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Standards Navigator

Standards Navigator Monthly Report

3-May-2014

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

April 2014 Standards Navigator Overview

Medical device software

- A Committee Draft for Vote of the Amendment to *IEC 62304: Medical device software – Software life cycle processes* is available for vote and comment. This will be the final opportunity to make technical comments on this amendment. The amendment modifies the way that the software safety class is determined, adds requirements for legacy products that were developed prior to IEC 62304 and makes other clarifications and modifications.

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

Medical Devices

- A draft for vote of *ISO 16142-1: Medical devices — Recognized essential principles of safety and performance of medical devices* is available for vote and comment. The essential principles of safety and performance of medical devices, originally developed by the Global Harmonization Task Force (GHTF) and now maintained by the International Medical Device Regulators Forum (IMDRF), were revised in 2012 to harmonize regulatory requirements for medical devices worldwide. This standard identifies significant standards and guides that can be used in the assessment of conformity of medical devices to the recognized essential principles that when met, indicate a medical device is safe and performs as intended.

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

- BSI has published a white paper on “The proposed EU regulations for medical and in vitro diagnostic devices”. This white paper provides an update of the proposed revisions to EU medical device regulation as of April 2014.

  The white paper is available on the SoftwareCPR Standards Navigator web page.

Health IT and mobile health regulation

- The European Commission has published a “Green Paper on mobile Health (mHealth)” for consultation. The Green Paper was issued by the DG Communications Networks, Content and Technology, which is a different part of the commission from the DG that regulates medical devices. The Green Paper seeks stakeholders’ views on various issues, including data protection, patient safety, interoperability and others. Comments on these issues are requested by July3, 2014.

  The green paper is available on the SoftwareCPR Standards Navigator web page.

Security

Software Engineering

- A final draft of *ISO 90003: Guidelines for the application of ISO 9001:2008 to computer software* is available for vote. This is a yes or no vote, no technical comments are allowed. ISO 90003 provides guidance to assist in understanding how the provisions of ISO 9001:2008 apply in the context of software.

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

- A final draft of *ISO 15289, 2nd Ed: Content of life-cycle information products (documentation)* is available for vote. This is a yes or no vote, no technical comments are allowed. ISO 15289 specifies the purpose and content of all identified systems and software life-cycle and service management information items (documentation). ISO 15289 provides a mapping of ISO/IEC 15288:2008, ISO/IEC 12207:2008, and ISO/IEC 20000-1:2011 and ISO/IEC 20000-2 clauses with a set of information items. It provides a consistent approach to meeting the information and documentation requirements of systems and software engineering and IT service management.

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

- A draft for ballot of *ISO 24748-4: Life cycle management — Part 4: Systems engineering planning* is available for vote and comment. This is one part of a multi-part standard intended to facilitate the joint usage of the process content of ISO/IEC 15288 and ISO/IEC 12207. This Part 4 focuses on the processes required for successful planning and management of the project's systems engineering effort.

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

- A new work item proposal for *ISO TS 24748-6: Life cycle processes — System integration engineering* is available for ballot. A draft of the proposed new technical specification is available for comment. ISO TS 24748-6 specifies the required activities and processes that are to be implemented for the engineering of integration of systems throughout the life cycle.

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

Activity – April 2014

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
IEC 62304 Amd CDV	Medical device software	Manufacturers	*IEC 62304: Medical device software – Software life cycle processes* The CDV of the Amendment can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on July 18.
ISO 16142-1 DIS	Medical devices	Manufacturers	*ISO 16142-1: Medical devices — Recognized essential principles of safety and performance of medical devices* The DIS can be found on the SoftwareCPR Standards Navigator web page
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
ISO 90003 FDIS	Software engineering	Manufacturers	*ISO 90003: Guidelines for the application of ISO 9001:2008 to computer software* The FDIS can be found on the SoftwareCPR Standards Navigator web page

