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Standards Navigator

Standards Navigator Monthly Report

3-April-2015

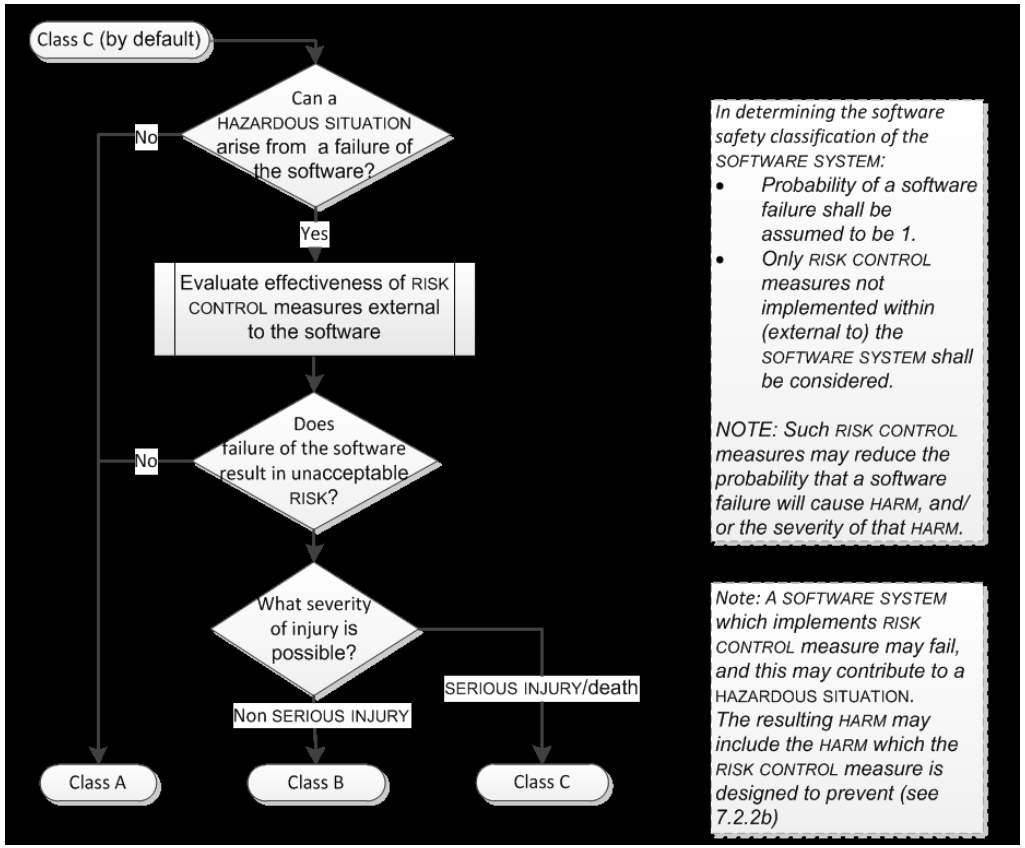
SoftwareCPR Standards Navigator provides information and tools related to standards that play a significant role in health software and software intensive medical devices. In addition to information on existing standards, SoftwareCPR Standards Navigator keeps you up to date on new standards activity and gives you expert insight into future changes to existing standards.

http://www.softwarecpr.com/topicsframepage.htm

March 2015 Standards Navigator Overview

Medical device software

- The FDIS for IEC 62304 Amendment 1 has been circulated for a 2 month final vote. The major changes in the amendment are to the determination of software safety class and a new section on using the standard for legacy software that was developed prior to the initial approval of 62304. The changes to safety classification can be seen in this figure from the amendment.



The draft amendment is available on the SoftwareCPR Standards Navigator web page. IEC will publish a consolidated version following approval and publishing of the amendment.

- The IMDRF SaMD working group has a working draft of a quality system for Software as a Medical Device available. A draft for public comment will be available in the near future on the IMDRF website.

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

- Work on the second edition of IEC 62304 has begun and a committee draft is expected by the end of this year.

Medical Devices

- No new documents this month.

Health IT and mobile health applications

- AAMI presented its new initiative for HIT standards. A background document and presentation were made available.

  The HIT standards initiative documents are available on the SoftwareCPR Standards Navigator web page.

Security

- No new documents this month.

Software Engineering and Information Technology

- A second committee draft for vote (DIS) of ***ISO/IEC 29119-5 - Systems and software engineering — Keyword driven testing*** has been circulated.

