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Standards Navigator

Standards Navigator Monthly Report

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SoftwareCPR Standards Navigator provides information and tools related to standards that play a significant role in health software and software intensive medical devices. In addition to information on existing standards, SoftwareCPR Standards Navigator keeps you up to date on new standards activity and gives you expert insight into future changes to existing standards.

http://www.softwarecpr.com/topicsframepage.htm

A look ahead at standards activity in 2016

A lot of standards and regulatory activity is expected in 2016. Here are some of the areas to watch.

- IEC 82304-1 *Health Software: General requirements for safety* will be completed during the first half of 2016. It is intended that this standard be harmonized in the EU, but it is not clear when this may happen.
- A first committee draft of the second edition of IEC 62304 will be circulated for review in the first half of 2016. The second edition will expand the scope of the standard to health software.
- New standards for health software covering all parts of the life cycle will be proposed in 2016.
- AAMI will move its work on HIT quality management systems and HIT risk management forward. The goal is to complete these by the end of 2016.
- A revision of IEC 80001-1 will begin in 2016.
- The revision to ISO 13485 will be published in the first half of 2016.
- ISO 14971 is currently under review. It is likely that a revision (amendment or new edition) will be started in 2016.
- A second amendment to IEC 60601-1 will be started in the second half of 2016. This amendment is scheduled to be completed in 2019. A fourth edition of 60601-1 will be started following the completion of the amendment and will be scheduled for completion in 2024. Discussions about the structure of the fourth edition will likely begin in 2017 and decisions made before work is started on the fourth edition.
- The first deliverables from UL/AAMI 2800 on medical device interoperability should be completed in 2016.
- AAMI TIR 57 on medical device cybersecurity risk management will be published in 2016.
- Many documents, both standards and regulations, on security and privacy will be in process during 2016.

November & December 2015 Standards Navigator Overview

Medical device software

- No new documents

Medical Devices

- A draft for vote has been circulated for *IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems,* has been circulated.

  This Technical Report provides guidance on assessing immunity, with regard to the intended use. Based on the intended use, medical electrical equipment and medical electrical systems should have adequate immunity to provide the performance specified by the manufacturer in the presence of electromagnetic disturbances.

  The draft is available on the SoftwareCPR Standards Navigator web page.

- A committee draft for comment for *IEC/TR 60601-4-1: Medical electrical equipment – Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy,* has been circulated.

  This technical report is intended to help a manufacturer through the key decisions and steps required to perform a detailed risk management process and usability engineering processes for medical electrical equipment or an medical electrical system, hereafter referred to as MEE or MES, employing a degree of autonomy (DOA).

  This technical report provides a definition of DOA of MEE or MES and MEDICAL ROBOT, and guidance on:

  – methodologies to perform the risk management process and usability engineering for MEE or MES with a DOA;
  – considerations of basic safety and essential performance of MEE and MES with a DOA; and
  – identifying the use of DOA and similar concepts in existing ISO/IEC standards dealing with MEE or MES with the goal to facilitate alignment of standards by consistent use of the concept of DOA, and
  – distinction between MEDICAL ROBOTS and other MEE and MES.

  The draft is available on the SoftwareCPR Standards Navigator web page.

Health IT and mobile health applications

- No new documents

Security

- A proposal for a new project on information security for remote maintenance of medical devices has been circulated. This is a proposed revision of *ISO/TR 11633-1:2009 "Information security management for remote maintenance of medical devices and medical information systems Part 1: Requirements and risk analysis"* to change it from a guidance document (TR) to a technical specification (TS) which can include requirements.

  This document focuses on remote maintenance services (RMS) for information systems in health care facilities as provided by vendors of medical devices or health information systems (RMS providers) and shows an example of carrying out a risk analysis in order to protect both sides' information assets (primarily the information system itself and personal health data) in a safe and efficient (i.e. economical) manner.

  The draft is available on the SoftwareCPR Standards Navigator web page.

- A proposed standard for *Connected diabetes device security*, has been circulated for comment by the Diabetes Technology Society. The purpose is to establish a standard that can be used to provide a high level of assurance that products deliver the security protections claimed by their developers. It is the expressed intent of the standard's authors that it can provide foundational work for effective cybersecurity standards across other medical devices.

  The draft is available on the SoftwareCPR Standards Navigator web page.

