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Standards Navigator

Standards Navigator Monthly Report

4-June-2018

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 devices

- The Committee Draft for Vote of the second edition of IEC 62304 was not approved. The major area of disagreement is whether ISO 14971 should be required for all health software. ISO 14971 is a medical device standard, but not all health software products are medical devices. Those saying 14971 should be required argue that it is not possible to determine risk if a process that conforms to 14971 is used. On the other side those are those who say that there are many risk management standards and products that are not medical devices should be able to conform to 62304 by using a process from one of those standards. The working group will attempt to find a path forward at its meeting in June.
- Drafts of the revisions of ISO 14971 and ISO/TR 24971 are expected following the working group meeting in June.
- There has been a request to add another change to the amendment to IEC 60601-1. The proposed change would adopt the requirements of IEC 62368-1 as an alternative design solution to IEC 60950-1 for means of operator protection. This change had been planned for the next edition of IEC 60601-1, but concerns have risen that component manufacturers may begin adopting IEC62368-1 and IEC 60950-1 compliant devices may not be available. If it is decided to make this change, the amendment to IEC 60601-1 may be delayed past its expected completion date in 2019.

Cybersecurity

- A new IEC guidance document, Guide 120, is being developed by ACSEC, Advisory Committee on Information Security and Data Privacy. A proposed final draft has been submitted for approval to IEC National Committees.
- A proposal has been made for a new guidance document for identification and authentication for connectable PHDs.

Health IT

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Standards Navigator New Documents in May 2018

Medical device software

- No new documents this month.

Medical Devices

- A committee draft of amendment 2 to *IEC 60601-1-10:2007: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers* has been circulated for comment. The amendment corrects errors and makes modifications that are considered too important to wait for the next edition.

  The draft standard 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 proposal for a new guidance for identification and authentication for connectable Personal Health Devices (PHDs) has been distributed. The scope of this document includes guidance for identification and authentication between the bidirectionally connected PHD and gateway by providing possible use cases and associated threats and vulnerabilities. Since some smart devices with mobile healthcare apps and software may connect to the healthcare service network, these devices will be considered as connectable PHDs in this document.

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

- A final draft of *IEC Guide 120 Security Aspects – Guidelines for their inclusion in publications* has been distributed by the Advisory Committee on Information Security (ACSEC). The target audience for this document is standards writers. This document provides guidelines on the security topics to be covered in IEC publications, and aspects of how to implement them. These guidelines can be used as a checklist for the combination of publications used in implementation of systems.

  The draft Guide 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 FDIS			*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 as provided by vendors of medical devices or health information systems. When RMS is implemented, the RMS provider and the healthcare facility should jointly perform and reach agreement on a risk analysis for the RMS implementation. This is a draft for vote.
IEC/ISO Security Proposals	Cybersecurity	Manufacturers	Proposal for a new standard for security lifecycle that covers both medical devices and non-regulated health software, and a new guidance for security functions that covers medical devices. This is a draft for discussion.