

Standards Navigator

Standards Navigator Monthly Report

13-November-2015

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>

October 2015 Standards Navigator Overview

Medical device software

- A new IMDRF document was finalized. It is *Software as a Medical Device (SaMD): Application of Quality Management System*. The objective of the document is to provide guidance on the application of existing standardized and generally accepted QMS practices to SaMD.

The document can be downloaded from the IMDRF website at <http://www.imdrf.org/documents/documents.asp>.

- A new work item for SaMD was approved. It is “*Software as a Medical Device(SaMD): Clinical Evaluation*.” The purpose of the new work is to give detailed guidance on when clinical data may be needed for an original SaMD and for a modification to a SaMD based on the risk classification for SaMD (SaMD N12) adopted by IMDRF to support market authorization. The goal is to have a draft for review by March and a published document by September 2016.
- The CDV/DIS of *IEC 82304-1: Health Software - Part 1: General requirements for product safety*, was approved, but there were about 300 comments. The project team will now resolve the comments and issue a Final Draft early in 2016.

Medical Devices

- No new documents
- *ISO 14971 Medical Devices – Application of risk management to medical devices* is currently undergoing its 5 year systematic review. After the review period ends on March 15, ISO TC 210 will determine whether to begin a revision of the standard.

Health IT and mobile health applications

- No new documents this month.

Security

- The Draft TR of *IEC TR 80001-2-8: Application of risk management for IT networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2*, was approved for publication. Following final comment resolution the TR will be published in early 2016.

Software Engineering and Information Technology

- A Final Draft of *ISO/IEC 19770-3: Information technology -- IT asset management -- Part 3: Entitlement schema*, has been circulated for vote.

This part of ISO/IEC 19770 provides a technical definition of a schema that can encapsulate the details of software entitlements, including usage rights, limitations and metrics.

The primary intentions of this document are:

1. To provide a basis for common terminology to be used when describing entitlement rights, limitations and metrics
2. To provide a schema which allows effective description of rights, limitations and metrics attaching to a software license.

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

- A Draft of *ISO/IEC 20741: Systems and Software Engineering -- Guideline for the evaluation and selection of software engineering tools*, has been circulated for vote.

This standard is designed to provide a consistent and coherent framework for the evaluation and selection of software engineering tools with a set of International Standards. The set of standards, as a whole, defines processes of evaluation and selection and characteristics and/or capabilities of software engineering tools.

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

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

These draft documents can be found on the SoftwareCPR Standards Navigator until their review period completes.

	Topic	Use / Users	Description
ISO/IEC 12207 DIS	Software engineering	Manufacturers	This International Standard 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 of a software system, product, or service and during the supply, development, operation, maintenance, and disposal of software products.
ISO 24748-4 FDIS	Software Engineering	Manufacturers	<i>ISO 24748-4 System and software engineering – Life cycle processes – System engineering planning</i> Final draft for vote ISO 24748 specifies the technical management processes from ISO/IEC/IEEE 15288 that are required to be implemented for planning a systems engineering project. This is a final draft for approval.
ISO/IEC 15026-3 FDIS	Software engineering	Manufacturers	<i>ISO/IEC/ 15026-3 Systems and software engineering — Systems and software assurance — Part 3: System integrity levels</i> Final draft for vote This part of ISO/IEC 15026 specifies the concept of integrity levels with corresponding integrity level requirements that are required to be met in order to show the achievement of the integrity level.

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	Topic	Use / Users	Description
ISO/IEC/IEEE 20246 DIS	Software engineering	Manufacturers	<i>ISO/IEC/IEEE 20246 Systems and Software Engineering - Work product reviews</i> Draft for vote.

REFERENCE LIBRARY

	Topic	Use / Users	Description
ONC 10-Year Vision	Health IT	Health IT infrastructure	<i>ONC 10-Year Vision to Achieve an Interoperable Health IT Infrastructure</i> The document can be found on the SoftwareCPR Standards Navigator web page or at http://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf
BSI white paper	Medical devices	Manufacturers	<i>"The proposed EU regulations for medical and in vitro diagnostic devices"</i> The white paper can be found on the SoftwareCPR Standards Navigator web page

