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Standards Navigator

Standards Navigator Monthly Report

11-April-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.

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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 March 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: 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: 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.

  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 will close in March and a decision will be made on whether a revision is necessary.

- 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.

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- 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 working group is doing a final review of the draft. 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.

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March 2016 Standards Navigator Overview

Medical device software

- No new documents

Medical Devices

No new documents.

Health IT and mobile health applications

- No new documents

Security

- *AAMI TIR 57 Principles for medical device security – Risk management*, is out for a final review. This technical information report provides guidance on performing security risk management in the context of safety risk management as described in ISO 14971 using the expanded view of risk management defined in IEC 80001-1 of protecting the key properties of safety, data and systems security and effectiveness. Considerations for security risk management are mapped to the risk management process in ISO 14971, as well as to the security risk management process of *NIST SP 800-30 Revision 1 Guide for Conducting Risk Assessments.*

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

Software Engineering and Information Technology

- The expected DIS for ISO/IEC 12207 Software life cycle processes has been withdrawn and a fourth committee draft will be circulated instead. The new version of 12207, the 3rd edition, is intended to harmonize the structure and content of 12207 and ISO/IEC 15288:2015 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 of a software system, product or service and during the supply, development, operation, maintenance and disposal of software products.

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

- A committee draft for vote has been circulated for ISO/IEC 19770-4 IT asset management — Resource utilization measurement. The ISO/IEC 19770 family of standards is intended to assist organizations of all types to implement and operate an IT asset management system using both process and technology. ISO/IEC 19770-4 provides an International Standard for resource utilization measurement (RUM). A RUM is a standardized structure containing usage information about the resources that are related to the use of an IT asset.

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

- A working draft for comment has been circulated for ISO/IEC 42020 Systems and software engineering — Architecture processes. This standard complements the architecture-related processes identified in ISO/IEC/IEEE 15288, ISO/IEC/IEEE 12207 and ISO 15704 with process requirements that enable architects and others to more effectively and efficiently implement architecture processes that ensure greater impact of the architecture on enterprise success. The purpose of this standard is the specification of a coherent set of processes for governance, management, conceptualization, evaluation and elaboration of architectures, and

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development and maintenance of enablers that support execution of these processes. The intent is to provide specifications applicable to a wide range of solution, system and enterprise types by a broad range of architects and users.

The draft WD 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 CD	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 25066 FDIS	Software engineering	Manufacturers	This standard describes the Common Industry Format (CIF) for reporting usability evaluations. This is a final draft for vote.
ISO 19514 DIS	Software engineering	Manufacturers	This specification defines a general-purpose language for systems engineering applications, called the OMG Systems Modeling Language (OMG SysML), or simply SysML. This is a draft for vote.
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 24748-2 NP	Systems engineering	Manufacturers	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. This is a new proposal for vote.
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.

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	Topic	Use / Users	Description
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/IEC 20246 CD	System and software engineering	Manufacturers	This standard defines a generic process for work product reviews that can be configured for a specific reviewing organization. The techniques in the standard can be used at various stages to identify defects and evaluate the quality of the work product.
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.

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