Safety Corner

What is ISO 14971?

ISO 14971 “Medical devices – application of risk management to medical devices” is an international standard that specifies the process for identifying the hazards associated with a medical device so that manufacturer can estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of these controls.

A key principle of the standard is that no medical device can be entirely risk-free. Rather it works on the basis of limiting risk to an acceptable level, taking into account both the likelihood and the potential severity of a device causing harm. Although the standard deals primarily with minimizing risks to patients, the manufacturer must also consider other stakeholders, including the device operators and caregivers, as well as the environment and the manufacturer’s reputation and industry standing. However, the standard does not apply to clinical decision making or specify acceptable risk levels.

ISO 14971 asks manufacturers to set up a risk management process throughout the life-cycle of a medical device, from research, development and production to product decommissioning and safe disposal. Thus, simply ensuring acceptable risk at the point of manufacture and sale is not sufficient. The risk management process must include four elements: analysis, evaluation, control and information.

Risk analysis involves understanding a device, its safety features, its potential hazards, and the potential damages the device can cause. Risk evaluation determines whether the assessed risk is acceptable or modifications are required. Risk control examines how risks can be mitigated and whether the risk control actions themselves may introduce new risks. Details of the risk management process should be compiled in a clear manner for future reference. The manufacturer’s senior management is required to ensure adequate resources are made available to carry out the process and to determine the risk acceptable level of the device. Those who actually carry out the risk management process must be adequately qualified or experienced, which can involve both understanding of risk management and expert knowledge of the device itself.

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