ISO 14971 Ed.3

Medical devices — Application of risk management to medical devices

＜Overview＞

ISO 14971 Ed.3 is the standard for risk management of medical devices that was revised to harmonize with ISO/IEC Guide 63: 2009 - Guide for safety aspects of medical devices, as well as to adapt to new technical fields such as security and changes in the environment in which medical devices are used.

＜Technical Committee＞

Joint Working Group 1 (JWG1) of ISO/TC 210 and IEC/SC 62A

＜Main Points＞

- In accordance with the ISO/IEC Directives, Part 2 (2018 edition), a clause for normative references has been added.
- The defined terms have been updated to align with ISO/IEC Guide 63:2019, the guide for safety aspects of medical devices, and new terms (benefit, reasonably foreseeable misuse, and state of the art) have been added.
- To align with terminology used in some regulations, "risk/benefit analysis" has been changed to "benefit-risk analysis."
- It has been clarified that the standard can address various risks associated with medical devices, including security.
- Because the criteria for the acceptability of the overall residual risk can be different from the criteria for acceptability of individual risks, it is required that this be defined in the risk management plan, in addition to the criteria for its acceptability.
- Several requirements concerning the disclosure of residual risk have been consolidated into Clause 8.
- As the pre-market review of medical devices is crucial for the execution of the risk management plan, the key points of the review have been clarified.
- The requirements for production and post-production activities have been clarified and restructured. Further details have been provided on the information to be collected and the actions to be taken when the collected information has been reviewed and determined to be safety-related.
- The annexes have been limited to content directly related to the requirements of the standard. Examples and application sections have been moved to ISO/TR 24971 or deleted.

＜Publication History＞

- During the periodic review of the second edition of ISO 14971 in 2016, a revision project was approved on November 14, 2016, partly due to requests for further explanation of the specified requirements.
- Subsequently, after extensive deliberation by JWG1, a DIS (Draft International Standard) was prepared on May 17, 2018 (approved on October 12, 2018), and an FDIS (Final Draft International Standard) was prepared on February 11, 2019 (approved on July 5, 2019). The standard was published on December 10, 2019.

＜PMDA Involvement ＞

Attendance at international conferences, teleconferences, and domestic committees.