Exploring Potential Revisions to 
ISO 14971 and ISO/TR 24971

For the second time since its inception, ISO 14971:2007, a risk management standard that is a cornerstone for medical device manufacturers and regulatory agencies, is being revised, and concerns are mounting over the nature of the changes. Drastic revisions to the standard could affect the way in which manufacturers manage the safety risks for the medical devices they produce. Along with 14971, the technical report (TR) that supports the standard, ISO/TR 24971:2013, also is undergoing revision.

The proposal approved in Delft, Netherlands, in November 2016 that started the work in earnest included the following plans:

• Performing a systematic review while maintaining the concepts and approaches of risk management within the standard
• Preserving the current scope of the standard
• Clarifying and potentially harmonizing 14971 with other risk management standards and standards that use 14971 within their process

The work proposal also requested that Joint Working Group 1 (JWG1), which is undertaking the revisions, consider data privacy and security within the risk management process. The second work proposal regarding the revision of 24971 included merging the guidance annexes from 14971 into the 24971. Both work proposals were given a 36-month timeline.

Possible Changes to 14971

As stated previously, the approved work item required no change to the risk management process. Certain definitions may be modified slightly, and new ones may be added (e.g., the term “benefit,” which is now used widely within regulations for many regulatory bodies, within regulatory guidance, and commonly for decision making).

In addition, commenters suggested adding clarification about risk related to data and systems security. Risk related to software within a medical device has always been included in the standard, and security risks should have been assumed to be part of that risk identification. However, recent issues with systems security and data privacy have led to the request to add more definitive requirements regarding these specific types of risks.

Requests also were made for two additional areas of confusion: residual risk and risk acceptability criteria. A request was made to add additional supportive information about what and how to manage residual
risk. Additional clarification related to the difference between the policy for determining risk acceptability criteria and the actual development of the risk acceptability criteria may also be added.

**Implications for Z Annexes**
The situation regarding the Z annexes in EN ISO 14971 is complicated. They were written by the European Committee for Standardization (CEN) as informative annexes and do not reflect the worldwide view of the 2007 version of ISO 14971. In addition, they were written to reflect the European medical device, active implantable medical device, and IVD medical device directives, which have been replaced by the E.U. Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

Changes related to risk management appear within the MDR and IVDR. Although the JWG1 has taken these changes under advisement, 14971 is an international standard and therefore is not meant to address national or regional regulations. The Z annexes are necessary for CEN harmonized standards to show the relationship between what the EU regulations require and what the standard provides. Therefore, although a new set of CEN annexes is expected to be added to 14971 at some point, numerous standards are in line for E.U. harmonization review and may be ahead of 14971.

**Potential Changes to 24971**
The biggest change to 24971 will be adding many of the annexes from 14971. Updates also will be made to include guidance related to the challenges industry has had in using the risk management process with newer health technology.

Two additional areas that may be supplemented are 1) performing benefit-risk analysis and 2) planning, gathering, and using production and postproduction information for feedback into the risk management process.

**Stay Tuned**
The exact nature of the potential changes that will await the medical device industry will be revealed when the draft of 14971 is distributed for review and voting sometime in the third quarter of this year. This distribution allows for 12 weeks for review, commenting, and voting.

The output of the comments and vote will be reviewed by the working group responsible for these two standards in Seoul, South Korea, in November. Then, after moving to the final draft international standard stage, the final vote will occur.

The new versions of 14971 and 24971 are expected to be published in the second half of 2019.

**References**

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