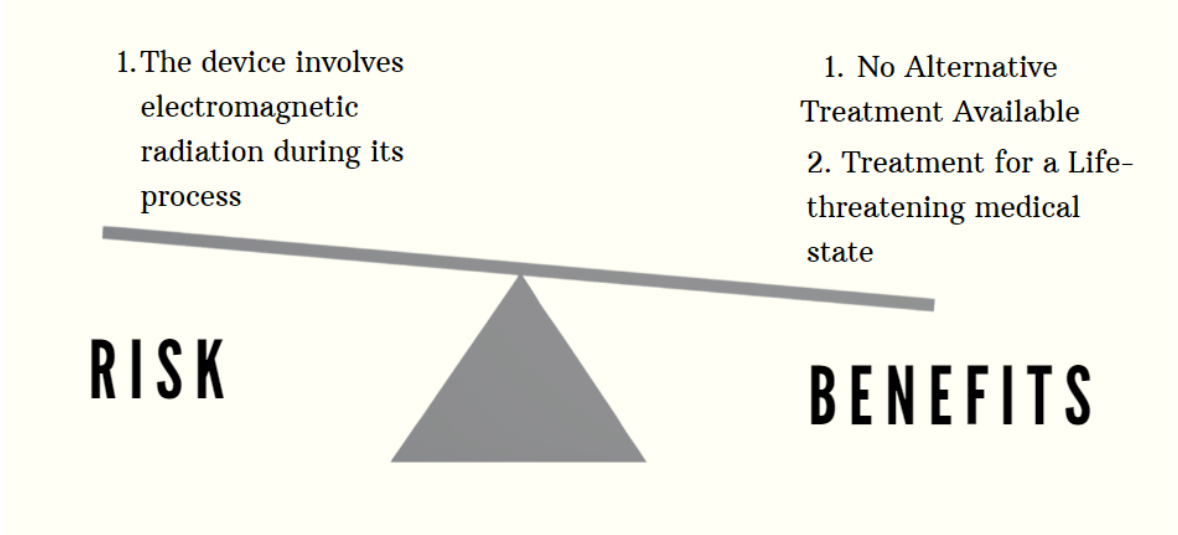
- Practicality (how useful the implemented control is)
- Simplicity (how easily it can be implemented)
- Economic feasibility (the cost of the control does not affect product profitability)

What should be done when Residual Risk is unacceptable?

If the residual risk is not acceptable, a risk benefit analysis is performed. Or when an additional control is impractical, then the risk-benefit analysis should direct whether the medical benefits of the device surpass the residual risk of that or not. Illustration for benefit-risk analysis is presented on **next page**.

Factors - Illustration

Benefit - Risk Analysis



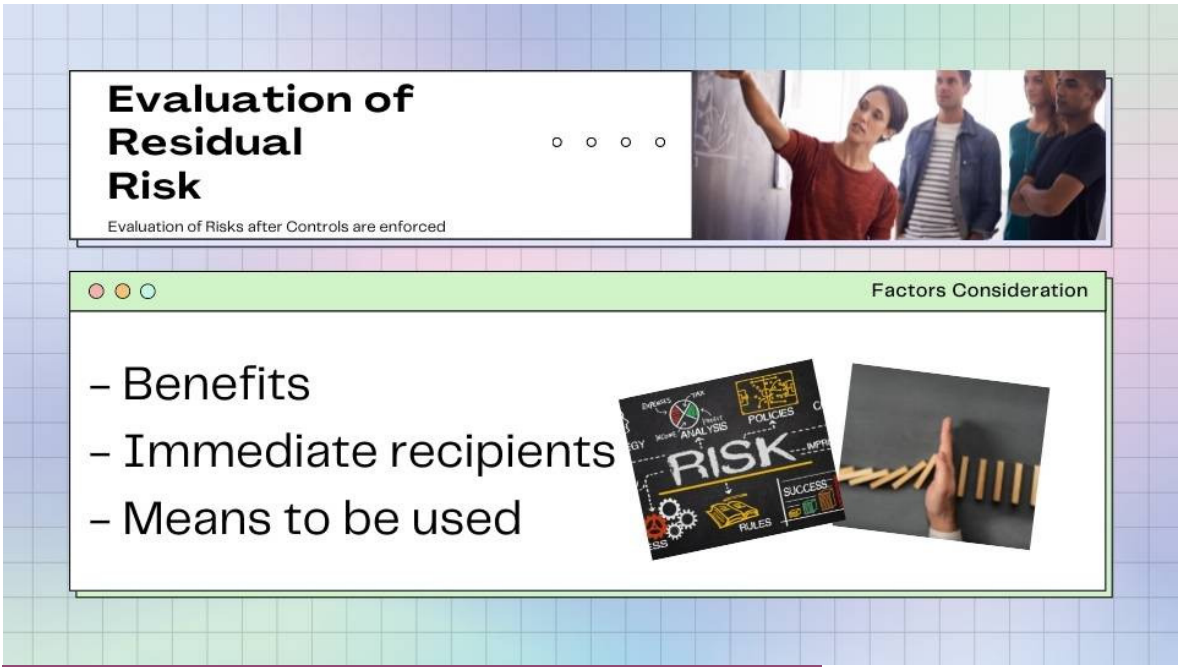
Note: More details about risk benefit analysis is presented in the next topic on ISO TR 24971.

