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Standards Navigator

Standards Navigator Monthly Report

15-October-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

Standards and regulatory activity overview

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: The FDIS was approved. The standard will be published after final editing. This is expected around the end of the year.

- 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: Comments have been received on the first CD. The project team met and has resolved about 80% of the comments. A second committee draft is planned for March 2017 after resolution of the remaining comments.

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

  Status: The proposal for a new standard, *ISO 81001-1 Health software and health IT systems safety, effectiveness and security – Part 1: Foundational principles, concepts, and terms,* has been approved by ISO and IEC. Work on the standard began in early October. The standard is planned to be published in 2020.

- 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: A decision was made to have this work be a 4-part standard. Part one will be on fundamentals, part two on risk management, part three on quality management and part four on usability. Working drafts of the four parts have been created. The next meeting of the AAMI HIT committee to review a draft of the standards will be in January. The current plan calls for publishing to begin in 2017.

- 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 has been approved by ISO and IEC. Work began in October on the second edition of IEC 80001-1 with a revised title and scope, *IEC 80001-1 Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software – Part 1: Application of risk management*. The expected date of publication is January, 2020.

- 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 was held in June to discuss whether a revision is necessary. The working group did not come to consensus on revising 14971. A meeting of the working group during the first week of October recommended that a revision be done with a limited scope. The final decision on whether to revise will be made at the ISO TC 210 meeting in November.

- 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: An approved list of issues to be addressed in the second amendment was finalized at a meeting of SC 62A in October.

- Draft texts of the EU Medical Device Regulation and the IVD regulation have been released. These still need legal editing and translation before being published in the Official Journal. Publication is expected around the end of the year.
- The first deliverables from UL/AAMI 2800 on medical device interoperability should be completed in 2016.

  Status: The committee met in June and hopes to have a draft of the first parts available for review soon.
- AAMI TIR 57 on medical device cybersecurity risk management will be published in 2016.

  Status: The TIR has been recognized by the FDA before it was even been made available for purchase by AAMI. The TIR is now available for purchase from AAMI.
- The AAMI Device Security working group intends to begin work on guidance for postmarket cybersecurity activities and plans at its next meeting in December.
- 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.

  The new General Data Privacy Regulation has been approved in the EU.

  The second edition of *ISO 27799 Health informatics -- Information security management in health using ISO/IEC 27002* has been submitted for publication. The published standard should be available before the end of 2016.

  A new standard has been released by the Diabetes Technology Society - Standard for Wireless Diabetes Device Security (DTSec).

  A new directive on network and information security has been published by the EU.

  Discussions at recent international standards meetings make it clear that medical device cybersecurity standards will be started next year. The exact form of these standards is not yet determined, but will probably be decided in the first half of 2017. Standards addressed to manufacturers may include development process, development risk management and post-market process.

September 2016 Standards Navigator New Documents

Most standards committees have meetings during the late September – mid November timeframe. During this period few new drafts are released as groups prepare for the meetings. During September there were no new draft documents released for the topics included in this report.

Medical device software

- No new documents this month

Medical Devices

- No new documents this month

Health IT and mobile health applications

- No new documents this month.

Medical device and Health Security

- No new documents this month.

Software Engineering and Information Technology

- No new documents this month.

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

These draft documents were issued in a previous month and are still being reviewed. They can be found on the SoftwareCPR Standards Navigator until their review period completes.

	Topic	Use / Users	Description
ISO/IEC 12207 DIS	Software Engineering	Manufacturers	ISO/IEC 12207 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, supply, development, operation, maintenance or disposal of software systems, products, and services.
ISO/IEC 29148 CD	Software Engineering	Manufacturers	This International Standard provides guidance for the execution of the ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207 processes that deal with requirements engineering.
ISO/IEC 25020 CD	Software Engineering	Manufacturers	This International Standard addresses the selection and construction of systems and software product quality measures. The System and software product quality measurement reference model (SPQM-RM) describes the relationship between a quality model, its associated quality characteristics (and subcharacteristics), and systems and software product attributes with the corresponding software quality measures, measurement functions, quality measure elements, and measurement methods.
ISO/IEC 25030 CD	Software Engineering	Manufacturers	This International Standard provides requirements and recommendations for the specification of system and software quality requirements. It complies with the technical processes defined in ISO/IEC 15288:2015, which are relevant for elicitation of stakeholders' quality needs and for definition and analysis of quality requirements.
ISO/IEC 20246 DIS	Software Engineering	Manufacturers	The purpose of ISO/IEC 20246 Work Product Reviews is to provide an International Standard that defines work product reviews, such as inspections, reviews and walkthroughs that can be used at any stage of the software and systems life cycle. It contains a generic process, activities, tasks, review techniques and documentation templates that are applied during the review of a work product.

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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.