PathWise

ISO TR 24971- What is this document and Why do I need it?

ISO 14971, the medical device risk management standard has been around for 20 years and has been reviewed every 5 years and either revised or reaffirmed based on the results of votes and comments that have been made by the national standards committees from both ISO and IEC, as this is a joint standard.

After the release of the 2007 document a number of requests for clarification and additional information were received by ISO and IEC, just as when the 2000 version was released. In reviewing the comments after the 2007 edition, and a subsequent reaffirmation in 2010, it was determined that several of the comments needed to be addressed quickly. Standards are reviewed and comments addressed every 5 years, and ISO and IEC decided not to wait longer, so an effort was made to develop a response to those questions, in the form of a Technical Report or TR. TR's do not make requirements, only provide information and all of the comments could be addressed with information or guidance without imposing additional requirements for the manufacturer. A TR could provide the information more rapidly as it did not have the same review and vote requirements as a standard, which contains requirements.

In 2013, a Technical Report, ISO TR 24971:2013 was released which addressed six specific categories that were based on comments received during the voting process which also reaffirmed ISO 14971:2007 and did not request any changes. Subsequent votes in 2015 also requested more information on implementation of the standard, but did not request any changes in the risk management process. It was decided however, that some realignment and editorial changes could benefit the users of the ISO 14971 standard, as well as improve the guidance for the entire standard, beyond the six categories in ISO 24971:2013.

Beginning in 2016, the technical committee responsible for ISO 14971 began an effort to improve the Technical Report's guidance and improve the structure and alignment of ISO

14971. The effort resulted in one standard, a revised ISO 14971:2019 which now contains 10 clauses of requirements, and 3 clauses containing information for implementation. A Technical Report containing all guidance, with no requirements, was also developed in parallel, a new edition, ISO TR 24971:2020. Unfortunately, the year-end crush at ISO has delayed the release of this report which has 100 pages of guidance on implementing ISO 14971:2019. The Technical Report is organized in such a way that the 10 clauses of requirements in the ISO 14971 standard are each addressed by 10 numbered clauses of guidance, one for each of the requirements. Additionally, the Technical Report contains 8 clauses which are identified by alphabetic characters, which are cross-cutting topics that address topics that pertain to multiple requirements or concepts.

So, for the reader of the Technical Report, you can find additional information developed by the team that was responsible for writing the standard in the comparable numbered clause in the TR. For information on a specific topic such as information for safety and information for residual risk, that topic has its own clause, Annex D, in ISO TR 24971:2020. The annexes A-H appear after the ten numbered clauses in 24971.

Of the three informative annexes remaining in ISO 14971:2019, the first is a must read for anyone that must implement the standard. Annex A in ISO 14971:2019 is the Rationale for Requirements, and explains the thought processes behind each of the ten clauses of requirements. A better understanding of the reasoning behind the requirements will help the manufacturer make better choices in developing their risk management system. Annex B of ISO 14971 provides a chart comparing the clauses of ISO 14971:2007 and the 2019 edition of the standard, as well as providing a flowchart for risk management activities updated from the 2007 edition.

The final annex in ISO 14971 covers fundamental risk concepts and is updated and revised information from the 2007 edition to assist in understanding terms and the basis for the standard. All other annexes that were in ISO 14971:2007 were moved to the

revised ISO TR 24971 which contains a wealth of information to assist medical device manufacturers in implementing risk management over the entire lifecycle for their products. It is vital that the manufacturer have both documents in their documentation systems, and use them to implement their risk management system that meets regulatory requirements, but most of all helps to develop medical devices that have the lowest possible risks for the users and the patients.

About the Author: Edwin Bills

During his career in medical devices, Mr. Bills has held a number of quality and regulatory affairs positions for major medical device companies, including a period as Corporate Director of Risk Management. He has over 36 years' experience in the field of quality and regulatory affairs, including time as Director of Quality and Regulatory concurrently for four US sites. Currently he consults and provides training in the area of medical device quality, regulatory and risk management. With Stan Mastrangelo, he co-authored Lifecycle Risk Management for Healthcare Products: From Research Through Disposal *published by PDA.*

Mr. Bills was also a member of the adjunct faculty serving Virginia Tech's graduate on-line degree program in Health Products Risk Management. ASQ has awarded Mr. Bills with Fellow status as well as Certified Quality Engineer, Certified Quality Auditor, Certified Manager of Quality and Organizational Excellence, and he is a Regulatory Affairs Certified by the Regulatory Affairs Professionals Society.

Additionally, Mr. Bills serves in international standards work, assisted in completing the revision of the third edition of ISO 14971 risk management standard as an international member of the technical committee. He also serves on the US national committee for the medical devices quality system standard, ISO 13485 and the AAMI technical committee CP, developing a combination products risk management guidance.