Risk Evaluation of Overall Residual Risk - Clause 8

What is Risk Evaluation of Overall Residual Risk?

Residual risk evaluation is conducted after all controls are implemented. Any change in any control, or in the process of medical device functionality may require reevaluation of overall residual risks.

Risk Analysis Factors - Illustration



Risk Management Review - Clause 9

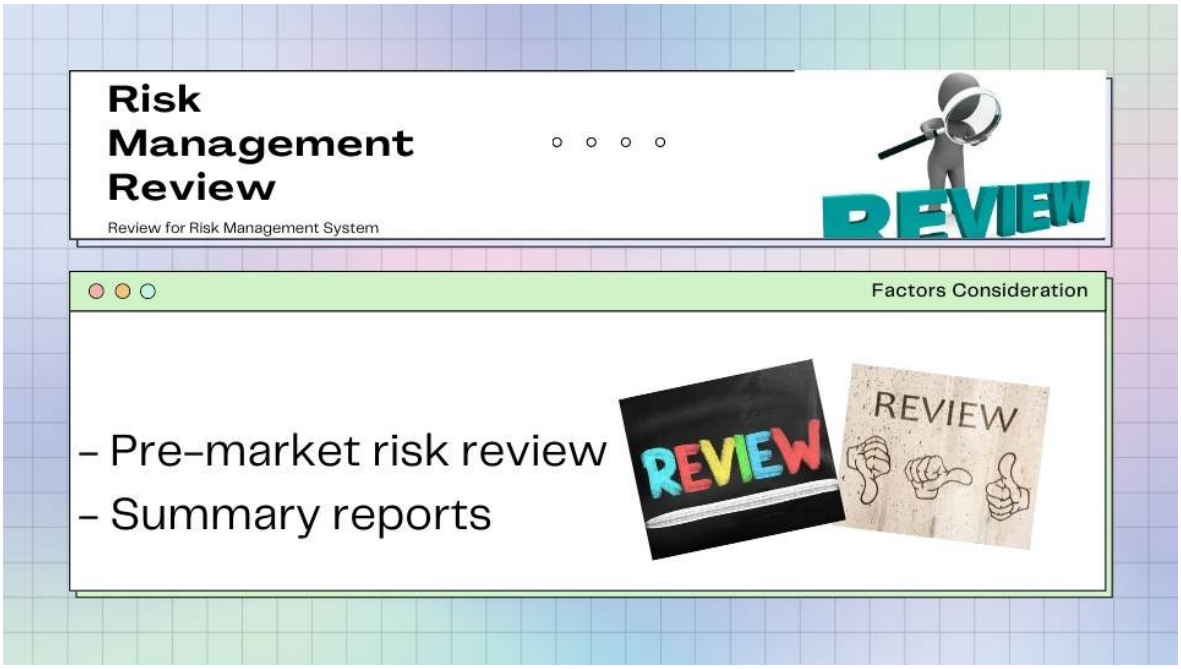
What is Risk Management Review?

As management reviews are conducted for the Quality Management System, similarly, such reviews should be performed for the risk management system as well. Before a medical device goes to the commercial market, a risk management review needs to be done. Based on the review, a risk management report is finalized. The report should incorporate the outcomes of the review and is incorporated into the overall risk management file.

Risk-Benefit Analysis

A risk benefit analysis is conducted when the residual risk is not tolerable. When incorporating more controls are not reasonable, then the risk benefit analysis should help the organization whether the medical benefits of the device outweighs the residual risk.

Factors - Illustration



Production & Post-production Activities - Clause 10

What is Production & Post-production Activities?

A monitoring system is needed to identify the performance of the medical device. The monitoring system should be instituted, developed, and maintained. The outcomes need to be recorded in the risk management file.

Examples

- Updates that comes from production incorporate any defects or failures in clinical trials.
- Updates from post-production activities incorporate any customer complaints or product failures that may enhance the risk (as likelihood of occurrence increases).

Factors - Illustration

Production & Post-Production Activities

Clause 10 has been renamed as “Production and post-production activities”. This clause now corresponds to Clause 8 of ISO 13485 on Measurement Analysis and Improvement, which deals with:

- Complaint handling

- Customer feedback
- Internal auditing
- Control of non-conforming products
- Data analysis
- Improvements

Annexes in ISO 14971:2019

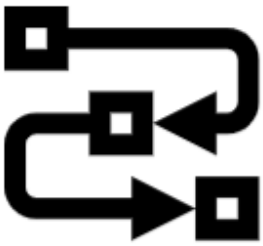
Annexes in ISO 14971:2019

The changes made in ISO 14971 do not encompass the clauses only. Significant changes have also been made in the annexes of the standard.

