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Standards Navigator

Standards Navigator Monthly Report

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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.

- 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.
- 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.
- 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.
- 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:

    - 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)

- 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.
- 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.
- 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 a new TIR addressing postmarket cybersecurity. It is expected to be completed in 2018.
- 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.

November/December 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. In the past two months only a few new draft documents were 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

- FDA released a final guidance for Postmarket management of cybersecurity in medical devices. The guidance is available here.

Software Engineering and Information Technology

- A draft for vote (DIS) of *ISO/IEC 24748-1 Systems and software engineering — Life cycle management — Part 1: Guidelines for life cycle management* has been circulated. 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.

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

- A committee draft for comment (CD) of *ISO/IEC/IEEE 26511 Systems and software engineering — Requirements for managers of information for users of systems, software, and services* has been circulated. This standard is for those who manage information for users as part of the Information Management process. This document defines the information-management process from the information-development manager's point of view. It was developed to assist those who provide input to, perform, and evaluate information-development.

  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_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. 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) This is a final draft for approval.