EC green paper	Health IT	Manufacturers	<p><i>“Green Paper on mobile Health (mHealth)”</i></p> <p>The green paper can be found on the SoftwareCPR Standards Navigator web page</p>
IMDRF SaMD Definitions	Software	Manufacturers	<p>Software as a Medical Device (SaMD): Key Definitions Report on international harmonization of definitions for software as a medical device. Adopted by IMDRF in November 2013.</p> <p><i>The report can be found on the SoftwareCPR Standards Navigator web page.</i></p>
Euro Commission	Medical Devices	Manufacturers	<p>Commission recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices.</p> <p><i>The document can be found on the SoftwareCPR Standards Navigator web page.</i></p>
FDA Safety communication on cybersecurity	Security	Manufacturers and hospitals	<p>FDA has become aware of cybersecurity vulnerabilities and incidents that could directly impact medical devices or hospital network operations. This safety communication recommends that medical device manufacturers take steps to limit opportunities for unauthorized access to medical devices and hospitals take steps to evaluate network security and protect the hospital systems. The FDA also recommends prompt reporting of events that have impacted the performance of a medical device or hospital network.</p>
ICS-CERT Alert regarding medical devices with hard-coded passwords	Security	Manufacturers , hospitals	<p>ICS-CERT is issuing this alert to provide early notice of a report of a hard-coded password vulnerability affecting roughly 300 medical devices across approximately 40 vendors. According to their report, the vulnerability could be exploited to potentially change critical settings and/or modify device firmware. The alert also identifies baseline mitigations for reducing risks to these and other cybersecurity attacks.</p>

ONC Patient Safety Action & Surveillance Plan	Health IT safety	Health IT manufacturers , hospitals	The final version of the ONC plan that has the objectives to use health IT to make care safer and to continuously improve the safety of health IT.
<i>ONC contract with the Joint Commission to investigate health IT-related safety events</i>	Health IT safety	Hospitals, health IT manufacturers	The purpose of this contract is to ensure that there is an early detection system on health IT-related safety issues, including those associated with EHRs.
ONC guidance on annual surveillance plans by authorized certification bodies	Surveillance of certified EHRs	Authorized EHR certification bodies	Authorized Certification Bodies are expected to conduct surveillance on EHRs that they have certified. This guidance provides the priorities for topics to assess in the surveillance plan. Safety-related capabilities and security capabilities are two of the four areas for priority identified in this guidance.
TEAM-NB position paper on use of ISO 14971:2012	Risk management	Manufacturers	Describes the steps TEAM-NB members plan to verify where relevant if requirements of EN ISO 14971:2012 have been met. This should help manufacturers update their risk management procedures and files to maintain compliance with the Essential Requirements of the directives, when building on the presumption of conformity. <i>The position paper can be found on the SoftwareCPR Standards Navigator web page.</i>

TEAM-NB “Vision on Revision”	Regulation	Regulators, Manufacturers , Notified bodies	<p>This document forms the input of TEAM-NB into the debate on The Revision of European Legislation on Medical Devices. Contributions came from BSI Germany, BSI UK, DEKRA Netherlands, TUV Austria, and TUV Sud.</p> <p><i>The report can be found on the SoftwareCPR Standards Navigator web page.</i></p>
Report	Interoperability	Medical device manufacturers , Hospitals, Regulators	<p>AAMI/FDA Interoperability Summit report</p> <p>An AAMI/FDA sponsored summit meeting on medical device interoperability was held in late 2012. This report documents the discussion and identifies themes from the summit.</p> <p>This report can be found at http://www.aami.org/interoperability/Interoperability_Summit_publication.pdf</p>
Report	Wireless	Hospitals, Medical device manufacturers	<p>AAMI Wireless Workshop report</p> <p>A workshop with approximately 80 invited medical wireless experts was held in late 2012. This report documents the discussion and outcomes of this workshop. A follow-up meeting is planned for March 2013.</p> <p>This report can be found at http://www.aami.org/wireless/2012_Wireless_Workshop_publication.pdf</p>