Rationale for Requirements (Annex-A)

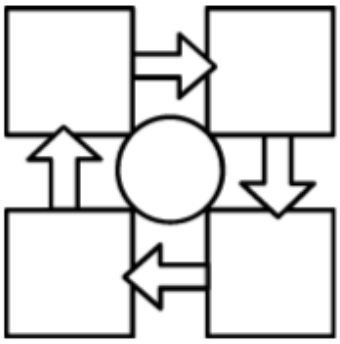
This annex clarifies the rationale for requirements in this standard. It can assist those manufacturers using this standard to learn about the reasons for the requirements given in this standard.

Risk Management Process (Annex-B)



Previously, this annex had a flowchart that gave an overview of the risk management process. However, Annex B in the revised standard contains the Risk Management Process for Medical Devices and a table that shows the correspondence between 2007 and the 2019 version of the standard.

Examples of Hazards, Foreseeable Events, and Hazardous Situations (Annex-C)



This annex differs from the one present in the 2007 version of the standard as it gives guidance information on Examples of Hazard, Foreseeable Events, and Hazardous Situations. This guidance information was previously present in Annex E of ISO TR 24971. In contrast, Annex C was used to identify Medical Device Characteristics, although now it has shifted to Annex A in ISO TR 24971.

ISO/TR 24971 - Medical Devices - Guidance on the Application of ISO 14971

ISO TR 24971 guides professionals how to implement and manage the requirements of ISO 14971:2019. We will show with examples how it is done.

Hazard Relationship with Situations Leading to Harm

Below is an interesting example of how an electrically motivated medical device can become a complex event with different harmful impacts along with different level of probabilities.

Hazard Analysi

Hazard: Electricity

Reality: A line voltage of 220 volts of an insulated wire is present beneath the cover of an electrically motivated medical device.

Events and Incidences:
a. Insulation material is deteriorated by cracks and is exposed (Pa = 0.01)
b. Insulation material wears off from the wire and is detached (Pb = 0.10)
c. User connects and turns on the device (Pc = 0.10)
d. User removes and discard cover (Pd = 0.10)

Hazardous Situation 1: User is exposed to line voltage i.e. P1 = Pa * Pb * Pc * Pd = 1 x 10-5

Probability of Harm

Probability that user touches the wire and experiences:

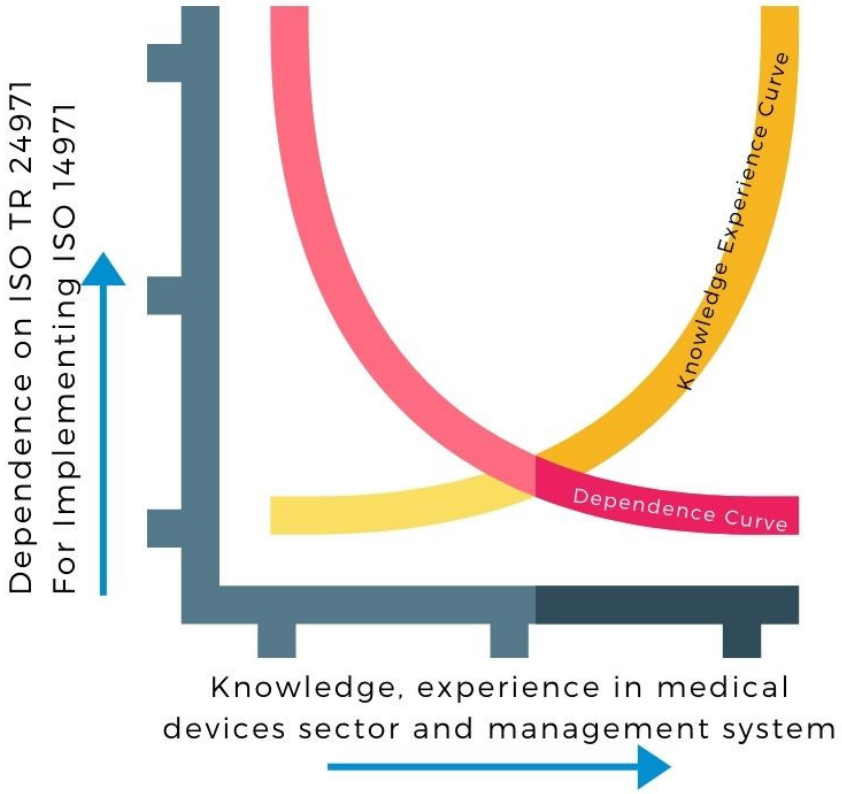
- Discomfort (P2 = 0.10)
- Burn (P2 = 0.01)
- Death (P2 = 0.001)

Dependence on ISO TR 24971 for Implementing ISO 14971

Explanation

In the next tab, an illustration is presented to show relationship between person's experience and the need of ISO TR 24971 for implementing ISO 14971. The illustration will show the dependence level with experience and knowledge. Obviously high experienced people in medical devices compliance won't need a guide like TR 24971 to implement ISO 14971. The red curve shows dependency on ISO TR 24971 for implementing ISO 14971 whereas the yellow curve shows the knowledge and experience of a professional.

