


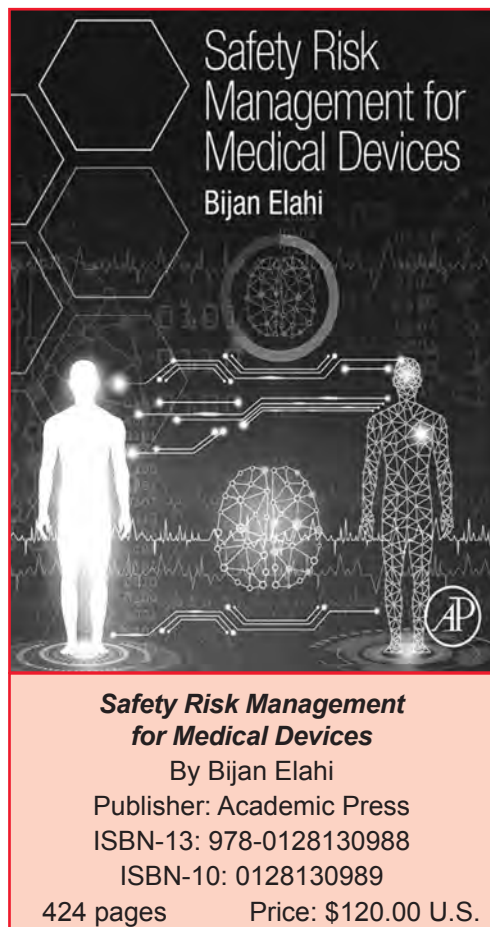
Applying Safety Standards to Life-Saving Equipment



Elsevier Academic Press has recently published a new safety book titled *Safety Risk Management for Medical Devices*, written by Bijan Elahi. This book explains how to conduct a risk management program that will show conformance to the FDA safety standards established for medical devices. It describes a safety process as well as some of the tools utilized in the process. Since medical devices are life-saving devices, they can be deemed as “safety critical,” requiring a rigorous process to ensure they are safe for public use.

This book revolves around ISO Standard 14971, “Medical devices — Application of risk management to medical devices.” This standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks and to monitor the effectiveness of the controls. The requirements of ISO 14971 are applicable to all stages of the lifecycle of a medical device.

Understanding and applying safety standards is a daunting process, particularly if one is not already familiar with the generic system safety engineering risk management process. The author presents risk management in a comprehensive and thorough fashion. He provides definitions, interprets unclear sections of the standards, offers templates, and includes step-by-step directions on how to perform risk management analysis of complex medical devices. The author also provides special tips to warn about confusing areas and how to avoid problems associated with these areas.



The author presents a methodology he has developed called the “BXM” method for conducting a thorough risk management process. This is a complete process that essentially follows the basic tenets of the system safety engineering process, thereby following the design-for-safety philosophy. He also provides a detailed demonstration of the risk management information discussed in the book through the application of his BXM method on an example system.

A sample of some of the topics covered in this book include:

- Understanding risk
- Requirements of the risk management process
- Risk management standards (for medical devices)
- Relationship between ISO 14971 and other standards
- The BXM method
- Risk analysis techniques
- Software risk management
- Risk estimation
- Risk controls
- Risk management process management metrics
- The BXM method applied to an example (hypothetical) medical device

In the chapter on risk analysis techniques, the author provides an introduction on how to perform Fault Tree Analysis, Failure Modes and Effects Analysis, Preliminary Hazard Analysis and Mind Map Analysis. Since these techniques are not trivial, the reader might need more detailed information from other sources in order to perform the analysis technique on a large complex system or product.

If you work in the medical device field, either in design or safety, this book is a definite required read. ●