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

- A preliminary draft Technical Report for ***ISO/IEC 33010 - Information Technology — Process Assessment — Guidance for performing an assessment*** has been circulated.

  The draft standard 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 13485 DIS	Medical devices	Manufacturers	A second draft for vote (DIS) of the third edition of ISO 13485 has been circulated. This third edition will replace ISO 13485:2003. It is based on, and follows the format of, ISO 9001:2008.
ISO/IEC/IEEE 12207 DIS	Software Engineering	Manufacturers	*ISO/IEC 12207 - Systems and software engineering — Software life cycle processes* Draft for vote. This new revision of ISO/IEC/IEEE 12207 is the product of a coordinated effort by IEEE and ISO/IEC JTC 1/SC 7 to completely harmonize life cycle process standards for systems and for software.
ISO/IEC 33010 FDIS	Software Engineering	Manufacturers	*ISO/IEC 33010 - Information Technology — Process Assessment — Process assessment model for software testing* Final draft for approval This standard provides an example of a process assessment model for software testing for use in performing a conformant assessment in accordance with the requirements of 'ISO/IEC 33002.
ISO/IEC 25011 CD	Information technology	Manufacturers	*ISO/IEC 25011 Information technology — Service Quality Requirements and Evaluation (SQuaRE) — Service Quality Model* Committee draft for comment. This International Standard defines a quality model for services that use IT made up from a combination of resources including people, processes, technology, facilities and information. The model is composed of characteristics (which are further subdivided into subcharacteristics) that can be used to support the requirements definition, design, deployment, delivery and improvement of services that use IT.

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	Topic	Use / Users	Description
ISO/IEC 19770-5 FDIS	Information technology	Manufacturers	ISO/IEC FDIS 19770-5 Information technology – IT asset management – Overview and vocabulary This International Standard provides an overview of software asset management, which is the subject of the ISO/IEC 19770 family of standards, and defines related terms. (2015-05-03)
ISO/IEC 25023 DIS	Software Engineering	Manufacturers	ISO/IEC DIS 25023 Systems and software Engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of system and software product quality This International Standard is a part of the SQuaRE series of international standards. It provides a set of measures for the characteristics of system/software products that can be used for specifying requirements and measuring and evaluating the system/software product quality. (2015-05-09)
ISO/IEC 30130 DIS	Software Engineering	Manufacturers	ISO/IEC 30130 Software engineering – Capabilities of Software Testing Tools This International Standard defines the framework to which capabilities of software testing tools are allocated in order to identify the capabilities of products being used by any project for software testing. The framework is defined by objectives of testing, granularity of software to be tested and capabilities. (2015-05-09)
ISO/IEC 25022 DIS	Software Engineering	Manufacturers	ISO/IEC DIS 25022 Systems and software Engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of quality in use This International Standard is a part of the SQuaRE series of international standards. It provides a set of measures for the characteristics of quality in use (defined in ISO/IEC 25010) that can be used for specifying quality in use requirements (in conjunction with ISO/IEC 25030) and measuring and evaluating quality in use (in conjunction with ISO/IEC 25040 and ISO/IEC 25041). (2015-05-11)

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	Topic	Use / Users	Description
ISO/IEC 25024 DIS	Software Engineering	Manufacturers	ISO/IEC DIS 25024 Systems and software Engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of data quality This International Standard is a part of the SQuaRE series of international standards. It provides a set of data quality measures that can be used for measuring and evaluating data quality, by referring other SQuaRE series of standards, especially ISO/IEC 25012 SQuaRE – Data quality model. (2015-05-11)
ISO/IEC 19770-3 DIS	Information Technology	Manufacturers	ISO/IEC DIS 19770-3 Information technology – IT asset management – Part 3: Software entitlement schema This part of ISO/IEC 19770 establishes a set of terms and definitions which may be used by the industry when discussing software entitlements (the key elements within software licenses). It also provides specifications for a file format which enables the digital encapsulation of software entitlements, including associated metrics and their management. (2015-05-09)
ISO/IEC 25066 DIS	Software Engineering	Manufacturers	*ISO/IEC 25066 Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Common industry Format for Usability — Evaluation Reports* This International Standard describes the Common Industry Format (CIF) for reporting usability evaluations. It provides a classification of evaluation approaches and the specifications for the content items in an evaluation reports (content elements). (2015-04-08)