Illustration

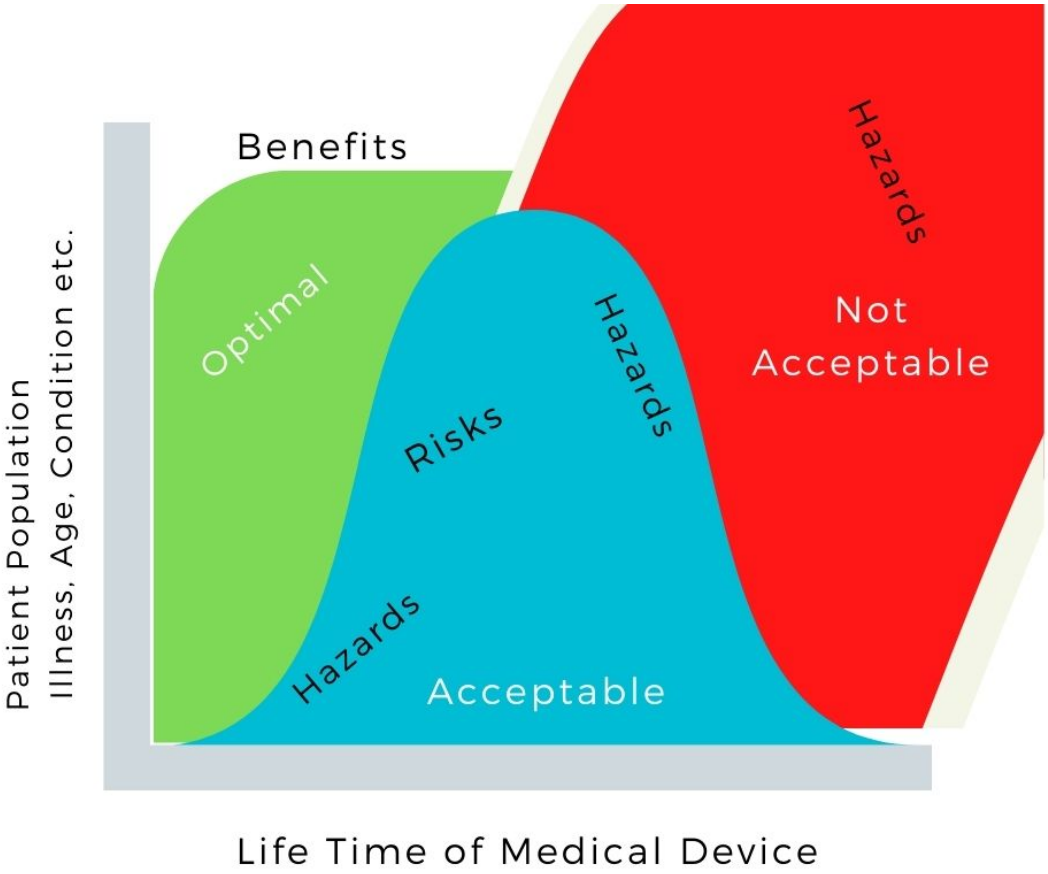


Time Oriented Analysis of Benefit Versus Risk

Explanation

As a new state-of-the-art medical device technology is introduced and approved. It has more benefits than hazards and is usually in the optimal range. As the time progresses there are new state-of-the-art medical devices in the market and the old design and technology is becoming obsolete with certain issues in it which are referred as hazards and other types of risks. For a certain time, it is acceptable in the market till the time comes when it becomes obsolete since the benefits are no longer recognized and the device has more hazards compared with new technology which is more safer.

Illustration



ISO TR 24971

The technical report of ISO 14971, i.e., ISO TR 24971, has also seen many significant updates in its 2020 version, and its revised version covers the following topics:

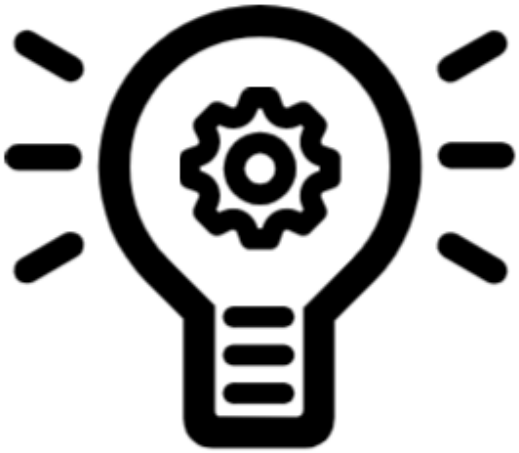
- Risk management for In-vitro diagnostic devices
- Risk management plans
- Risk concepts and techniques
- Guidance on hazard identification

This information was previously present in the older version ISO 14971. Still, with the input from the ISO Technical Management Board, the technical committee decided to list the information annexes primarily in ISO TR 24971.

The new annexes which have been added to the technical report cover different topics on guidance. However, it should be noted that this guidance information cannot be confused with the requirements of this standard. These annexes are the source of information that the manufacturers may require to comply with the standard and its

implementation.
Annexes are continued on next page...

