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Standards Navigator

Standards Navigator Monthly Report

15-February-2016

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.

  Status: The project team for IEC 82304-1 met in January to resolve comments from the CDV ballot. Comment resolution will be finalized during February and a Final Draft International Standard (FDIS) will be circulated for final approval following the completion of the comment resolution.

- 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.

  Status: Still waiting for the first committee draft. The project team has scheduled a meeting in Frankfurt, Germany during the first week of October to respond to comments from the committee draft.

- New standards for health software covering all parts of the life cycle will be proposed in 2016.

  Status: Work has begun on creating proposals for two new standards; one for foundations of health software and health IT and a second on general requirements for Health software and health IT implementation and use. These proposals are expected to be finalized in May and then submitted to ISO and IEC for approval to begin developing the standards.

- 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.

  Status: Drafting of these standards has begun. An HIT committee has been established in AAMI. The next meeting of the committee to review a draft of the standards will be in June.

- A revision of IEC 80001-1 will begin in 2016.

  Status: Work has begun for a proposal for changing the scope of the 80001 series and for 80001-1. The proposal will be reviewed in May and submitted to ISO and IEC for approval to begin the revision.

- 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.

  Status: The review of 14971 will close in March.

- 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.

  Status: A meeting of the advisory group for the second amendment will be held in February. This meeting is to identify the most important changes that are needed to be made in the amendment. The proposed changes will be discussed and an approved list finalized at a meeting in October.

- The first deliverables from UL/AAMI 2800 on medical device interoperability should be completed in 2016.

The Final Draft International Standard was approved at the end of 2015 and will be submitted for publication. The standard is expected to be published by the end of March. A three year transition period has been proposed.

- AAMI TIR 57 on medical device cybersecurity risk management will be published in 2016.

  The working group is finalizing revisions from comments received on the last ballot. It has not yet been determined whether to have another ballot on this document or to just publish the current revision.

- Many documents, both standards and regulations, on security and privacy will be in process during 2016.

January 2016 Standards Navigator Overview

Medical device software

- No new documents

Medical Devices

- *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 approved. This technical report should be published during the second half of 2016.

  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 FDA published a new draft guidance document for pre-market submission recommendations for interoperable medical devices. The draft guidance can be found at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482649.pdf

- The FDA published a new draft guidance document on Applying Human Factors and Usability Engineering to Medical Devices. The draft guidance can be found at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259760.pdf. The FDA will hold a webinar to review the guidance document on February 19. Following the webinar, a transcript, audio recording and slides will be available. Information about the webinar can be found at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm484392.htm.

Health IT and mobile health applications

- No new documents

Security

- The FDA released its long awaited draft guidance for post-market cybersecurity for medical devices. The draft guidance is available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf. The FDA also held a public workshop on Collaborative Approaches to Medical Device Cybersecurity during January. The agenda, presentations and webcast archive of the workshop are all available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm474752.htm.

Software Engineering and Information Technology

- A draft international standard (DIS) ballot has been circulated for *ISO 19514 Information technology — Object Management Group Systems Modeling Language (OMG SysML).* Adoption of this publicly available specification (PAS) will make the OMG SysML version 1.4 an International Standard. This specification defines a general-purpose language for systems engineering applications, called the OMG Systems Modeling Language (OMG SysML), or simply SysML. SysML supports the specification, analysis, design, verification, and validation of a broad range of complex systems. These systems may include hardware, software, information, processes, personnel, and facilities. SysML reuses a subset of OMG UML 2 and provides additional extensions needed to address the requirements in the UML for Systems Engineering (SE).

A combined explanatory report and draft DIS is available on the SoftwareCPR Standards Navigator web page.

