SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

# Standards Navigator

## Standards Navigator Monthly Report

## 06-March-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

Copyright 2017 SoftwareCPR®

## Standards and regulatory activity overview

A lot of standards and regulatory activity is continuing in 2017. Here are some of the areas to watch.

- 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 will be circulated in the first half of 2017.
- IEC TR 80002-2 *Medical device software - Part 2: Validation of software for medical device quality systems* will be published in 2017. This TR provides guidance for new requirements in ISO 13485:2016 for validating software used in quality systems. 80002-2 has been approved and comments have been resolved. The draft TR will now go through IEC editing and will then be published.
- 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* will be published in 2017. 80001-2-9 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.
- 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:

**Copyright 2017 SoftwareCPR®**

- 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 will have final approval in 2017. The MDR will have a transition period of three years and the IVDR will have a transition period of five years. The final text of the regulations has been published. The EU member states have approved and the EU parliament is expected to approve soon. The regulations are expected to come into force by April or May. This will begin the transition period of 3 years for the MDR and 5 years for the IVDR.

**Copyright 2017 SoftwareCPR®**

- 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.
- 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. A series of standards that apply to product line development for a family of products are under development. Several of these have drafts currently available.

## Standards Navigator New Documents in February 2017

### Medical device software

- No new documents this month

Copyright 2017 SoftwareCPR®

**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 for final approval (FDIS) of *ISO/IEC 12207 Systems and software engineering — Software life cycle processes (Revision of ISO/IEC/IEEE 12207:2008)* has been circulated. 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..

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

- A committee draft for vote (CD) of *ISO/IEC/IEEE 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 processes and methods of specifying and documenting system and software quality requirements.

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

- A committee draft for vote (CD) of *ISO/IEC CD 25020 Systems and software engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement reference model and guide* has been circulated. This document provides reference model and guidance for selection and construction of system and software product quality measures, data quality measures and quality in use measures. This document contains the following:
  - System and software product measurement reference model;
  - Relationship between different quality models;
  - Selecting system and software quality measures;
  - Constructing system and software quality measures;
  - Description of quality measure.

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

- A committee draft for vote (CD) of *ISO/IEC/IEEE 21839 Software and systems engineering – Systems of Systems considerations in engineering of systems* has been circulated. This International Standard addresses systems of systems (SoS) considerations that apply to systems at key stages in the life cycle of systems.

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

**Copyright 2017 SoftwareCPR®**

## 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 20741 | | | This document gives guidelines for the evaluation and selection of software engineering tools, covering a partial or full portion of the software engineering life cycle. It establishes processes and activities to be applied for the evaluation of software engineering tools and selecting the most appropriate software engineering tools from several candidates. |
| ISO/IEC/IEEE 26512 | | | This document supports the interest of system users in having consistent, complete, accurate, and usable information. It addresses both available approaches to standardization: a) process standards, which specify the way that information products are to be acquired and supplied; and b) information product standards, which specify the characteristics and functional requirements of the information. |
| ISO/IEC 26553 | | | Product line realization supports the detailed design and implementation of a product line. Reusable components and member product specific components are built through this International Standard. This International Standard, within the context of tools and methods of detailed design and implementation for software and system product lines:<br>• provides the terms and definitions specific to realization for software and systems product lines.<br>• defines processes performed during product line realization. Those processes are described in terms of purpose, inputs, tasks, and outcomes.<br>• defines method capabilities to support the defined tasks of each process.<br>• defines tool capabilities to automate/semi-automate tasks or defined method capabilities.<br>This International Standard concerns processes and capabilities of realization methods and tools for a family of products, not for a single system. |

Copyright 2017 SoftwareCPR®

## 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 26554 | | | This International Standard within the methods and tools of testing for software and systems product lines:<br>• provides the terms and definitions specific to testing for software and systems product lines;<br>• defines processes performed during product line testing. Those processes are described in terms of purpose, inputs, tasks, and outcomes;<br>• defines method capabilities to support the defined tasks of each process;<br>• defines tool capabilities to automate/semi-automate tasks or defined method capabilities.<br>This International Standard concerns processes and capabilities of testing methods and tools for a family of products, not for a single system. |
| ISO/IEC 26556 | | | This International Standard within the methods and tools of organizational management for software and systems product lines:<br>• enables the users of this standard to holistically understand, adopt, and enact the processes, tools, and methods for product line organizational management. And this standard helps the users evaluate and select relevant tools and methods based on business and user-related criteria.<br>• helps product line engineers, developers, and tool vendors make informed about capabilities of tools and methods that are required for supporting product line implementation from organizational aspects.<br>• provides product line-specific processes and capabilities of tools and methods in organizational management.<br>This International Standard concerns processes and capabilities of methods and tools for organizational management for a family of products, not for a single system. |

Copyright 2017 SoftwareCPR®

## 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 26558 | | | This International Standard, within the context of methods and tools for supporting explicit and/or separate variability modelling, variability model management and variability model support in software and systems product lines:<br>• provides the terms and definitions specific to variability modelling for software and systems product line;<br>• defines processes for variability modelling, variability model management and variability model support throughout the product line lifecycle. Those processes are described in terms of purpose, inputs, tasks and outcomes;<br>• defines method capabilities to support the defined tasks of each process;<br>• defines tool capabilities that automate or semi-automate tasks and methods.<br>This International Standard does not concern processes and capabilities of tools and methods for a single system but rather deals with those for a family of products. |
| ISO/IEC 26559 | | | This International Standard, within the context of the tools and methods of variability traceability for software and system product lines:<br>• provides the terms and definitions specific to variability traceability for software and systems product lines;<br>• defines process groups and their processes for establishing and managing variability traceability at product line lifecycle processes. Those processes are described in terms of purpose, inputs, tasks, and outcomes;<br>• defines method capabilities to support the defined tasks of each process;<br>• defines tool capabilities to automate/semi-automate tasks or defined method capabilities.<br>This International Standard does not concern processes and capabilities of tools and methods for a single system but rather deals with those for a family of products. |

Copyright 2017 SoftwareCPR®

## 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 TS 33073 | | | This Technical Specification provides a Quality Management Process Assessment Model (PAM) for use in performing a conformant assessment of process capability in accordance with the requirements of ISO/IEC 33002. It is structured in accordance with the requirements of ISO/IEC 33004 to reflect processes that enable implementation of ISO 9001. |
| ISO/IEC 24748-1 | Software Engineering | Manufacturers | The purpose of this International Standard is to facilitate the joint usage of the process content of the latest revisions of ISO/IEC/IEEE 15288 and ISO/IEC 12207, by providing unified and consolidated guidance on life cycle management of systems and software. This is to help ensure consistency in system concepts and life cycle concepts, models, stages, processes, process application, key points of view, adaptation and use in various domains.<br>This is a draft for vote. |
| ISO_26513 | Software Engineering | Manufacturers | This International Standard provides the minimum requirements for testing and reviewing user documentation, including both printed and online documents used in work and other environments by the users of software which includes application software, systems software, and software that controls machinery or hardware devices. It applies to printed user manuals, online help, user assistance for mobile devices, tutorials, websites, and user reference documentation.<br>This is a draft for vote. |
| ISO/IEC/IEEE 24748-5 FDIS | Software Engineering | Manufacturers | This standard focuses on the processes required for successful planning and management of the project's software development effort and for development of the software development plan (SDP)<br>This is a final draft for approval. |

Copyright 2017 SoftwareCPR®