Risk Concepts (Annex-D)



Annex D covers Risk Concepts Applied to Medical Devices. This annex was omitted entirely from the ISO 14971 and was instead redistributed as a numbered clause in ISO TR 24971.

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

The ISO Technical Committee 212, responsible for IVD standards, performed extensive revisions in this annex. The revised annex now includes information not only on IVD devices but on all medical devices. It provides manufacturers with valuable information on how they should deal with false positives and false negatives within the risk management system.

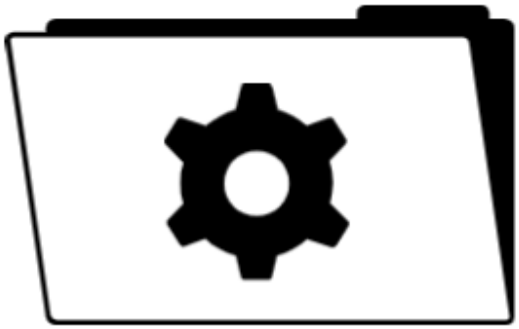
New Annexes in ISO TR 24971

Two new annexes, i.e., Annex F and Annex G, have been added to the technical report, and they cover Risk Management for Cyber-security and Risk Management File, respectively.

Risk-Management for Cyber-Security (Annex-F)

This four-page long annex covers risk management for cyber and data security as well as other cyber-security processes related to ISO 14971.

Risk Management File (Annex G)



The components and devices covered by this annex do not comply with the requirements of ISO 14971. It discusses the appropriate process that can help in the remediation of the risk management file. This annex may be helpful for the companies who are planning to update their risk management systems to comply with the requirements of ISO 14971:2019.

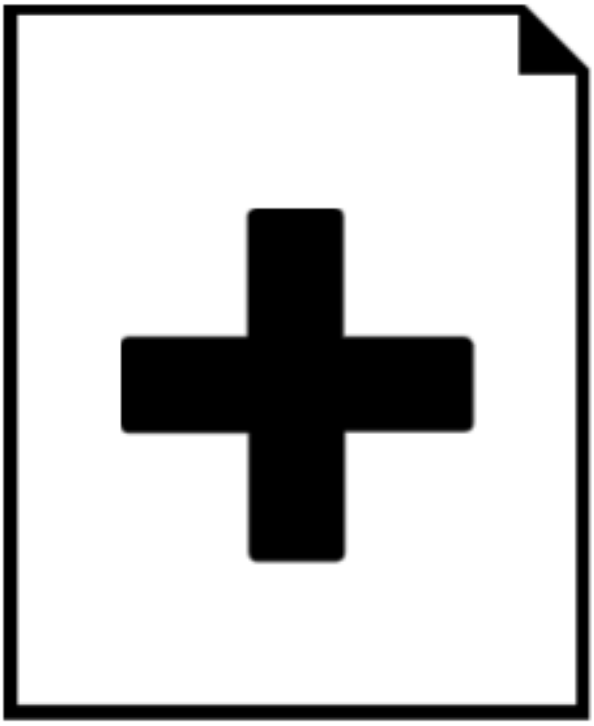
Clauses in ISO TR 24971

Benefit-Risk Analysis

Clause 7.4 in ISO TR 24971 now contains three more pages to cover benefit and benefit-risk analysis. For example, it tells manufacturers about the benefit, which does not help attain economic or business advantages.

Clause 7.4.2 gives an overview of clinical benefits, while clause 7.4.5 provides three examples of the conclusions of the benefit-risk analysis.

Risk Management in Post-Market Surveillance



Compared to ISO TR 24971:2013, which contained only one page on risk management in post-market surveillance, four additional pages are now present in ISO TR 24971:2019 in Risk Management in Post-Market

Surveillance.

Risk Management Process Steps in ISO 14971:2019

In industrial manufacturing processes, the process of risk management is of great importance. It assists the manufacturers in determining the risks associated with the manufactured products, or otherwise, there will be chances of incidents that can happen with the consumers.

The importance of this risk management process increases several folds when it comes to medical devices. Therefore the International Organization for Standardization (ISO) has formulated a standard with ISO 14971 in this regard. ISO 14971 provides a complete risk management framework to address the risks associated with design, development, production, and post-production activities for all medical devices.

Deficiencies in EU MDR & IVDR

The European directives and regulations such as EU MDD, and EU IVDR require manufacturers to implement a quality management system that addresses risk management. However, these steps are not sufficient enough as they do not address every aspect of risk management. Therefore, there was a need for a more detailed and state-of-the-art standard to address this risk management issue.

ISO 14971:2019 & ISO/TR 24971

The publication of the third edition of ISO 14971 along with its technical report, i.e., ISO/TR 24971, provides detailed guidance on the risk management concepts while showing its compliance to the essential safety and performance principles. These standards thus can assist in risk management regarding the life-cycle of medical devices to a greater extent.

