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Standards Navigator

Standards Navigator Monthly Report

19-June-2017

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 continuing in 2017. Here are some of the areas to watch. (Changes are in red)

- IEC 82304-1 *Health Software: General requirements for safety* has been published. It is intended that this standard be harmonized in the EU, but it is not clear when this may happen. Although this standard has not been harmonized in the EU, notified bodies are treating it as "state-of-the-art" and are likely to expect it to be used for software products that are regulated as medical devices.
- A first committee draft of the second edition of IEC 62304 was circulated in 2016. The second edition will expand the scope of the standard to health software. A second committee draft for comment has been circulated.
- IEC TR 80002-2 *Medical device software - Part 2: Validation of software for medical device quality systems* has been published. This TR provides guidance for new requirements in ISO 13485:2016 for validating software used in quality systems. ISO/TR 80002-2:2017 applies to any software used in device design, testing, component acceptance, manufacturing, labelling, packaging, distribution and complaint handling or to automate any other aspect of a medical device quality system as described in ISO 13485.
- A new standard for health software covering all parts of the life cycle was started in 2016, *ISO 81001-1 Health software and health IT systems safety, effectiveness and security – Part 1: Foundational principles, concepts, and terms.* A committee draft for comment will be circulated in 2017. The standard is planned to be published in 2020.
- AAMI is working on a multi-part standard for health software and health IT. These standards are intended for HIT products that are not regulated by the FDA but that are (or may be in the future) certified under ONC rules. Four parts have begun work:
    - AAMI HIT1000-1, Health IT software and systems — Part 1: Fundamental concepts and principles
    - AAMI HIT1000-2, Health IT software and systems — Part 2: Application of quality systems principles and practices
    - AAMI HIT1000-3, Health IT software and systems — Part 3: Application of risk management
    - AAMI HIT1000-4, HIT1000-4, Health IT software and systems — Part 4: Application of human factors engineering

  Drafts for comment will be circulated in 2017. Publication is hoped to be in 2017 and 2018.
- A second edition of IEC 80001-1 began in 2016. The second edition will have 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*. A committee draft for comment will be circulated in 2017. The expected date of publication is January, 2020.
- IEC 80001-2-9 *Application of risk management for IT-networks incorporating medical devices - Part 2-9: Application guidance - Guidance for use of security assurance cases to demonstrate confidence in IEC TR 80001-2-2 security capabilities* has been published. This TR shows how a security assurance case can be used to demonstrate confidence that 80001-2-2 security capabilities have been achieved.
- A European Standard for application of ISO 9001 by Healthcare Delivery Organizations will be published in 2017.
- Work is continuing on revising ISO/IEC Guide 63. This guidance gives recommendations and requirements on how to include safety aspects using risk management in standards for medical devices. The work is to reflect current developments in applying risk management to medical devices considering the concepts in ISO/IEC Guide 51:2014 and ISO 31000:2009. A second committee draft was circulated in April.

- ISO 14971 and ISO/TR 24971 will be revised beginning in 2017. ISO 14971 will be revised with the following plan:

  1) maintain the concepts of and the approach to risk management,

  2) clarify the normative requirements, particularly concerning the following topics:

  - production and post-production information,
  - clinical benefits and risk-benefit analysis,

  3) move guidance in the informative annexes to ISO/TR 24971, *Medical devices -- Guidance on the application of ISO 14971*,

  4) keep the annex with the rationale in ISO 14971, *Medical devices -- Application of risk management to medical devices,*

  5) no change in scope

  6) with a 36 month track (expected publication would be in 2019),

  In addition, the the following items will be considered in the revision of ISO 14971:

  1) include references to ISO/TR 24971 and IEC/TR 80002-1, *Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software*;

  2) Clarify the relationship with 62366-1, *Medical devices -- Part 1: Application of usability engineering to medical devices,*

  3) Consider to harmonize the vocabulary with ISO 31000, *Risk management -- Principles and guidelines ,* where appropriate,

  4) Address data privacy and security.