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO 15289, 2nd Ed FDIS	Software engineering	Manufacturers	*ISO 15289, 2nd Ed: Content of life-cycle information products (documentation)* The FDIS can be found on the SoftwareCPR Standards Navigator web page
ISO 24748-4 DIS	Software engineering	Manufacturers	*ISO 24748-4: Life cycle management — Part 4: Systems engineering planning* The DIS can be found on the SoftwareCPR Standards Navigator web page
ISO 24748-6 NP	Software engineering	Manufacturers	*ISO TS 24748-6: Life cycle processes — System integration engineering* The NP can be found on the SoftwareCPR Standards Navigator web page

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

IMDRF draft recommendation for comment	Medical device software	Manufacturers	*Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Controls* The draft recommendation can be found on the SoftwareCPR Standards Navigator web page. The comment period ends May 31.
FDASIA Health IT Report	Health IT	Manufacturers	*Proposed Strategy and Recommendations for a Risk-Based Framework* The draft proposal can be found on the SoftwareCPR Standards Navigator web page. The comment period ends July 7. FDA will hold a public meeting on May 13.
IEC 60601-1-12 FDIS	Medical devices	Manufacturers	*IEC 60601-1-12: Medical electrical equipment – General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*. The FDIS can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 30.
IEC 60601-1-11 CDV	Medical devices	Manufacturers	*IEC 60601-1-11: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* The CDV can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 30.
ISO/IEC/IEEE 12207 CD	Software engineering	Manufacturers	*ISO/IEC/IEEE 12207 Systems and software engineering — Software life cycle processes* The CD can be found on the SoftwareCPR Standards Navigator web page

ISO/IEC 15026-3 CD	Software engineering	Purchasers and Manufacturers	*ISO/IEC 15026-3 Systems and software engineering —Systems and software assurance — Part 3: Systems integrity levels* The CD can be found on the SoftwareCPR Standards Navigator web page
ISO/IEC 29119-5 CD	Software engineering	Manufacturers	*ISO/IEC 29119-5 Software and Systems Engineering — Software Testing — Part 5: Keyword-Driven Testing* The CD can be found on the SoftwareCPR Standards Navigator web page
ISO/IEC 25011 CD	Information Technology	Service procurers and providers	*ISO/IEC 25011 Information technology — Service Quality Requirement and Evaluation (SQuaRE) – Service Quality Model* The CD can be found on the SoftwareCPR Standards Navigator web page
ISO 13485 DIS	QMS	Manufacturers	ISO 13485 Medical Devices – Quality Management systems – Requirements for regulatory purposes. Committee draft for vote. **The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 22.**
IEC 60878 CD	Medical Devices	Manufacturers	*IEC/TR 60878: Graphical symbols for electrical equipment in medical practice* Includes new symbols created since the previous version in 2003. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. Review ends May 23.***
ISO/IEC 29119-4 DIS			*ISO/IEC 29119-4 Software and Systems Engineering — Software Testing — Part 4: Test Techniques* Part 4 defines software test design techniques (also known as test case design techniques or test methods) ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 27.***

ISO/IEC 29169 DIS			*ISO/IEC 29169 Information technology — Process assessment — The application of conformity assessment methodology to the assessment of process quality characteristics and organizational maturity* Defines the application of a conformity assessment methodology to the process assessment of process quality characteristics and organizational process maturity. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 27.***
ISO/IEC TR 12182 pDTR	Software engineering	Manufacturers	*ISO/IEC TR 12182 Systems and software engineering — Framework for categorization of IT systems and software, and guide for applying it* Specifies the manner in which categorizations of IT systems and software are organized and expressed. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 27.***
ISO/IEC 25022 CD	Software engineering	Manufacturers	*ISO/IEC 25022 Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of quality in use* Provides measures and measurement methods for quality characteristics of quality in use. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 18.***
ISO/IEC 25023 CD	Software engineering	Manufacturers	*ISO/IEC 25023 Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of system and software product quality* Provides measures and measurement methods for quality characteristics of product quality. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 18.***
ISO/IEC 25024 CD	Software engineering	Manufacturers	*ISO/IEC 25024 Systems and software engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of data quality* Provides measures and measurement methods for the quality characteristics of data quality. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 18.***

