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Standards Navigator

Standards Navigator Monthly Report

05-August-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 has been submitted to IEC and the French translation is complete. The FDIS is now waiting for final editing by the IEC editors, but because of a heavy workload that may take 6 to 8 weeks. So the FDIS should now be circulated by the end of September for final approval. This is a two month up or down vote so the approval should occur by December and publication in early 2017.

- 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 first CD has been circulated for comments. The closing date for comments is 9/2 and the project team will meet October 3-5 in Frankfurt to resolve the comments.

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

  Status: A proposal for a new standard, Health software and health IT systems safety, effectiveness and security – Foundational principles, concepts, and terms has been circulated to ISO and IEC for approval to begin developing the standard.

  The FDA has published guidance on general wellness apps.

- 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 approved new work on EHR Usability. This 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 has been submitted to ISO and IEC for approval to begin the revision. Work on the revision is expected to start in October.

- 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. Another meeting of the working group will be held in October and a final decision 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: 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.

- 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.

July 2016 Standards Navigator New Documents

Medical device software

- No new documents this month

Medical Devices

- No new documents this month

Health IT and mobile health applications

- The FDA has published a final guidance on *General Wellness: Policy for Low Risk Devices.* This policy applies to low risk products that promote a healthy lifestyle. FDA defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use, and (2) present a low risk to the safety of users and other persons. These general wellness products will not be regulated as medical devices. The guidance gives examples of products that meet the definition of general wellness products. Any product that is invasive or implanted is not considered low risk and so does not meet the definition. A set of questions is provided that determine whether a product is a general wellness product that falls within the scope of the guidance and will not be regulated.

  The FDA guidance is available on the SoftwareCPR Standards Navigator web page.

Medical device and Health Security

- The European Union has published a Directive concerning measures for a high common level of security of network and information systems across the Union. The directive calls for a great deal of cooperation, creates a computer security incident response team network and establishes security and notification requirements for operators of essential services and for digital service providers. Health care facilities are included as operators of essential services. Clause 50 of the directive addresses manufacturers that are not operators of essential services or digital services and does not impose any new requirements. Instead, it relies on existing rules on product liability.

  "(50) While hardware manufacturers and software developers are not operators of essential services, nor are they digital service providers, their products enhance the security of network and information systems. Therefore, they play an important role in enabling operators of essential services and digital service providers to secure their network and information systems. Such hardware and software products are already subject to existing rules on product liability."

  The EU directive is available on the SoftwareCPR Standards Navigator web page.

Software Engineering and Information Technology

- A new draft of *ISO/IEC 12207 Systems and software engineering — Software life cycle processes* has been circulated for vote. This revision of ISO/IEC 12207 is intended to be fully harmonized with ISO/IEC 15288:2015, Systems and software engineering – System life cycle processes. 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. These life cycle processes are accomplished through the involvement of stakeholders, with the ultimate goal of achieving customer satisfaction. The purpose of this standard is to provide a defined set of processes to facilitate communication among acquirers, suppliers and other stakeholders in the life cycle of a software system.

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

- A draft for comment of *ISO/IEC 29148 Systems and software engineering — Life cycle processes — Requirements engineering* has been circulated. 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. This International Standard also provides normative definition of the content and recommendations for the format of the information items or documentation that result from the implementation of these processes.

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

- A draft for comment of *ISO/IEC 25020 Systems and Software Engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Measurement reference model and guide* has been circulated. 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.

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

- A draft for comment of *ISO/IEC 25030 Systems and Software Engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — System and software quality requirements* has been circulated. 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.

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

- A draft for comment of *ISO/IEC 25011 Information technology — Systems and software Quality Requirements and Evaluation (SQuaRE) — Service Quality Models* has been circulated. This Technical Specification applies to services that make use of IT systems as tools to support the needs of an individual user or a business. These include two types of IT services:
  - a) Services completely automated provided by an IT system
  - b) Services provided by a human assisted by an IT system

  The IT service quality is the degree to which the properties of an IT service can satisfy stated and implied needs for the IT service when used under specified conditions.

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

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
IEC 62304 ed. 2 CD	Health Software	Manufacturers	The second edition of IEC 62304 extends the scope to health software. In addition, new general requirements have been added for: ○ determining and complying with all appropriate laws and regulations, ○ security risk management, and ○ usability engineering. This is a draft for comment.
IEC TR 60601-4-1 DTR	Medical devices	Manufacturers	This Technical Report is intended to help a manufacturer through the key decisions and steps required to perform a detailed risk management and usability engineering process for medical electrical equipment employing a degree of autonomy (DOA). Current medical electrical equipment standards do not fully address higher DOA modes of operation, and this Technical Report is intended to provide guidance for on how DOA could be introduced into medical electrical equipment and medical electrical systems. This is a draft for vote.
health_sw_and_IT_foundations_NP	Health IT	Manufacturers, integrators, Implementers, users	A new project for a standard on Health software and health IT systems safety, effectiveness and security – Foundational principles, concepts, and terms has been proposed. The intent of this new proposal is to provide a common explanation of the principles, concepts and terms for health software and health IT systems across the entire lifecycle, from concept to disposal. The need for this standard became apparent when it was recognized that different communities in healthcare had different understandings of same or similar terms. This document will provide a unifying foundation for other standards that collectively address all lifecycle stages, the context of use, and focus areas necessary to ensure the safety, effectiveness, and both data and system security (including privacy) of health software and health IT systems. This work is intended to complement existing established standards.
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.