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Standards Navigator

Standards Navigator Monthly Report

18-May-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. Changes to status since the last report are in red text.

- 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: All comments have been resolved by the project team and the material is ready for submission to IEC. The French National Committee has up to 2 months to provide a French translation if they wish to have one included in the FDIS ballot. The FDIS should be circulated by the end of July for final approval.

- 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: The project team is doing a final review of the first committee draft before it is circulated to national bodies for comment. The project team is expected to finalize the draft and have it circulated to the national bodies in May. 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: At the meeting in Amsterdam in May, it was decided to just go forward with one new standard at this time. This will be a standard on foundations of health software and health IT. This proposal will be finalized in May and submitted to ISO and IEC for approval to begin developing the standard.

- 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. The AAMI standards board will decide whether to begin work on HIT Usability at its next meeting. If the work is approved it will be added to the work of the AAMI HIT committee.

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

  Status: The proposal for extending the scope of the 80001 series and for revising 80001-1 was agreed to by the working group in Amsterdam. It will be 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.

  Status: The 2016 edition of ISO 13485 has been published by ISO.

- 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 has been completed with mixed results. A meeting of the working group will be held in June to discuss whether a revision is necessary. It seems likely that some changes will be proposed.

- 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 was held in February. This meeting identified 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 of SC 62A in October.

- 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.

  The final review of the draft has been completed. It is expected to be approved for publication at the AAMI standards committee meeting in June and be published following that approval.

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

  NIST has announced that it will be revising SP 800-53, the most complete compilation of security controls.

  UL has begun publishing a series of standards on security, UL 2900.

  A group in Germany active in medical device standards has expressed an intention to propose an international standard for medical device security risk management.

April 2016 Standards Navigator Overview

There were no new draft documents circulated during April for any of the areas being tracked.

Medical device software

- No new documents

Medical Devices

- No new documents.

Health IT and mobile health applications

- No new documents

Medical device and Health Security

- No new documents

Software Engineering and Information Technology

- No new documents

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 30754 DIS	Software engineering	Manufacturers	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. This is a draft for vote.

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	Topic	Use / Users	Description
ISO 33053 NP	Quality management	Manufacturers	This technical specification 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. This is a new proposal for vote.
ISO 33073 NP	Quality management	Manufacturers	This Technical Specification defines a process capability assessment model (PAM) for quality management based on the PRM defined in ISO/IEC TS 33053. It defines an exemplar PAM 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 and provides guidance, by example, on the definition, selection and use of assessment indicators of process performance and process capability.
ISO 11633-1 NP	Software engineering	Manufacturers	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) This is a new proposal for vote.
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.

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	Topic	Use / Users	Description
ISO/IEC 29119-5 FDIS	Software Engineering	Manufacutrers	This standard defines a unified approach for describing test cases in a modular way, which assists with the creation of items like keyword-driven test specifications and test automation frameworks. Keywords are elements used to compose test cases, such as building blocks. The standard defines the main concepts and application of keyword-driven testing and defines attributes of frameworks designed to support keyword-driven testing.