Steps for Risk Management Process in ISO 14971:2019

Following are the steps which constitute the Risk Management Process in ISO 19471:2019:

Risk Management Plan (Step-1)

A risk management plan tells the manufacturers regarding the risk management activities which they should conduct over the life cycle of a medical device. This plan contains criteria for:

- Risk acceptability that is based on regulations
- International standards
- State-of-the-art
- Stakeholder concerns
- Activities that will help in verifying the implementation and effectiveness of risk control measures
- The information which is collected during production and post-market activities.

The manufacturer will be liable to develop a risk management report after reviewing the plan’s execution.

Risk Assessment (Step-2)

Risk Analysis

Risk analysis comprises of recognition and documentation of:

- The intended use of the medical device
- Reasonably Foreseeable Misuse errors (which also include abnormal use of the medical device) along with its correct use.

These risks are considered and reduced by adding controls through the methods of Usability Engineering.
In this risk analysis, those reasonably foreseeable events that can contribute to hazardous situations, such as the medical devices' intended use, reasonably foreseeable misuse, and safety-related characteristics, are added. In the final step of risk analysis, the severity of harm and the probability of each hazardous situation are estimated.

Risk Evaluation

During this phase, risks are analyzed using criteria for risk acceptability which is defined in the risk management plan. The risk becomes a residual risk if it becomes acceptable, or otherwise, it becomes necessary to perform risk control activities. All of these evaluations, as part of the risk management file, are listed down.

Risk Control (Step-3)

Reduction of risks at an acceptable level can be achieved by designing the devices with inherent safety to prevent the occurrence of hazardous situations. If this is not convenient, then a device should be designed to minimize the probability of occurrence of any dangerous situation. In case these protective measures do not play their role in risk reduction, safety information should be provided to the device’s users in the

following form:

- Instructions
- Warnings
- Contraindications
- User training

Ensuring the Measures

It is important to ensure that these risk control measures do not pose additional risks to the users.

Implementing & Analyzing

The measures taken for reducing risks are implemented, verified for their effectiveness, and documented. Residual risks are analyzed using risk acceptability criteria. More risk control activities should be implemented if the risk is considered unacceptable.

Benefit-Risk Analysis

In cases where risk controls are not feasible to implement, a **Benefit-Risk Analysis** can help determine whether the benefits of using a medical device will exceed its residual risk. The device can then either be modified or limited in its intended use.

Evaluation of Overall Residual Risk (Step-4)

An analysis of all the individual risks should be made to ensure that these small risks do not combine themselves into a significant unexpected risk. For this purpose, a method and criteria are documented in the risk management plan, ensuring the acceptability of the overall residual risk.

The criteria for tolerating overall residual risk can vary from the requirements of acceptability of basic risk. This variation is found from organization to organization in their procedure of determining the acceptable risk. The users should be told about any residual risks inherent with a device's use even after all the risk control measures have been taken. Thus, this will allow the users to choose to continue with the same device or find its alternative.

Risk Management Review (Step-5)

This step ensures the integrity of the risk management plan by ensuring its proper execution. It also documents the acceptability of residual risks. This risk management review is then stated in the risk management report, providing evidence regarding its effective implementation, achieving objectives, and establishing methods used to collect production and post-production information.

Production and Post-Production Activities (Step-6)

This step is divided into the following four phases:

Phase 1

Establishment of a system for the collection and analysis of information collected from production and post-production activities.

Phase 2

Collect relevant information for the medical device from users, distributors, publicly available information, literature, etc.

Phase 3

Reviewing the information collected in phase 2 to determine if it is appropriate for the device's safety. If a new Benefit-Risk Assessment is required, it will be necessary to assess any previously unidentified hazards or hazardous situations, any unknown risks, or significant changes affecting the risks.

Phase 4

After reviewing the risk management file, implementation of actions to determine whether new risks need to be assessed or if the previous risks need an assessment. This phase also determines whether it will be appropriate to take action against the already placed devices on the market. This step can also help in assessing the effects of previous risk management activities. There may also be a need for taking additional risk control measures.

Benefit Risk Analysis - Demystified for Implementation

Factors for Benefit Evaluation

ISO TR 24971:2020 Clause 7.4.2 states factors needed to reflect when evaluating benefit. Factors are:

- Expected device performance
- Expected clinical outcome at that performance level
- Competing devices
- Alternative treatment modalities

Reliability of Benefit Estimation

Reliability of the benefit estimate is vital and is reliant on validity of information. One issue is trying to assess various outcomes for instance pain versus mobility or short-term versus long-term effects.

Other Considerations for Benefit

There are some other considerations which needs to be taken into account such as:

- Benefit Type
- Benefit Magnitude
- Probability the patient will experience the benefit
- Benefit Duration

Benefit Risk Analysis

Benefit Risk analysis needs to be a rational study with a focus to prove that your device benefits outweighs its risks and that there is no other device in the market that undermines your benefits and disturbs the Benefit-Risk Analysis for your device.

State of the Art - Medical Device

The state of the art reflects what is presently and commonly acknowledged as good practice. The state of the art does not mandate the most bleeding technology. Thus, it is more beneficial to consider

state of the art as meaning the present state of all competitive treatment solutions.