- A publically available specification, BSI PAS 754:2014 “Software Trustworthiness. Governance and management. Specification” has been submitted for transposition into an International Standard. This Publicly Available Specification (PAS) provides a consensus specification for software trustworthiness, either as a stand-alone document or as a companion and complement to other relevant standards. This specification identifies five aspects of software trustworthiness: safety, reliability, availability, resilience and security, and defines a framework of principles and techniques which can be tailored to suit the context and intended use. It describes a widely applicable approach to achieving software trustworthiness, which is based on the following concepts:
    - Governance. Before producing or using any software which has a trustworthiness requirement, ensuring an appropriate set of governance and management measures are set up.
    - Risk assessment. The risk assessment process involves considering the set of assets to be protected, the nature of the adversities that may be faced, and the way in which the software may be susceptible to such adversities.
    - Control application. Risk shall be managed through the treatment of risk by the application of appropriate personnel, physical, procedural and technical controls.
    - Compliance. A compliance regime shall be set up to ensure that creators and users of software ensure that governance, risk and control decisions have been implemented.

  It also recommends the use of a Trustworthy Software Management System, either as a standalone entity or by relevant extension to existing Management System(s).

  A combined explanatory report and draft DIS is available on the SoftwareCPR Standards Navigator web page.

- A New Work Item Proposal has been circulated to revise *ISO/IEC TR 24748-2 Guide for the application of ISO/IEC 15288 (System life cycle processes)* and make it an International Standard, *ISO/IEC 24748-2 Systems and software engineering — Life cycle management — Part 2: Guidelines for the application of ISO/IEC 15288 (System life cycle processes).* This part of ISO/IEC 24748 is a guideline for the application of ISO/IEC/IEEE 15288:2015. It addresses system, life cycle, process, organizational, project, and adaptation concepts, principally through reference to ISO/IEC 24748-1 and ISO/IEC/IEEE 15288:2015. It then gives guidance on applying ISO/IEC/IEEE 15288:2015 from the aspects of strategy, planning, application in organizations, and application on projects.

  A combined NWIP report and draft is available on the SoftwareCPR Standards Navigator web page.

- A New Work Item Proposal has been circulated to create a Technical Specification, *ISO/IEC TS 33053 Information Technology — Process Assessment — Process reference model for quality management* that defines a process reference model (PRM) for the domain of quality management. The scope of the quality management domain is determined by the requirements in ISO 9001:2015. The model specifies a process architecture for this domain, and comprises a set of processes, with each described in terms of process purpose and outcomes.

  A combined NWIP report and draft is available on the SoftwareCPR Standards Navigator web page.

- A New Work Item Proposal has been circulated to create a Technical Specification that defines a process capability assessment model (PAM) for quality management based on the PRM defined in ISO/IEC TS 33053. This Technical Specification, *ISO/IEC TS 33073 Information technology — Process assessment — Process capability assessment model for Quality Management*:
    - defines an exemplar PAM that meets the requirements of ISO/IEC 33004 and that supports the performance of an assessment by providing indicators for guidance on the interpretation of the process purposes and outcomes as defined in ISO/IEC TS 33053;
    - provides guidance, by example, on the definition, selection and use of assessment indicators of process performance and process capability.

      A combined NWIP report and 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 25022 FDIS	Software engineering	Manufacturers	This standard defines quality in use measures for the characteristics defined in ISO/IEC 25010. This is a final draft for vote.
ISO 25023 FDIS	Software engineering	Manufacturers	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. This is a final draft for vote.
ISO 25066 FDIS	Software engineering	Manufacturers	This standard describes the Common Industry Format (CIF) for reporting usability evaluations. This is a final draft for vote.

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	Topic	Use / Users	Description
ISO 26513 DIS	Software engineering	Manufacturers	This standard provides the minimum requirements for testing and reviewing user documentation, including both printed and online documents. This is a draft for vote.
ISO 24748-5 DIS	Software engineering	Manufacturers	This standard provides a common framework for planning and controlling the technical processes and activities to produce and sustain software products. This is a draft for vote.
ISO 19770-1 CD	Software engineering	Manufacturers	This standard specifies requirements for an IT asset management system within the context of the organization. This is a draft for comment.