  ISO/TR 24971 will be revised with the following plan:

  1) update the guidance ISO/TR 24971,

  2) merge and update guidance from informative annexes of ISO 14971,

  3) no change in scope,

  4) with a 36 month track (expected publication would be in 2019)

  The joint working group responsible for 14971 and 24971 met in Israel in February to begin work on the revisions.

- A second amendment to IEC 60601-1 has been started. This amendment is scheduled to be completed in 2019. Amendments will also be made to IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-10 and IEC 60601-1-11. The amendments to these collateral standards are also expected to be completed in 2019. Committee drafts for comment should be circulated in 2017. 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.

- Agreement to amend IEC 62366-1 has been reached. The amendment seeks to correct multiple, significant inaccuracies, while strictly limiting modifications to the standard to corrections. It is intended that there be no fundamental changes to the USABILITY ENGINEERING PROCESS as originally conceived in 62366-1. Work on the amendment will start in March. The amendment is planned to be published by mid-2019.

- The EU Medical Device Regulation and IVD regulation have been approved. The MDR will have a transition period of three years and the IVDR will have a transition period of five years.
- Work on the UL/AAMI 2800 series of standards on medical device interoperability will continue in 2017. It is unclear when drafts will be available for public review and when the first standards might be published.
- AAMI has begun work on *TIR97 Principles for medical device security – Post-market security management for device manufacturers*. It is expected to be completed in 2018. This guidance is intended to assist manufacturers and other users of the standard in the following:
    - Establishing a corporate level process to manage security interactions with users and others;
    - Creating design features that enable post-market management of security risk and effective integration with HDO network security policies and technologies;
    - Understanding and communicating the security needs of manufacturers and HDOs;
    - Methods needed to observe fielded devices for newly discovered security vulnerabilities and communicate that information to both the HDO and the manufacturer;
    - Methods to assess both safety and security risk to decide when action is required;
    - The development of a coordinated vulnerability disclosure policy;
    - Recommendations on methods to manage device patching;
    - Planning for device retirement.
- AAMI has begun work on SW96, a process standard for application of security risk management to medical devices. The new standard will provide the specific process to support the guidelines and concepts outlined in TIR 57. The standard will supplement and work in conjunction with TIR 57 and there is no intention to replace AAMI TIR57:2016. The objective would be to have TIR 57 to serve in a similar fashion to ISO 24971, which provides guidance and support for implementation of ISO 14971. Then this standard would serve as the process upon which the TIR 57 concepts are applied.
- UL has begun developing a series of standards on security, UL 2900. The first of these will be published in 2017.
- 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 be decided in 2017. Standards addressed to manufacturers may include development process, development risk management and post-market process. Proposals being considered (as of April 2017) include:
    - Guideline for authentication framework of the networked smart healthcare devices
    - Application of privacy management to Personal Health Information
    - Product life cycle activities for product security
- A proposal to begin work on a new standard in the area of environmental design has been approved. Work will begin on *IEC 63120 ED1 Environmental conscious design of medical electrical equipment – Particular requirements for refurbishment of medical electrical equipment and systems, for re-use of parts, for a management of critical or hazardous substances contained in medical electrical equipment and systems and for a closed loop Business-to-Business take back system* with a first draft expected in early 2018 and publication planned for 2020. The rationale for this standard is that eco-design regulations require

manufacturers on a global basis to decrease the environmental impact of their products. Globally many regulators have adopted ambitious Circular Economy plans, which include revised legislative proposals on waste to stimulate the transition towards a circular economy which is intended to boost competitiveness, foster sustainable economic growth and generate new jobs. By setting internationally accepted standards, manufacturers do not have to navigate through multiple national regulations when launching their products on the market.