ISO/IEC/IEEE 15288 DIS	System Engineering	Manufacturers	*ISO/IEC/IEEE DIS 15288:201x(E) Systems and software engineering — System life cycle processes* This International Standard establishes a common process framework for describing the full life cycle of man-made systems from conception through retirement. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends June 27.***
ISO/IEC/IEEE 26531 DIS	Software products	Manufacturers	*ISO/IEC/IEEE 26531 Systems and software engineering — Content management for product life-cycle, user, and service management documentation* This standard provides requirements for the management of the content used in product life cycle, software, and service management system documentation. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 21, 2014.***
ISO/IEC/IEEE 23026 DIS	Websites	Manufacturers	*ISO/IEC/IEEE 23026 Systems and software engineering — Engineering and management of websites for systems, software, and services information* This standard defines system engineering and management requirements for the life cycle of websites, including strategy, design, engineering, testing and validation, and management and sustainment for Intranet and Extranet environments. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 25, 2014.***

REFERENCES

	Topic	Use / Users	Description
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 draft premarket cybersecurity guidance	Security	Manufacturers	Recommendations for security controls to assure medical device cybersecurity and documentation to submit in a premarket review to demonstrate effective cybersecurity management. Recommends identifying cybersecurity risks and providing a traceability matrix that links cybersecurity controls to cybersecurity risks that were identified. Also recommends documentation to demonstrate that the device will be provided to purchasers free of malware and a plan for providing updates and patches to provide up-to-date protection.
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.
NIST draft outline of a cybersecurity framework for critical	Security	Hospitals, manufacturers	NIST was directed to prepare a cybersecurity framework for critical infrastructure in Presidential Executive Order 13636. Healthcare was identified as one of the areas with critical infrastructure. This draft for comment is only an outline of the framework. NIST intends the framework to take a risk management approach at a high level, focusing on key functions of cybersecurity management which are broken down into categories and subcategories. References such as existing standards, guidelines and practices will be provided for each

infrastructure			subcategory. A draft of the framework will be released in October.
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

Presentation	Research	Medical device manufacturers	Medical Device Innovation Consortium (MDIC) Presentation from FDA and MDIC FDA and Life Science Alley have been collaborating on establishing a public-private partnership for research into regulatory science. A non-profit organization called the Medical Device Innovation Consortium has been created. This presentation by the FDA and the temporary director of the non-profit describes the need and the plans for this organization. ***This presentation can be found on the Standards Navigator web page.***
Announcement	Interoperability	Medical device manufacturers, Hospitals, Regulators	AAMI/UL collaboration on interoperability standards AAMI and UL have announced that they will collaborate on a series of standards for medical device interoperability. The press release announces the collaboration and its benefits. This announcement can be found at http://www.aami.org/news/2012/091712_press_AAMI_UL_Interoperability.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. This report can be found at http://www.gao.gov/products/GAO-12-816

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 first CD are being resolved. Next step: Second CD or CDV will be circulated. Expected completion: January 2014
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: Second CD has been circulated. Ballot closing February 28, 2014. Next step: Comments on second CD will be resolved and a CDV circulated. Expected completion: 2015

IEC 62366-1	Medical devices	Medical device manufacturers, Regulators	The standard on human factors engineering is being revised and divided into two documents. The first is a standard that includes requirements for the process. The second will be a technical report providing information about good practices for implementing the human factors process. This document is the first part. Current status: Comments have been resolved on the first CD and a second CD circulated. Next step: Comments received on the second CD. Expected completion: 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. Current status: Comments have been received on the first CD and are being resolved. Next step: Second CD or DIS. Expected completion: 2015