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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

January 2013 Standards Navigator Overview

A number of draft standards completed review in January. The draft TR 24971 on Application of ISO 14971 was approved and will be published by about mid-2013. CDVs were approved for amendments to 62366 and 60601-1-9 and 60601-1-10. These three amendments will have FDIS submitted for final approval later this year. There continues to be confusion over the scope and relationship of IEC 82304-1 and IEC 62304. Both standards completed reviews of CDs in January and a need for a clear alignment was noted by comments in both.

NWIPs in January included a standard for IT Service Quality and a guidance for HDOs on how to self-access to 80001-1. There was also a draft technical specification on Security and privacy requirements of EHR systems and the draft TR ISO 17791 on guidance on standards for enabling safety in health software. A DIS was circulated for ISO/IEC 15026-1 Systems and software assurance – concepts and vocabulary.

Medical device security was again called into question with the announcement that a security firm had succeeded in hacking a Phillips XPER system and gaining control of the workstation. This would allow attackers to communicate with and potentially control any other medical device connected to the XPER system.

Activity – January 2013

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
DTS ISO/TS 14441	Security	EHR vendors	ISO/TS 14441 Security and privacy requirements of EHR systems for use in conformity assessment. This technical specification identifies a set of requirements necessary to allow point of service clinical record systems to communicate securely with EHRs. The vote on this TS closes on March 11. ***The DTS can be found on the SoftwareCPR Standards Navigator web page.***
DTR ISO/TR 17791	Health software safety	Standards writers, hospitals	ISO/TR 17791 Health Informatics Guidance on standards for enabling safety in health software This Technical Report provides guidance to National Member Bodies (NMBs) by identifying a coherent set of international standards relevant to the development, implementation and use of safer health software. It also addresses overlaps and gaps in these standards. The vote on this TR closes on April 05. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
CDV ISO/IEC 15026-1	Assurance	MD manufacturer, regulator	ISO/IEC 15026-1 System and software assurance – concepts and vocabulary Software and systems assurance and closely related fields share concepts but have differing vocabularies and perspectives. This International Standard provides a unifying set of underlying concepts and an unambiguous use of terminology across these various fields. It provides a basis for elaboration, discussion, and recording agreement and rationale regarding concepts and the vocabulary used uniformly across all parts of ISO/IEC 15026. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
NP ISO 80001-2-x	Assessment	Hospitals	ISO 80001-2-x Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1 This document: • defines a process reference model (PRM) comprising a set of processes, described in terms of process purpose and outcomes that demonstrate coverage of the requirements of IEC 80001-1. • defines an exemplar process assessment model (PAM) that meets the requirements of ISO/IEC 15504-2 for process assessment and that supports the performance of an assessment by providing indicators for guidance on the interpretation of the process purposes and outcomes as defined in the IEC 80001-1 PRM and the process attributes as defined in ISO/IEC 15504-2; • provides guidance, by example, on the definition, selection and use of assessment indicators. The ballot for this NP closes on April 20. ***The NP can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
NP Working draft	Assessment	Hospitals, IT vendors	ISO/IEC NP IT Service Quality Model The standard establishes the IT service quality model, which is used for defining IT service quality requirements and evaluation. ***The NP can be found on the SoftwareCPR Standards Navigator web page.***
Report	Security	MD Manufacturer	This report of a presentation at the S4 SCADA Conference in Miami on Jan. 17, 2013 discusses a security vulnerability in a medical device. http://www.securityweek.com/researchers-uncover-privilege-escalation-bug-philips-medical-devices

STANDARDS & GUIDANCE STILL IN REVIEW

IEC 62366-1 CD	Human factors	MD manufacturer	IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices has been circulated. IEC 62366 is being divided into two parts. The new part 1 will contain updated normative requirements for the application of usability engineering to medical devices. A new part 2 which is also under development will contain guidance on the application of usability engineering. These activities are separate from the amendment to 62366 that is currently under development. Comments are due by 1 March, 2013. ***The CD can be found on the SoftwareCPR Standards Navigator web page.***
NP **ISO 80001-2-x**	Health IT	Hospitals, MD manufacturer	New work item proposal for ISO 80001-2-x: Application of risk management for IT-networks incorporating medical devices – Part 2-x Guidance for responsibility agreements. This Technical Report provides guidance on implementing RESPONSIBILITY AGREEMENTS, which are required in ISO/IEC 80001-1 for the purpose of defining the roles and responsibilities of all relevant stakeholders in the MEDICAL IT-NETWORK. The ballot for this NP closes on February 15 ***The NP can be found on the SoftwareCPR Standards Navigator web page.***

REFERENCES

	Topic	Use / Users	Description
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 IN DEVELOPMENT

	Topic	Use / Users	Description
IEC 62304 ed. 2	Software Life Cycle	Medical Device manufacturers, Regulators	Second edition of the Medical Device Software Life Cycle standard. This standard is harmonized in the EU. The second edition 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 will be circulated. Expected completion: 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 first CD are being resolved. Major issues are scope and terminology. Next step: Second CD will be 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: The first CD is currently out for comment. The comment period ends on March 1. Next step: Resolution of comments received on the first CD. Expected completion: 2015