- Many system and software engineering standards continue to be developed or revised. These standards are not used in medical device regulation, but may be useful to use as guidance to provide evidence that state of the art process and practices were used in developing a medical device.
- AAMI is working on a standard for classifying software defects in health software. A committee draft for vote was circulated in April.
- CEN will begin work on a new technical specification for health apps. This European Technical Specification will provide a set of requirements for developers of health and wellness apps, intending to meet the needs of health care professionals, patients, carers and the wider public. It will include a set of quality criteria and cover the app project life cycle, through the development, testing, releasing and updating of an app, including native, hybrid and web based apps, those apps associated with wearable, ambient and other health equipment and apps that are linked to other apps. It will also address fitness for purpose and the monitoring of usage. This new work will be based on BSI PAS 277 and will be developed in such a way that it may be incorporated into the 82304 series by ISO and IEC.

Standards Navigator New Documents in May 2017

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**

- A draft international standard (DIS) of *ISO/IEC 24748-2 Systems and software engineering — Life cycle management — Part 2: Guidelines for the application of ISO/IEC/IEEE 15288 (System life cycle processes)* has been circulated for ballot. This part of ISO/IEC 24748 is a guideline for the application of ISO/IEC/IEEE 15288:2015. It addresses system, life cycle, organizational, project, and process, concept application, principally through reference to ISO/IEC 24748-1 and ISO/IEC/IEEE 15288:2015.

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

- A final draft international standard (FDIS) of *ISO/IEC 29155-1 Systems and software engineering — Information technology project performance benchmarking framework — Part 1: Concepts and definitions* has been circulated for ballot. This document identifies a framework for information technology (IT) project performance benchmarking (e.g. development or maintenance productivity) and related aspects (e.g. data collection and software classification). The framework consists of activities and components that are necessary to successfully identify, define, select, apply, and improve benchmarking for IT project performance. It also provides definitions for IT project performance benchmarking terms.

  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
ISO 11633-1 CD	Information Security	Manufacturers	*ISO 11633-1 Health Informatics — Information security management for remote maintenance of medical devices and medical information systems — Part 1: Requirements and risk analysis.* This document focuses on remote maintenance services (RMS) for information systems in healthcare facilities (HCFs) as provided by vendors of medical devices or health information systems. This is a draft for comment.
AAMI SW91 CDV	Software Engineering	Manufacturers	This standard identifies a defect classification system that can be used for classifying the type of defects that may exist in the software. The use of a common taxonomy will allow industry-wide aggregation of defect occurrence data that can be used to improve software quality.
IEC TR 60601-4-3 CD	Medical devices	Manufacturers	This document contains a series of recommendations developed in response to questions of interpretation of the third edition of IEC 60601-1 and related collateral standards in the IEC 60601 series. It is expected that these recommendations within IEC 60601-4-3 will be considered when preparing future revisions of IEC 60601-1 and related collateral standards in the IEC 60601 series.

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	Topic	Use / Users	Description
ISO/IEC/IEEE 26515 DIS	Software Engineering	Manufacturers	*ISO/IEC/IEEE 26515 Systems and software engineering — Developing information for users in an agile environment*. This document supports the interest of information developers and associated roles responsible for producing information for users for software and systems developed within an agile environment. This is a draft for vote.
ISO/IEC/IEEE 42020 DIS	Systems and Software	Manufacturers	*ISO/IEC/1 IEEE 42020 Enterprise, systems and software — Architecture processes*. This document establishes a set of process descriptions for the governance and management of a collection of architectures and the architecting of entities. This is a draft for vote.
ISO 25065 CD	Software Engineering	Manufacturers	*ISO 25065 Systems and software engineering — Software product Quality Requirements and Evaluation (SQuaRE) — Common Industry Format (CIF) for Usability: User requirements specification*. This document defines the Common Industry Format (CIF) for specifying user requirements for the user interfaces of interactive systems. This document specifies the contents of a User Requirements Specification for the user interface and the format for stating requirements. This is a draft for comment.
ISO/IEC 12207 FDIS	Software Engineering	Manufacturers	This document 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.