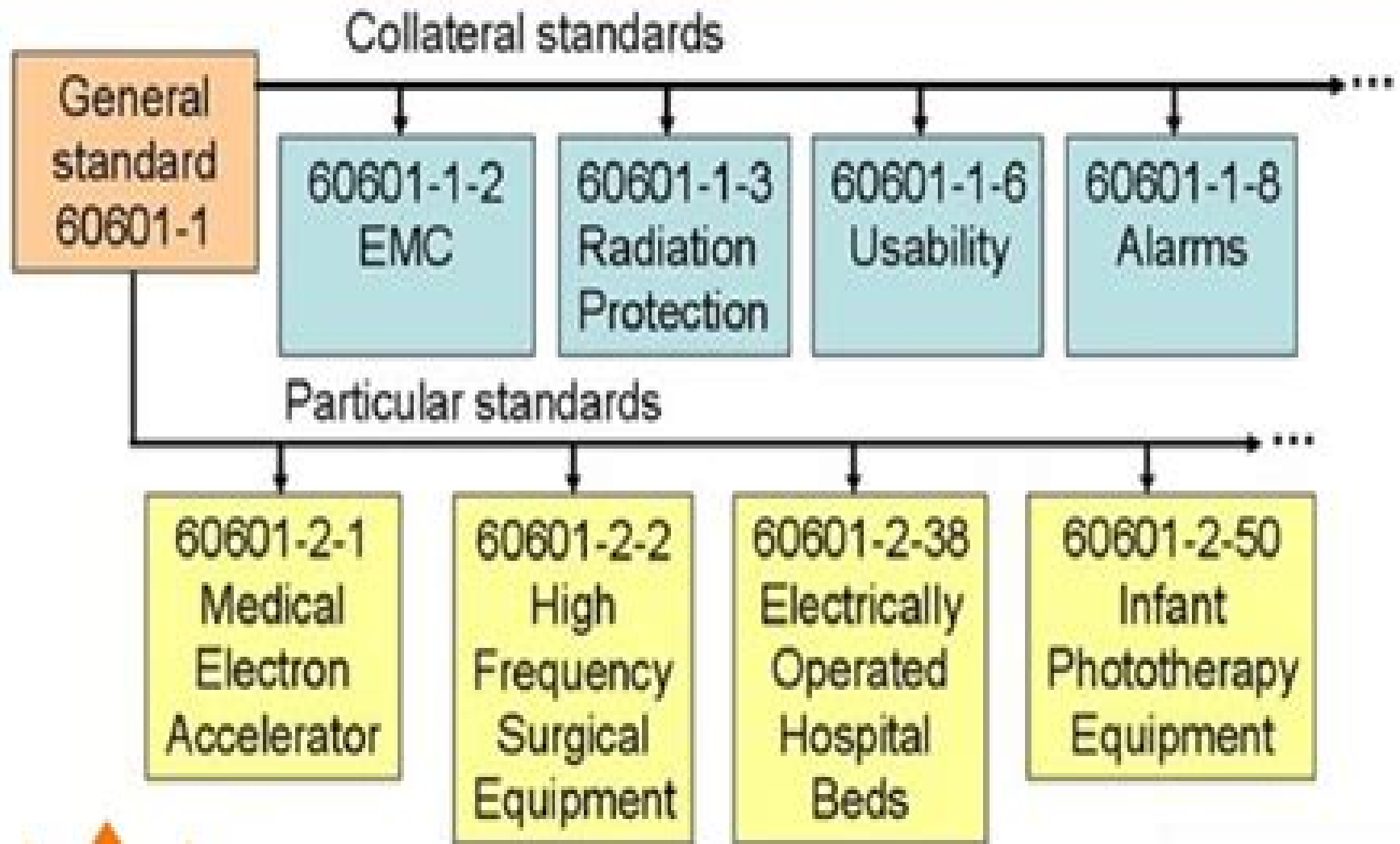


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Safety Risk Management for Medical Devices Bijan Elahi, 2018-06-29 Safety Risk Management for Medical Devices demystifies risk management providing clarity of thought and confidence to the practitioners of risk management as they do their work Written with practicing engineers safety management professionals and students in mind this book will help readers tackle the difficult questions such as how to define risk acceptance criteria and how to determine when to stop risk reduction This book delivers not only theory but also practical guidance for applying the theory in daily risk management work The reader is familiarized with the vocabulary of risk management and guided through a process to ensure compliance with the international standard ISO 14971 a requirement for all medical devices This book outlines sensible easily comprehensible and state of the art methodologies that are rooted in current industry best practices Opening chapters introduce the concept of risk the legal basis for risk management and the requirements for a compliant risk management process The next group of chapters discusses the connection between risk management and quality systems usability engineering and biocompatibility This book delves into the techniques of risk management such as fault tree analysis and failure modes and effects analysis and continues with risk estimation risk control and risk evaluation Special topics such as software risk management clinical investigations and security are also discussed The latter chapters address benefit risk

analysis and production and postproduction monitoring This book concludes with advice and wisdom for sensible efficient and successful safety risk management of medical devices Teaches industry best practices on medical device risk management in compliance with ISO 14971 Provides practical easy to understand and step by step instructions on how to perform hazard analysis and manage the risks of medical devices Offers a worked out example applying the risk management process on a hypothetical device *Consumer's Resource Handbook* ,1998 **Climatological Data for the United States by Sections** , Collection of the monthly climatological reports of the United States by state or region with monthly and annual national summaries

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