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IEC/TR 80002-1:2009 provides guidance for risk assessment as per ISO 14971:2007. It does not add to or change the requirements of ISO 14971:2007 or IEC 62304:2006. IEC/TR 80002-1:2009 aims at risk management practitioners who perform risk management when software is included in medical device or system.

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IEC 80002-1, which is a technical report, has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO technical committee 210: Quality management and corresponding general aspects for medical devices.

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IEC/TR 80002-1 Edition 1.0 2009-09 TECHNICAL REPORT Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software INTERNATIONAL ELECTROTECHNICAL COMMISSION XB ICS 11.04.01 PRICE CODE ISBN 978-2-88910-779-7 colour inside This is a preview - click here to buy the full publication

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IEC/TR 80002-1:2009 is a 58-page guidance document that goes into detail on how to apply ISO 14971 to medical device software, so you should definitely get a copy of this.

Medical Device Software (SaMD) Risk Management Requirements

IEC/TR 80002-1 Edition 1.0 2009-09 TECHNICAL REPORT Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software INTERNATIONAL ELECTROTECHNICAL COMMISSION XB ICS 11.04.01 PRICE CODE ISBN 2-8318-1061-9 colour inside

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This book constitutes the refereed proceedings of the 14th International Conference on Software Process Improvement and Capability Determination, SPICE 2014, held in Vilnius, Lithuania, in November 2014. The 21 revised full papers presented together with 6 short papers were carefully reviewed and selected from 49 submissions. The papers are organized in topical sections on developing process models for assessment; software process and models; software models and product lines; assessment; agile processes; processes improvement and VSE.

This book constitutes the refereed proceedings of the 15th International Conference on Software Process Improvement and Capability Determination, SPICE 2015, held in Gothenburg, Sweden, in June 2015. The 17 revised full papers presented together with three short papers were carefully reviewed and selected from 48 submissions. The papers are organized in topical sections on industrial frameworks; implementation and assessment; process improvement; agile processes; assessment and maturity models; process and education.

Neurorehabilitation Technology provides an accessible, practical overview of the all the major areas of development and application in the field. The initial chapters provide a clear, concise explanation of the rationale for robot use and the science behind the technology before proceeding to outline a theoretical framework for robotics in neurorehabilitative therapy. Subsequent chapters provide detailed practical information on state-of-the-art clinical applications of robotic devices, including robotics for locomotion; posture and balance and upper extremity recovery in stroke and spinal cord injury. Schematic diagrams, photographs and tables will be included to clarify the information for the reader. The book also discusses standard and safety issues and future perspectives.

This book constitutes the refereed proceedings of the 13th International Conference on Software Process Improvement and Capability Determination, SPICE 2013, held in Bremen, Germany, in June 2013. The 21 revised full papers presented and 7 short papers were carefully reviewed and selected from numerous submissions. The papers are organized in topical sections on process quality; medical device software processes; design and use of process models; studies of software development; agile development; IT service management; assessment for diagnosis.

Software and Systems Traceability provides a comprehensive description of the practices and theories of software traceability across all phases of the software development lifecycle. The term software traceability is derived from the concept of requirements traceability. Requirements traceability is the ability to track a requirement all the way from its origins to the downstream work products that implement that requirement in a software system. Software traceability is defined as the ability to relate the various types of software artefacts created during the development of software systems. Traceability relations can improve the quality of a product being developed, and reduce the time and cost of development. More specifically, traceability relations can support evolution of software systems, reuse of parts of a system by comparing components of new and existing systems, validation that a system meets its requirements, understanding of the rationale for certain design and implementation decisions, and analysis of the implications of changes in the system.

In this book, the following subjects are included: information security, the risk assessment and treatment processes (with practical examples), the information security controls. The text is based on the ISO/IEC 27001 standard and on the discussions held during the editing meetings, attended by the author. Appendices include short presentations and check lists. CESARE GALLOTTI has been working since 1999 in the information security and IT process management fields and has been leading many projects for companies of various sizes and market sectors. He has been leading projects as consultant or auditor for the compliance with standards and regulations and has been designing and delivering ISO/IEC 27001, privacy and ITIL training courses. Some of his certifications are: Lead Auditor ISO/IEC 27001, Lead Auditor 9001, CISA, ITIL Expert and CBCL, CIPP/e. Since 2010, he has been Italian delegate for the the editing group for the the ISO/IEC 27000 standard family. Web: www.cesaregalotti.it.

This book constitutes the refereed proceedings of the 12th International Conference on Software Process Improvement and Capability Determination, SPICE 2012, held in Palma de Mallorca, Spain, in May 2012. The 21 revised full papers presented and 14 short papers were carefully reviewed and selected from numerous submissions. The papers are organized in topical sections on organizational process improvement; SPI in small and very small enterprises; process models; SPI in automotive software and security; SPI in medical and safety critical systems; short papers.

This volume constitutes the refereed proceedings of the 18th EuroSPI conference, held in Roskilde, Denmark, in June 2011. The 18 revised full papers presented together with 9 key notes were carefully reviewed and selected. They are organized in topical sections on SPI and assessments; SPI and implementation; SPI and improvement methods; SPI organization; SPI people/ teams; SPI and reuse; selected key notes for SPI implementation.

Imaging modalities in radiology produce ever-increasing amounts of data which need to be displayed, optimized, analyzed and archived: a "big data" as well as an "image processing" problem. Computer programming skills are rarely emphasized during the education and training of medical physicists, meaning that many individuals enter the workplace without the ability to efficiently solve many real-world clinical problems. This book provides a foundation for the teaching and learning of programming for medical physicists and other professions in the field of Radiology and offers valuable content for novices and more experienced readers alike. It focuses on providing readers with practical skills on how to implement MATLAB® as an everyday tool, rather than on solving academic and abstract physics problems. Further, it recognizes that MATLAB is only one tool in a medical physicist's toolkit and shows how it can be used as the "glue" to integrate other software and processes together. Yet, with great power comes great responsibility. The pitfalls to deploying your own software in a clinical environment are also clearly explained. This book is an ideal companion for all medical physicists and medical professionals looking to learn how to utilize MATLAB in their work. Features Encompasses a wide range of medical physics applications in diagnostic and interventional radiology Advances the skill of the reader by taking them through real-world practical examples and solutions with access to an online resource of example code The diverse examples of varying difficulty make the book suitable for readers from a variety of backgrounds and with different levels of programming experience.

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