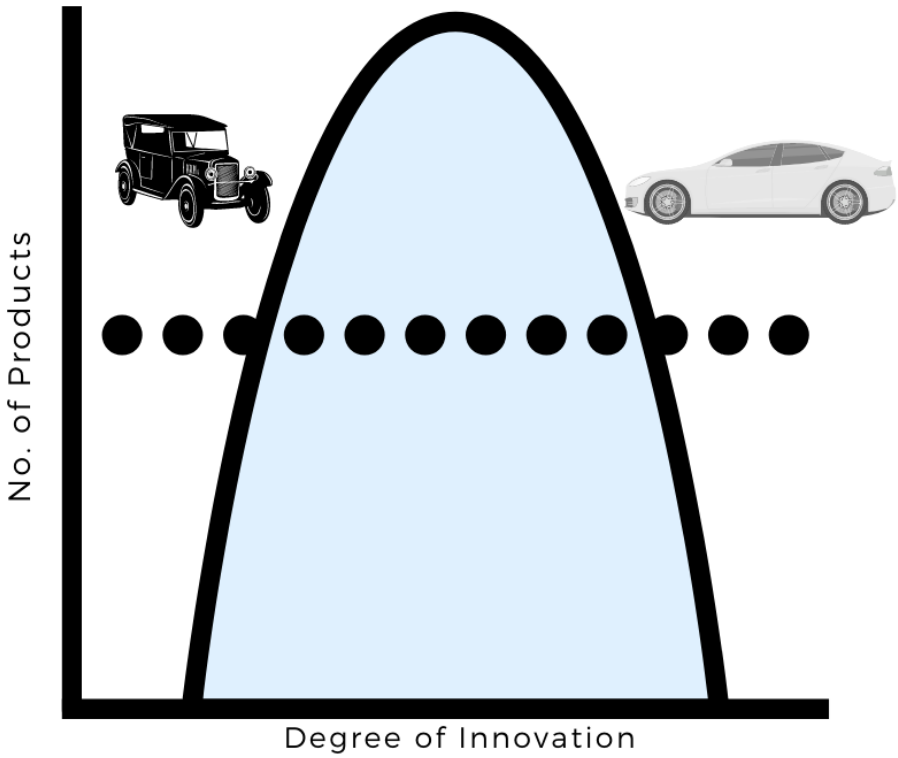
Misconception

Most of the professionals think “state of the art” as being the most latest stage of a technology. For instance, many will consider a solar energy motivated pacemaker to be state of the art, which is not the case at the moment.

The Fact!

“State of the art” implies only to those devices that are developed and endorsed by regulatory procedures for marketing in the designated area. It means any device undergoing trials with some innovative high-tech idea is not a "State of the art". On the innovation axis as illustrated in next tab, state of the art is in the middle of the bell curve rather than in the right extreme.

Illustration



Impact of ISO 14971:2019 in Europe

ISO 14971:2019 is an international standard that deals with risk management in medical device manufacturing and can be applied anywhere globally. But since other national bodies have not completely

endorsed this standard, many regions have chosen to implement specific requirements of this standard by changing the guidance information. They have done this by selecting the annexes from the standard and then applying them in their respective regions.

Controversies in EN ISO 14971:2012

To address the issues present in the risk management process of Medical Devices, Active Implantable, and In Vitro Diagnostic Directives, the European Committee for Standardization (CEN) added informative annexes (Z annexes) in 2012's version of the standard. However, this CEN move was considered the misinterpretation of ISO 14971 by the international medical device community.

EU MDR and EN ISO 14971:2019:
As a form of corrective measure, the EU MDR and EN ISO 14971:2019 now address these controversies found in the 2012 version.

ISO 14971:2019 and the European Union

Although the previous version of ISO 14971:2012 with the name EN ISO 14971:2012 is still in existence in the European Union, it has lost its status as a "state-of-the-art" risk management standard after the release of the European version of ISO 14971:2019 (known as EN ISO 14971:2019) on December 18, 2019.

Harmonization of EN ISO 14971:2019

The British Standards Institution (BSI) has declared the EN ISO 14971 as the “state-of-the-art” risk management standard for medical devices. The 2012 version is no longer considered a state-of-the-art standard anymore. Although declared a state-of-the-art standard for risk management, it will not be harmonized with EU Medical Device Directives (EU MDD).

Also, this standard has not been harmonized with the EU Medical Device Regulations (EU MDR) as of yet. The European Commission is now proposing a plan to harmonize the EN guidance with 14971 requirements.

Other Important Online Courses

Other important courses on Alison under this subject area are:

- Essentials of European Medical Device Regulations (EU MDR) - 2017/745
- ISO 9001:2015 - Quality Management System (QMS)
- ISO Management System Audit Techniques and Best Practices
- ISO 13485:2016 - Quality Management Systems for Medical Devices
- Fundamentals of Six Sigma (6σ) - Six Sigma White Belt
- The Seven Basic Quality Control (7 - QC) Tools

Lesson Summary

- **What is ISO 14971?**
  ISO 14971 is an international standard that helps manufacturers to develop a risk management system to cope with the risks associated with medical devices. The complete name of the

standard is ISO 14971:2019 Medical Devices-Application of Risk Management to Medical Devices.