Report	Security	Medical device manufacturers, Regulators	<p>GAO report on FDA review of certain medical devices</p> <p>The General Accounting Office does investigations for the US Congress. In this report they reviewed how FDA reviewed implanted medical devices that used wireless communications for security vulnerabilities that could cause safety concerns. They looked at two devices that researchers had shown could be controlled by use of off-the-shelf radio devices. In their findings, they criticized FDA for not reviewing security capabilities in these devices, even though they determined that FDA had the authority to do so. This will certainly result in FDA increasing their scrutiny of security for these type of devices. Since a security vulnerability in a device that is wirelessly communicating over a network seems to surely pose a risk as well, it is likely that FDA will also increase security scrutiny of all devices that use wireless communications.</p> <p>Dr. Kevin Fu testified to the National Institute of Standards and Technology <u>Information Security & Privacy Advisory Board</u> that "Conventional malware is rampant in hospitals because of medical devices using unpatched operating systems. There's little recourse for hospitals when a manufacturer refuses to allow OS updates or security patches."</p> <p>A report of the meeting can be found in the MIT Technology Review http://www.technologyreview.com/news/429616/computer-viruses-are-rampant-on-medical-devices-in-hospitals/</p> <p>The article states that "In September, the Government Accountability Office issued a <u>report</u> warning that computerized medical devices could be vulnerable to hacking, posing a safety threat, and asked the FDA to address the issue. The GAO report focused mostly on the threat to two kinds of wireless implanted devices: implanted defibrillators and insulin pumps. The vulnerability of these devices has received widespread press attention (see "<u>Personal Security</u>" and "<u>Keeping Pacemakers Safe from Hackers</u>"), but no actual attacks on them have been reported.</p> <p>Fu, who is a leader in researching the risks described in the GAO report, said those two classes of device are "a drop in the bucket": thousands of other network-connected devices used for patient care are also vulnerable to infection. "These are life-saving devices. Patients are overwhelmingly safer with them than without them. But cracks are showing," he said. (Fu was <i>Technology Review's</i> <u>Innovator of the Year</u> in 2009.)"</p> <p>One of Dr. Fu's collaborators in research that showed an implanted defibrillator could be hacked was Dr. William Maisel who is now the Deputy Director for Science at CDRH. FDA staff has indicated that they are in the process of revising the FDA Cybersecurity Guidance. This guidance will likely include recommendations for manufacturer's security programs for devices and additional recommendations for security information to be provided during pre-market review of devices that are intended for use on a network. In addition, the guidance is now expected to provide information on when a security issue is reportable to the FDA and when a security event will result in a recall.</p> <p>Another interesting bit of information in this report was the FDA response that they had hired a consultant (later determined to be McKinsey) to assess how they review software and make suggestions for improvements. This assessment is supposed to be completed by the end of 2012.</p>
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Report	Mobile medical devices	Medical devices manufacturers, Hospitals, Regulators	<p>FCC report on Mobile Medical Devices</p> <p>The FCC created an independent mHealth Task Force, to research the barriers to rapid deployment of mHealth technology and develop recommendations to government and industry to address those barriers. This report documents the task force recommendations for achieving 5 goals:</p> <p>Goal 1: FCC should continue to play a leadership role in advancing mobile health adoption.</p> <p>Goal 2: Federal agencies should increase collaboration to promote innovation, protect patient safety, and avoid regulatory duplication.</p> <p>Goal 3: The FCC should build on existing programs and link programs where possible in order to expand broadband access for healthcare.</p> <p>Goal 4: The FCC should continue efforts to increase capacity, reliability, interoperability and RF safety of mHealth technologies.</p> <p>Goal 5: Industry should support continued investment, innovation, and job creation in the growing mobile health sector.</p> <p>Recommendations include:</p> <ul style="list-style-type: none"> • greater collaboration with other US Federal agencies • promoting the availability of broadband for healthcare • harmonizing spectrum allocations for healthcare internationally • industry use of standards based technologies for transmitting authenticated messages and encrypted health information <p><i>This report can be found on the Standards Navigator web page</i></p>
Report	Health IT	Hospitals, EHR vendors, MD manufacturers	<p>Institute of Medicine report – Health IT and patient safety</p> <p>The Institute of Medicine produced a report on the impact of Health IT on patient safety. The report had a number of recommendations for the Secretary of HHS.</p> <p><i>A presentation on the recommendations and the entire report are available at the SoftwareCPR Standards Navigator web page.</i></p>

Regulation	Regulation	Medical device manufacturers , IVD manufacturers	<p>EU draft proposed new Medical Device Regulation and In-Vitro Device Regulation</p> <p>These draft regulations can be found at http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf - medical devices http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf - In-vitro devices</p>
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STANDARDS CURRENTLY UNDER DEVELOPMENT OR REVISION

	Topic	Use / Users	Description
IEC 62304 Edition 2	Software Life Cycle	Health Software Vendors including medical device manufacturers	<p>The second edition expands the scope of 62304 from medical device software to health software. Health software is any software that is developed with an intended purpose of being used for health services. This includes software developed for medical devices.</p> <p>Current status: An initial committee draft is being developed.</p> <p>Next step: A draft is expected to be circulated in October 2015.</p> <p>Expected completion: 2018</p>
IEC 82304-1	Health Software	Medical device manufacturers, Regulators	<p>New standard on Health Software: General Requirements. This standard is intended to be for standalone software products and to cover the product level requirements such as product validation, labeling, documents to be provided to the user, etc.</p> <p>Current status: CDV has been circulated and is currently out for vote.</p> <p>Next step: Resolution of comments on the CDV.</p> <p>Expected completion: 2016</p>

ISO 13485	Medical devices	Medical device manufacturers, Regulators	<p>The Quality Management System standard is being revised to bring it into alignment with ISO 9001:2008.</p> <p>Current status: Second DIS was approved in ISO but not in CEN.</p> <p>Next step: FDIS to be circulated in ISO.</p> <p>Expected completion: 2016</p>
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