- The European Union Agency for Network and Information Security (ENISA) has circulated a report on *Security and Resilience in eHealth*. The aim of this study is to investigate the approaches and measures EU Member States take to protect critical healthcare systems, having as a main goal improved healthcare and patient safety. In that respect this study analyses:
  - The policy context in Europe and the legislation of the Member States
  - The perception of the Member States on critical assets in eHealth infrastructures
  - The most important security challenges
  - The most common security requirements
  - Relevant good practices that have been deployed in the Member States for eHealth security

  The report also includes an Annex that describes the current status of security in eHealth information systems in the Member States.

  The report and Annex are available at https://www.enisa.europa.eu/activities/Resilience-and-CIIP/critical-infrastructure-and-services/ehealth_sec/security-and-resilience-in-ehealth-infrastructures-and-services

Software Engineering and Information Technology

- A Final Draft of *ISO/IEC 25022: Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of quality in use,* has been circulated for vote.

  This standard defines quality in use measures for the characteristics defined in ISO/IEC 25010, and is intended to be used together with ISO/IEC 25010. This standard contains:
  - a basic set of measures for each quality in use characteristic;
  - an explanation of how quality in use is measured.

The draft is available on the SoftwareCPR Standards Navigator web page.

- A Final Draft of *ISO/IEC 25023: Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of system and software product quality,* has been circulated for vote.

  This standard defines quality measures for quantitatively evaluating system and software product quality in terms of characteristics and sub-characteristics defined in ISO/IEC 25010, and is intended to be used together with ISO/IEC 25010. This standard contains:

  - an explanation of how to apply software product and system quality measures
  - a basic set of quality measures for each characteristic and sub-characteristics

  The draft is available on the SoftwareCPR Standards Navigator web page.

  A Final Draft of *ISO/IEC 25066: Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Common Industry Format (CIF) for usability: Evaluation Reports*, has been circulated for vote.

  This standard describes the Common Industry Format (CIF) for reporting usability evaluations. It provides a classification of evaluation approaches and the specifications for the content items (content elements) to be included in an evaluation report based on the selected evaluation approach(es). The intended users of the usability evaluation reports are identified, as well as the situations in which the usability evaluation report can be applied.

  The draft is available on the SoftwareCPR Standards Navigator web page.

- A Draft for Vote of ISO/IEC 26513: Systems and software engineering — Requirements for testers and reviewers of user documentation, has been circulated for vote.

  This standard provides the minimum requirements for testing and reviewing user documentation (clause 7), including both printed and online documents used in work and other environments by the users of software which includes application software, systems software, and software that controls machinery or hardware devices. It applies to printed user manuals, online help, user assistance for mobile devices, tutorials, websites, and user reference documentation.

  The draft is available on the SoftwareCPR Standards Navigator web page.

- A Draft for Vote of *ISO/IEC 24748-5: Systems and software engineering — Life cycle management — Part 5: Software development planning*, has been circulated for vote.

  This standard provides a common framework for planning and controlling the technical processes and activities to produce and sustain software products. The complete life cycle is covered by this standard, from idea conception to the retirement of a software product. The framework described by this standard provides for best practices in communication and cooperation among parties that plan for, develop, utilize, and manage modern software. This standard

  - specifies the required information items to be produced through the implementation of the required planning and control processes,
  - specifies the required content of the required information items, and
  - gives guidelines for the format and content of the required and related information items.

  The draft is available on the SoftwareCPR Standards Navigator web page.

- A Committee Draft for comment of *ISO/IEC 19770-1: Information technology — IT asset management — Part 1: IT asset management systems — Requirements*, has been circulated for comment.

This standard specifies requirements for an IT asset management system within the context of the organization. This standard can be applied to all types of IT assets and by all types and sizes of organizations.

The draft is available on the SoftwareCPR Standards Navigator web page.

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

These draft documents can be found on the SoftwareCPR Standards Navigator until their review period completes.

	Topic	Use / Users	Description
ISO/IEC 12207 DIS	Software engineering	Manufacturers	This International Standard establishes a common framework for software life cycle processes, with well-defined terminology, that can be referenced by the software industry. It contains processes, activities, and tasks that are to be applied during the acquisition of a software system, product, or service and during the supply, development, operation, maintenance, and disposal of software products.
ISO 24748-4 FDIS	Software Engineering	Manufacturers	*ISO 24748-4 System and software engineering – Life cycle processes – System engineering planning* Final draft for vote ISO 24748 specifies the technical management processes from ISO/IEC/IEEE 15288 that are required to be implemented for planning a systems engineering project. This is a final draft for approval.