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	Topic	Use / Users	Description
ISO/IEC 19770-2 DIS	Software Engineering	Manufacturers	*ISO/IEC 19770-2 Information technology — Software asset management — Part 2: Software identification tag* This part of ISO/IEC 19770 provides an International Standard for software identification (SWID) tags. The software identification tag is a standardized data structure containing identification information about a software product that supports new and automated management functions. (2015-04-08)

REFERENCES

	Topic	Use / Users	Description
ONC 10-Year Vision	Health IT	Health IT infrastructure	*ONC 10-Year Vision to Achieve an Interoperable Health IT Infrastructure* 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	*"The proposed EU regulations for medical and in vitro diagnostic devices"* The white paper can be found on the SoftwareCPR Standards Navigator web page
EC green paper	Health IT	Manufacturers	*"Green Paper on mobile Health (mHealth)"* The green paper can be found on the SoftwareCPR Standards Navigator web page

IMDRF SaMD Definitions	Software	Manufacturers	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. ***The report can be found on the SoftwareCPR Standards Navigator web page.***
Euro Commission	Medical Devices	Manufacturers	Commission recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices. ***The document can be found on the SoftwareCPR Standards Navigator web page.***
FDA Safety communication on cybersecurity	Security	Manufacturers and hospitals	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.
ICS-CERT Alert regarding medical devices with hard-coded passwords	Security	Manufacturers, hospitals	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.
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.

ONC contract with the Joint Commission to investigate health IT-related safety events	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. ***The position paper can be found on the SoftwareCPR Standards Navigator web page.***
TEAM-NB "Vision on Revision"	Regulation	Regulators, Manufacturers, Notified bodies	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. ***The report can be found on the SoftwareCPR Standards Navigator web page.***

Report	Interoperability	Medical device manufacturers, Hospitals, Regulators	AAMI/FDA Interoperability Summit report 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. This report can be found at http://www.aami.org/interoperability/Interoperability_Summit_publication.pdf
Report	Wireless	Hospitals, Medical device manufacturers	AAMI Wireless Workshop report 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. This report can be found at http://www.aami.org/wireless/2012_Wireless_Workshop_publication.pdf

Report	Security	Medical device manufacturers, Regulators	GAO report on FDA review of certain medical devices 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. Dr. Kevin Fu testified to the National Institute of Standards and Technology Information Security & Privacy Advisory Board 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." 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/ The article states that “In September, the Government Accountability Office issued a report 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 "Personal Security" and "Keeping Pacemakers Safe from Hackers"), but no actual attacks on them have been reported. 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 *Technology Review's* Innovator of the Year in 2009.)” 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. 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.

Report	Mobile medical devices	Medical devices manufacturers, Hospitals, Regulators	FCC report on Mobile Medical Devices 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: Goal 1: FCC should continue to play a leadership role in advancing mobile health adoption. Goal 2: Federal agencies should increase collaboration to promote innovation, protect patient safety, and avoid regulatory duplication. Goal 3: The FCC should build on existing programs and link programs where possible in order to expand broadband access for healthcare. Goal 4: The FCC should continue efforts to increase capacity, reliability, interoperability and RF safety of mHealth technologies. Goal 5: Industry should support continued investment, innovation, and job creation in the growing mobile health sector. Recommendations include: • 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 ***This report can be found on the Standards Navigator web page***
Report	Health IT	Hospitals, EHR vendors, MD manufacturers	Institute of Medicine report – Health IT and patient safety 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. ***A presentation on the recommendations and the entire report are available at the SoftwareCPR Standards Navigator web page.***

Regulation	Regulation	Medical device manufacturers, IVD manufacturers	EU draft proposed new Medical Device Regulation and In-Vitro Device Regulation 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

STANDARDS CURRENTLY UNDER DEVELOPMENT OR REVISION

	Topic	Use / Users	Description
IEC 62304 Amendment 1	Software Life Cycle	Medical Device manufacturers, Regulators	Amendment to the Medical Device Software Life Cycle standard. This standard is harmonized in the EU. The amendment addresses software safety classification and how to be compliant with legacy software. Current status: Comments received on the CDV have been resolved and the FDIS is being edited by IEC. Expected completion: mid 2015
IEC 82304-1	Health Software	Medical device manufacturers, Regulators	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. Current status: Comments received on the second CD are being resolved. Next step: A CDV is expected to be circulated in early 2015. Expected completion: end of 2015
ISO 13485	Medical devices	Medical device manufacturers, Regulators	The Quality Management System standard is being revised to bring it into alignment with ISO 9001:2008. Next step: Second DIS is currently out for ballot. Expected completion: 2016