SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

Standards Navigator

Standards Navigator Monthly Report

7-July-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

June 2014 Standards Navigator Overview

Medical device software

- A call for experts for the second edition of IEC 62304 has been issued by IEC and ISO. Because the second edition scope has been expanded to health software, responsibility for the second edition has been moved to JWG7, a joint working group that includes ISO TC 215 on health informatics. Work on the second edition will begin at the JWG7 meeting in Berlin on October 7-9. The project is expected to take 3 years before publication of the new edition.

  The call for experts is available on the Software Standards Navigator web page.

Medical Devices

- A Notified Bodies Recommendation Group working group has completed a working draft on a consensus document on the interpretation and application of the Z annexes in EN ISO 14971:2012. This draft is now being reviewed by the NBRG and will be discussed at their next meeting in October. It makes recommendations for medical device manufacturers in relation to the 7 “content deviations” between the wording in the Essential Requirements in the MDD and the wording in ISO 14971.

  The draft report is available on the Software Standards Navigator web page. **NOTE – This draft report has not yet been adopted by the full NB Recommendation Group.**

- The FDA has released a draft guidance document for Medical Device Data Systems and certain other medical image storage and communication devices. The FDA is issuing this draft guidance document to inform manufacturers, distributors, and other entities that the Agency does not intend to enforce compliance with the regulatory controls that apply to these devices. This means that for these devices, the FDA does not intend to enforce compliance with the regulatory controls, including registration and listing, premarket review, postmarket reporting and quality system regulation for manufacturers. The guidance also proposes modifying the Mobile Medical Applications guidance to indicate that these types of mobile devices will not be actively regulated.

  The draft FDA guidance is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm401785.htm.

Health IT and mobile health applications

- A draft for ballot of IEC TR 80001-2-5 *Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 2-5: Application guidance – Guidance on distributed alarm systems* has been released. This Technical Report provides recommendations for the integration, communication of responses and redirection (to another operator) of alarm conditions from one or more sources to ensure safety and effectiveness. The ballot closes on September 5.

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

- A draft for ballot of ISO TR 80001-2-7 *Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 2-7: Application guidance – Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1* has been released. This technical report provides an exemplar assessment method which includes a set of questions which can be used to assess the performance of risk management of a Medical IT-Network incorporating a medical device.

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

Security

- No new documents

Software Engineering

- No new documents

Activity – June 2014

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
IEC 62304 call for experts for 2nd edition	Health software	Manufacturers	This administrative document requests that National members of IEC SC 62A and ISO TC 215 appoint members who have expertise in the development of health software (including medical device software) to the project team for the second edition of IEC 62304. The scope of the second edition has been expanded to cover all health software. The request for experts can be found on the SoftwareCPR Standards Navigator web page.
NBRG Consensus paper on the interpretation and application of EN 14971:2012	Risk management	Manufacturers	This working draft provides background on the issues related to the Annexes Z in the EN version of ISO 14971 released in 2012. It attempts to bridge the gap between the wording in the Essential Requirements of the MDD and the use of ISO 14971 to develop medical devices that are “compatible with a high level of protection of health and safety” as required by the MDD. The draft makes recommendations for the seven “content deviations” between the wording in the MDD and the wording in ISO 14971. The working draft can be found on the SoftwareCPR Standards Navigator web page. **NOTE that this working draft has not yet been adopted by the entire NBRG.**

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
FDA draft guidance for MDDS	Medical devices	Manufacturers	*Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices – Draft Guidance for Industry and Food and Drug Administration Staff* In this draft guidance FDA notifies MDDS manufacturers that it does not intend to enforce compliance with regulatory controls for this type of medical device. The draft FDA guidance is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm401785.htm
IEC TR 80001-2-5 DTR	Medical devices	Manufacturers	IEC TR 80001-2-5 *Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 2-5: Application guidance – Guidance on distributed alarm systems* This Technical Report provides recommendations for the integration, communication of responses and redirection (to another operator) of alarm conditions from one or more sources to ensure safety and effectiveness. The draft TR can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on September 5.
ISO TR 80001-2-7 DTR	Risk Management	Healthcare Delivery Organizations	ISO TR 80001-2-7 *Application of Risk Management for IT-Networks Incorporating Medical Devices – Part 2-7: Application guidance – Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1* This technical report is intended for use by hospitals to assess their compliance with IEC 80001-1. The draft TR can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on September 5.

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

NIST 800-160	Security	Manufacturers and hospitals	*NIST Special Publication 800-160 Systems Security Engineering* The initial public draft can be found on the SoftwareCPR Standards Navigator web page. The comment period ends July 11.
ISO 27799 WD	Security	Manufacturers and hospitals	*ISO 27799 Health informatics — Information management in health using ISO/IEC 27002* The working draft can be found on the SoftwareCPR Standards Navigator web page.
IEC TR 80001-2-8 CD	Security	Manufacturers and hospitals	*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* The committee draft can be found on the SoftwareCPR Standards Navigator web page. Comment period closes on August 8.
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. The ballot closes on July 28.

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. The ballot closes on July 28.
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. The ballot closes on September 10.

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
ISO TC 215 standards framework for health software Safety	Health software	Manufacturers	*Health Software Ad hoc group Interim Report – May 2014* *Health Software Safety Standards* *FUTURE STATE Architecture/Framework – DISCUSSION DRAFT* The report 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
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 infrastructure	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 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