- **There are two standards**
  1. ISO 14971:2019 consists of the documented part, i.e., what to do.
  2. ISO/TR 24971 consists of the standard's technical report, i.e., how to do.

- **Overview of Changes in the ISO 14971 Standard**
  Some major revisions have been made in the updated version of ISO 14971. The document has been rearranged in certain aspects. In addition, many new terms and definitions have been included, along with additional risk management guidance and other detailed requirements.

- **Specific Changes Made in Revised Version of ISO 14971**
  • Addition of Normative References
  • Addition of New Terms and Definitions
  • Risk Management Plan
  • Clarity in Risk Analysis
  • Benefit-Risk Analysis
  • Production & Post-Production Activities

Annexes in ISO 14971:2019

The changes made in ISO 14971 do not encompass the clauses only. Significant changes have also been made in the annexes of the standard.

- **Rationale for Requirements (Annex-A)**
- This annex clarifies the rationale for requirements in this standard. It can assist those manufacturers using this standard to learn about the reasons for the requirements given in this standard.
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Foreseeable Events, and Hazardous Situations. This guidance information was previously present in Annex E of ISO TR 24971. In contrast, Annex C was previously to identify Medical Device Characteristics, although now it has shifted to Annex A in ISO TR 24971.

- **Summary of ISO TR 24971 Update**
  The technical report of ISO 14971, i.e., ISO TR 24971, has also seen many significant updates in its 2019 version, and its revised version covers the following topics:
  • Risk management for In-vitro diagnostic devices
  • Risk management plans
  • Risk concepts and techniques
  • Guidance on hazard identification.

- **Risk Concepts (Annex-D)**
  Annex D covers Risk Concepts Applied to Medical Devices. This annex was omitted entirely from the ISO 14971 and was instead redistributed as a numbered clause in ISO TR 24971.

- **In-Vitro Diagnostic (IVD) Devices (Annex-H)**
  The ISO Technical Committee 212, responsible for IVD standards, performed extensive revisions in this annex. As a result, the revised annex now includes information not only on IVD devices but on all medical devices. In addition, it provides manufacturers with valuable information on how they should deal with false positives and false negatives within the risk management system.

- **New Annexes in ISO TR 24971**
  Two new annexes, i.e., Annex F and Annex G, have been added to the technical report, and they cover Risk Management for Cyber-security and Risk Management File, respectively.

- **Risk-Management for Cyber-Security (Annex-F)**
  This four-page long annex covers risk management for cyber and data security as well as other cyber-security processes related to ISO 14971.

- **Risk Management File (Annex G)**
  The components and devices covered by this annex do not comply with the requirements of ISO 14971. It discusses the appropriate process that can help in the remediation of the risk management file. This annex may be helpful for the companies who are planning to update their risk management systems to

comply with the requirements of ISO 14971:2019.

- **Benefit-Risk Analysis**
  Clause 7.4 in ISO TR 24971 now contains three more pages to cover benefit and benefit-risk analysis. For example, it tells manufacturers about the benefit, which does not help attain economic or business advantages.
- Clause 7.4.2 gives an overview of clinical benefits, while clause 7.4.5 provides three examples of the conclusions of the benefit-risk analysis.

- **Risk Management Process Steps in ISO 14971:2019**
  The importance of this risk management process increases several folds when it comes to medical devices. Therefore the International Organization for Standardization (ISO) has formulated a standard with the name of ISO 14971 in this regard. ISO 14971 provides a complete risk management framework to address the risks associated with design, development, production, and post-production activities for all medical devices.
- **Flaws in EU MDR & IVDR**The European directives and regulations such as EU MDD, EU MDR, and EU IVDR require manufacturers to implement a quality management system that addresses risk management. However, these steps are not sufficient enough as they do not address every aspect of risk management. Therefore, there was a need for a more detailed and state-of-the-art standard to address this risk management issue.
- **ISO 14971:2019 & ISO/TR 24971**
- The publication of the third edition of ISO 14971 and its technical report, i.e., ISO/TR 24971, provides detailed guidance on the risk management concepts while showing its compliance with the essential safety and performance principles. These standards thus can assist in risk management regarding the life-cycle of medical devices to a greater extent.

Steps for Risk Management Process in ISO 14971:2019

- Risk Management Plan (Step-1)
- Risk Assessment (Step-2)
  • Risk Analysis
  • Risk Evaluation

- Risk Control (Step-3)
- Evaluation of Overall Residual Risk (Step-4)
- Risk Management Review (Step-5)
- Production and Post-Production Activities (Step-6)
- This step is divided into four phases.

Impact of ISO 14971:2019 in Europe

ISO 14971:2019 is an international standard that deals with risk management in medical device manufacturing and can be applied anywhere globally. But since other international bodies have not reviewed this standard, many regions have chosen to implement specific requirements of this standard by changing the guidance information. They have done this by selecting the annexes from the standard and then applying them in their respective regions.