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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

February 2013 Standards Navigator Overview

How Health IT will be regulated in the US is being discussed in February. A Health IT Patient Safety Action & Surveillance Plan http://www.healthit.gov/sites/default/files/safetyplanhhspubliccomment.pdf was circulated by the Office of the National Coordinator for HIT (ONC) in December. A report on An Oversight Framework for Assuring Patient Safety in Health http://bipartisanpolicy.org/sites/default/files/Patient%20Safety%20Health%20IT.pdf was released by the Bipartisan Policy Center in February. And the ONC solicited members for a work group for developing the report on a framework for regulating HIT http://www.fcc.gov/membership-applications-sought-fda-safety-innovation-act-workgroup required by the Food and Drug Administration Safety Innovation Act (FDASIA) legislation that was adopted last summer.

Australia has released a proposal paper on changes to the premarket assessment requirements for medical devices. This proposal paper is seeking to:

- refine a risk-based approach to regulation;
- ensure that the TGA undertakes a more comprehensive review of higher risk medical devices, in particular implantable and surgically invasive medical devices intended for long term use;
- increase transparency and accountability of the TGA's decision making; and
- allow Australian manufacturers of lower risk medical devices to have the option of European Conformity assessment for supply of their devices in Australia.

The proposal can be found at http://www.tga.gov.au/newsroom/consult-medical-devices-premarket-assessment-130114.htm

The standards for System Engineering Processes (ISO/IEC 15288) and Software Engineering Processes (ISO/IEC 12207) are being revised by JTC1/SC7 to be more harmonized. A committee draft of a revised 15288 has been circulated and a draft of the revision of 12207 is expected this summer. This is of interest because of the foundational role of these standards and the relationship of IEC 62304 to ISO/IEC 12207. The need for a systems engineering approach has also been repeated regularly at medical device conferences over the past two years.

The revision of the IT Service Management series of standards and guidance continued with committee drafts of ISO/IEC 20000-5 An exemplar implementation plan for ISO/IEC 20000-1 and ISO/IEC 20000-10 Concepts and terminology.

Both ISO TC 215 and IEC TC 62 will be meeting during April. A report from the IEC 62 Software and Network Advisory Group calls for more cooperation with TC 215 and involvement with the proposed UL/AAMI standards development work on interoperability standards.

Activity – January 2013

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
CD ISO/IEC 15288	System Engineering	Manufacturers	ISO/IEC/IEEE 15288 Systems and software engineering — system life cycle processes The harmonization of 15288 and 12207 is required as 1) the standards are due for a 5-year revision cycle; 2) There is substantial feedback and requirements from the user community and other SC 7 Working Groups; and 3) There were issues unresolved in 2008 version that SC 7/WG 7 needs to address. Those include: • Early project processes (Business and Mission Analysis) • Handling of Requirements (Process) • Handling of Architecture (Processes) • Handling of Validation and Verification (Processes) • Handling of the end-of-life cycle (processes) • Handling of System Integration • Improved Configuration Management (process) • Better connection to Quality Management Systems • Better connection to 20000 Series of standards. The goal of this project is that the revised ISO/IEC/IEEE 15288 and 12207 will have the same set of processes. Some of the processes will differ at the activities, tasks and notes levels for the two documents. The conformance clauses will not be changed in either of the standards. ***The CD of 15288 can be found on the SoftwareCPR Standards Navigator web page. The comment period ends on 20 May.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
DTR ISO/IEC TR 20000-5	IT Service Management	Hospitals	Revision of ISO/IEC TR 20000-5: 2010: Information technology – Service management – Part 5: An exemplar implementation plan for ISO/IEC 20000-1:2011 This second edition cancels and replaces the first edition (ISO/IEC TR 20000-5:2010), which has been technically revised. The major differences are changes in terminology to reflect international usage and realignment to the second edition of ISO/IEC 20000-1:2011. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***
DTR ISO/IEC TR 20000-10	IT Service Management	Hospitals	Information technology — Service management — Concepts and terminology This part of ISO/IEC 20000 provides an overview of the concepts and the terminology of ISO/IEC 20000. It establishes a common framework for helping organizations to understand the purpose of all the parts of ISO/IEC 20000 and the relationships between the parts. When the published parts of ISO/IEC 20000 that include defined terms are updated, these defined terms can be removed from those parts until all defined terms are included only in this part of ISO/IEC 20000. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
TC 62 Software and Networks Advisory Group report	Proposals for TC 62	Developers of standards for manufacturers and hospitals	Report of the Software and Network Advisory Group to the IEC TC 62 Chairman's Advisory Group 31 January 2013 The SNAG has been especially looking at the need for additional standards work in the communication of data from medical devices. The SNAG believes that there are three areas where TC 62 should consider taking action now to initiate new projects or to engage as partners with standards organizations that have existing or planned projects. The three topic areas are: a) Security of information from medical devices and networks that incorporate medical devices b) Interoperability of medical devices c) Mobile apps intended for health purposes These three areas fall within the scope of TC 62 and have regulatory or standards activities underway or being considered. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

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 DTS can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on 11 March.***
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. The ballot closes on 6 April.***
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. The ballot closes on 18 June.***

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. The ballot closes on 20 April.***
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. The ballot closes on 10 April.***

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 CURRENTLY UNDER DEVELOPMENT OR REVISION

	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