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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

Medical device software

- Two webinars were held for the National Committees of IEC/SC 62A and the Member Bodies of ISO/TC 215, Health informatics, as well as the Member Bodies of ISO/TC 210, Quality management and corresponding general aspects for medical devices. These webinars were being held to explain the status of the IEC 62304 project. Following these webinars, a questionnaire was prepared to ask the National Committees and Member Bodies to choose an option for how to address risk management in the second edition of IEC 62304. The presentation made during the webinars and the questionnaire regarding risk management can be found on the SoftwareCPR Standards Navigator web page.

Medical devices

- The committee draft international standard for vote (IEC CDV and ISO DIS) of ISO 14971 Edition 3 was approved. Comments that were received will be resolved and the draft will move to Final Draft International Standard. No changes to the technical content of the standard will be allowed after the resolution of the comments that were received on the CDV. The new edition is expected to be approved in 2019.
- Nearly 500 comments were received on the committee draft of ISO TR 24971 Edition 2. This document is guidance on the application of ISO 14971. The comments will be resolved and another draft circulated.
- A committee draft for vote (CDV) of IEC 62366-1 Edition 1 Amd1 has been circulated. This amendment corrects identified inaccuracies in IEC 62366-1:2015 while making no fundamental changes to the usability engineering process as originally conceived in that document.
- A committee draft for comment of an amendment to the fourth edition of IEC 60601-1-2 Electromagnetic disturbances – Requirements and tests has been circulated. This amendment includes high priority issues that were considered important enough to resolve before the next full revision of the standard, which will occur no earlier than 2024.
- FDA has indicated that it will replace its Quality System Regulation (21CFR820) with ISO 14985 in the future. AAMI is developing a comparison of the requirements of 21CFR820 and ISO 13485:2016. A working draft of this comparison has been circulated for comments and is available on the SoftwareCPR Standards Navigator web page.

Cybersecurity

- Work has begun on a new technical report in the IEC 60601 series. IEC 60601-4-5: Guidance and interpretation – Safety related technical security specifications for medical devices. This document provides IT security specifications for Medical Devices connectable to Medical IT Networks as network components, including medical software applications.

Health IT

- Work is continuing on new drafts of IEC 80001-1 second edition and the new ISO 81001-1. Drafts of both standards are expected to be circulated by the end of 2018.

Standards Navigator New Standards and Guidance Documents in October 2018

Medical device software

- No new documents this month.

Medical Devices

- A draft for vote of *ISO/IEC Guide 63 Guide to the development and inclusion of aspects of safety in international standards for medical devices* has been circulated. Guide 63 provides practical guidance to standards writers on how to include safety aspects in the development of medical device standards including management system standards related to medical devices.

  The draft Guide is available on the SoftwareCPR Standards Navigator web page

- A committee draft for vote of *AAMI TIR38 Medical device safety assurance case guidance* has been re-circulated with some changes to the example. This revision includes an annex on Lessons learned regarding safety cases that provides both general industry lessons and some common problems that FDA has recognized in medical device safety cases.

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

- A committee draft for vote of an amendment to *IEC 62366-1 Application of usability engineering to medical devices* has been circulated. This amendment corrects identified inaccuracies in IEC 62366-1:2015 while making no fundamental changes to the usability engineering process as originally conceived in that document.

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

- A committee draft for comment of an amendment to the fourth edition of *IEC 60601-1-2 Electromagnetic disturbances – Requirements and tests* has been circulated. This amendment includes high priority issues that were considered important enough to resolve before the next full revision of the standard, which will occur no earlier than 2024

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

- A committee draft for vote of *AAMI TIR 75 - Factors to consider when multi-vendor devices interact via an electronic interface; Practical applications and examples* has been circulated. This document is intended to assist stakeholders in considering risks associated with connectivity when designing, testing, installing, and maintaining devices that interact via an electronic interface. It identifies a number of specific factors that should be considered as part of risk management activities. It also provides examples where these factors are used to identify causes, hazards, and hazardous situations related to interoperability.

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

- A draft for comment of *AAMI SW95 Forensic Data Logger for an Integrated Clinical Environment (ICE)* has been circulated. This standard provides general functional and interoperability requirements for system data logging capabilities including the recording and storage of the data in support of forensic analysis of ICE systems. Data logs, data logging, and data loggers can play an important role in the basic safety and essential performance of integrated clinical environments by enabling the assessment of the performance of the ICE system and its components.

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

- A working draft of *AAMI TIR 102 comparison of the requirements of 21CFR820 and ANSI/AAMI/ISO 13485:2016* has been circulated. This TIR is a correspondence of requirements between 21 CFR 820 and ANSI/AAMI/ISO 13485 that highlights similarities, differences, and key considerations for medical device manufacturers. The comparison covers all parts of 21CFR820 including appropriate references to the Preamble to QS Regulation and ANSI/AAMI/ISO 13485.

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

Health IT and mobile health applications

- No new documents this month.

Medical device and Health Security

- A draft of *AAMI TIR 97 Principles for medical device security — Postmarket risk management for device manufacturers* has been circulated for comments. The objective of this TIR is to provide guidance on how medical device manufacturers should manage security risk in the production and post-production phases of the life-cycle of a medical device within the risk management framework defined by ISO 14971:2007. TIR97 is intended to be used in conjunction with AAMI TIR57:2016.

  The draft of the TIR 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 web page until their review period completes.

	Topic	Use / Users	Description
MDS2	Cyber security	Manufacturers and HDOs	A draft of a revision of the Manufacturer Disclosure Statement for Medical Device Security (MDS2) has been circulated for comments. This document and accompanying form has been prepared by the US National Electrical Manufacturers Association (NEMA) and other collaborating organizations. The MDS2 is widely requested by hospitals when they ask for proposals for purchasing medical equipment. In addition to adding questions to some existing sections, new sections were added covering remote service, software bill of materials, connectivity capabilities and software roadmap. This is a draft for comment.
MDS2 Form	Cyber security	Manufacturers and HDOs	Draft of the form that accompanies the MDS2. This is a draft for comment.