Things to Know About ISO 14971:2019

General information about ISO 14971
ISO 14971, Medical devices — Application of risk management to medical devices, provides guidance for the application of risk management processes for the manufacturers of medical devices. The standard helps manufacturers identify the hazards associated with the devices, estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of the controls.


Implementation of risk management processes according to ISO 14971 is required by multiple standards, for example IEC 60601-1 (for medical electrical equipment), IEC 61010-2-040 (for sterilizers) and IEC 61010-2-101 (for in vitro diagnostic medical equipment).

Why should I care about ISO 14971?

Compliance with the requirements of ISO 14971:2019 will be required by newly published IEC 60601-1:2005/AMD 2:2020. Additionally, the U.S. Food and Drug Administration (FDA) has already granted Recognized Consensus Standard status to the 2019 edition of the ISO 14971. The agency will accept declarations of conformity to ISO 14971:2007 included in premarket submissions until Dec. 25, 2022. From that point on, providing declarations of conformity to the standard’s 2019 edition will be required.
What changes with ISO 14971:2019?

The best way to start reading any standard is to verify the scope first. The scope of ISO 14971 has changed to include risks related to data and systems security and emphasize the importance of cybersecurity. With this change, manufacturers can no longer limit their risk analysis to electrical, mechanical and fire related hazards. Product safety shall now be understood much more widely and include topics like security of sensitive patient data.

Terms and definitions (cl. 3)

In the section “Terms and definitions” (cl. 3), pay attention to following changes:

- The definition of accompanying documentation (cl. 3.1) was modified to include auditory, visual or tactile materials. This means the accompanying documentation is no longer only a user manual, but it also includes training, videos and other materials provided with the product.
- The definition of benefit (cl. 3.2) was added to the standard. The standard now clearly defines the benefit of a medical device as the positive impact or desirable outcome on the health of an individual or the positive impact on patient management or public health.
- The word “physical” was removed from the definition of harm (cl. 3.3). The change significantly extends the definition and scope of ISO 14971:2019. For example, harm now also includes mental discomfort caused by an incorrect or false positive diagnosis or leakage of sensitive, medical records.
- New notes were added to the definition of manufacturer (cl. 3.9). The notes clarify which entity shall be considered the manufacturer:
  - 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 or the person responsible for the design and/or manufacture of that accessory.
- The definition for reasonable foreseeable misuse (cl. 3.15) was added. The manufacturer shall consider the reasonable, foreseeable misuse of a product in a way not intended by the manufacturer but which can result from readily predictable human behavior. The manufacturer shall consider behavior of all types of users (lay operator and professional users). Remember that reasonably foreseeable misuse can be intentional or unintentional.
- The definition of state of the art (3.28) was added. The definition clarifies that the state of the art is a developed stage of technical capability at a given time. It is worth noting that the state of the art does not necessarily imply the most technologically advanced solution.
- New notes for the definition of use error (cl. 3.30) were added. The definition now includes user action or lack of user action that leads to a different result than intended by the manufacturer or expected by the user, including the inability of the user to complete a task. The standard emphasizes that users might be aware or unaware that a use error has occurred. It also clarifies that an unexpected physiological response of the patient or a malfunction of a medical device shall not be treated as use error.

General requirements for risk management system (cl. 4)

In the section “General requirements for risk management system” (cl. 4), it is worth noting the change in requirements to “Risk management plan” (cl. 4.4). The manufacturer needs to establish risk acceptability criteria that are appropriate for the particular medical device. Now these criteria shall also include information about a method to evaluate the overall residual risk and criteria for acceptability of the risk. ISO 14971:2019 does not specify one, preferred way for evaluating the overall residual risk. The manufacturer is responsible for determining an appropriate evaluation method. However, guidance document ISO/TR 24971:2020 provides examples of approaches that can be used in defining the evaluation method.
**Risk analysis (cl. 5)**

The text of the “Intended use and reasonably foreseeable misuse” (cl. 5.2) clause was revised to emphasis that the intended use should take into account information such as the intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment and operating principle. The use specification according to IEC 62366 can be used as an input to determine the intended use.

A note was added to the “Identification of characteristics related to safety” (cl. 5.3) clause that creates a connection between characteristics related to loss or degradation of the clinical performance of a medical device that can result in unacceptable risk and essential performance according to IEC 60601-1.

During identification of hazards and hazardous situations, the manufacturer shall consider the reasonably foreseeable sequences or combinations of events that can result in hazardous situation. As the “Identification of hazards and hazardous situations” (cl. 5.4) clause specifies, the sequence of events can be initiated in all phases of the life cycle of the product and that different sequences of events related to a single hazard can lead to different hazardous situations.

**Risk control (cl. 7)**

Inherently safe manufacture and trainings for users as risk mitigation options was added to “Risk control option analysis” (cl. 7.1). Inherently safe design and manufacture remains the first and most important option in the risk control option analysis. The manufacturing process can contribute to risks, for example contamination of components, residues of hazardous substances used in the process or mix-up of parts. Such risks can be controlled by designing the manufacturing process to be inherently safe. For example, eliminate hazardous substances, use separate production lines or apply protective measures such as visual inspection steps in the process.

“Benefit-risk analysis” (cl. 7.4) enforces the requirement that was already written in the second edition of the EN version of ISO 14971. The clause states clearly that risk-benefit analysis cannot be used to weigh residual risks against economic advantages. This statement corresponds with the new definition of benefit, which includes only positive impacts on the health of the patient, patient management or public health.
Evaluation of overall residual risk (cl. 8)
According to this clause, the manufacturer shall evaluate the overall residual risk posed by the medical device using the method and the criteria defined in the risk management plan.

Additionally, for an overall residual risk that is judged acceptable, the manufacturer shall now decide which information is necessary to include in the accompanying documents in order to disclose the overall residual risk.

Production and post-production activities (cl. 10)
In ISO 14971:2019, information about required production and post-production activities was significantly revised and is much better described now. New sections, such as “Information collection” (cl. 10.2), specify what information shall be collected. “Information review” (cl. 10.3) specifies how manufacturer shall analyze collected data. “Actions” (cl. 10.4) explains what actions apply if collected information was considered relevant to safety.

Remember that compliance with ISO 14971 clause 10 is not required by standard IEC 60601-1.
ISO 14971:2019 is more an evolution than a revolution in the requirements. The manufacturer, who prepared their documentation according to requirements from ISO 14971:2007 and truly focused on proper applying of the requirements, would not need to invest a lot of effort to comply with ISO 14971:2019.

The five most important changes brought by the ISO 14971:2019 edition are:
1. The addition of system security (cybersecurity) to the scope of risk management
2. Extending the definition of harm
3. Enforcement of risk control priority order
4. A clear statement that economic advantage cannot be taken under consideration for risk-benefit analysis
5. A requirement to inform users about significant residual risks

Please note that in this document we covered the most important modifications that were made in ISO 14971:2019. We strongly encourage you to compare editions of the standard by yourself.

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