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Standards Navigator

Standards Navigator Monthly Report

22-April-2013

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/April 2013 Standards Navigator Overview

Much discussion continues on how Health IT will be regulated and the boundary between Health Software that is or is not a medical device. Movement appears to be happening in a number of different venues.

- The EC Directorate General for Communications Networks, Content and Technology (DG CONNECT) is the department of the EC responsible for managing the EU Digital Agenda. They have indicated that they will propose a regulatory framework for eHealth (similar to Health IT in the US) that is separate of the regulatory framework for medical devices that is the responsibility of the Directorate General for Health & Consumers (DG SANCO). They have not provided any details about their plans, but have indicated that there will be discussion of them at the eHealth week being held in Dublin May 13-15.
- DG Connect and ONC announced agreement on a roadmap to strengthen transatlantic cooperation in eHealth and Health IT. This includes two areas:
    - Standards Development – creation of an action plan to create standards and use internationally recognized standards which support transnational interoperability of electronic health information and communication technology
    - Workforce Development – plans to develop and expand a skilled health IT workforce in Europe and the US.

  This will include an in-person joint EU-US eHealth/Health IT Cooperative Assembly during the EU's eHealth week in Dublin May 13-15.
- A US Congressional committee held three days of hearings related to the regulation of mobile apps. Both the ONC and the FDA testified at these hearings. The FDA said that the final version of their mobile medical device guidance would be released by October and that they would not regulate mobile platforms as accessories to devices.
- The FDA Safety and Innovation Act (FDASIA) workgroup has been formed and will meet on April 29. The chair will be Dr. Paul Tang, HIT Policy Committee Chair. This workgroup will advise the FDA, ONC and FCC on the report to Congress on a regulatory framework for Health IT, particularly in the area of mobile apps.
- Sweden has updated their guidance document on determining if standalone software is a medical device. The initial guidance document was released in 2009 and was the starting point for the EU MedDev document on determining whether standalone software is a medical device.
- The International Medical Device Regulators Forum has initiated a new work item on the international harmonization of the approach to standalone medical device software and on the definition of common data elements describing medical devices through the regulatory lifecycle. Bakul Patel from the FDA will chair the standalone medical device working group. Mats Olson from the Swedish regulatory agency, who led both the work on the initial Swedish guidance document and the work on the latest revision of it, will also be on this work group.
- IEC SC 62A decided to extend the scope of IEC 62304 to cover health software, including health software that is not regulated as a medical device. In order to meet current industry needs for revised requirements for software safety classification and conformance of legacy software to IEC 62304, it was decided to separate the work on the expanded scope to a separate project. The work that has been started for a second edition of 62304 will now become an amendment to the first edition and the second edition will have the expanded scope.
- IEC SC 62A and ISO TC 215 are also working on a harmonization of terminology and a framework for standards applying to health software. The ISO TR 17791 which was approved in April will be an input to this work.
- The UK National Health Service has adopted an updated standard for the development of health software that is not regulated as a medical device. This standard generally follows ISO 14971, but also requires that the manufacturer provide a safety assurance case to demonstrate by objective evidence that they have satisfactorily implemented the standard's requirements.

All this activity is attempting to resolve how to regulate standalone health software. The problem arises from the fact that medical device regulation is only loosely based on the safety risk of a device. While much health software has little or no safety risk, some health software that is not currently regulated as a medical device presents more safety risk than many medical devices. While medical device regulators are attempting to clarify what software will be considered a medical device, they cannot solve the entire problem because they do not set policy and a rational regulation based on risk will require changes to policy and legislation. With regulators unable to oversee the safety of all health software, some customers such as the NHS are asking for the information to decide for themselves whether the safety of a software product

is acceptable. But in most countries, customers are not well enough organized to force manufacturers to provide this information. Leadership in the international standards organizations are moving in the direction of creating standards based on risk and hoping that both regulators and customers will use them as appropriate to achieve their purposes, so that manufacturers can develop a product to meet a single set of safety requirements.

The debate over ISO 14971 continues between industry and the European Commission. The joint ISO & IEC working group responsible for ISO 14971 met and determined that ISO 14971 still represents the state of the art for medical device risk management and that no changes were needed despite the position of the EC that ISO 14971 does not meet the essential requirements of the directives. Several notified bodies and COCIR/Eucomed have produced guidance for how manufacturers can use ISO 14971 in claiming conformance to the essential requirements.

Along with the activity related to software regulation, other standards continue to be developed, studies done, and changes made to national regulatory frameworks. Developments of interest include:

- The EU Notified Bodies group has issued an FAQ on use of EN 62304:2006 to meet the essential requirements of the EU medical device and IVD directives.
- A final draft of Amendment 1 to IEC 60601-1-9: Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design was circulated for vote.
- A second CDV of IEC 60601-1-12: Medical electrical equipment - Part 1-12: 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 was circulated for vote.

Activity – March/April 2013

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
EN 62304:2006 - Frequently Asked Questions	Medical device software	Manufacturers, Notified bodies	Provides answers to questions that have been asked to notified bodies regarding using EN 62304 for regulatory purposes in the EU. ***The FAQ can be found on the SoftwareCPR Standards Navigator web page.***
UK NHS ISB 0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems	Risk management for the deployment, use, maintenance and decommissioning of Health IT systems	Network integrators and operators	This standard is addressed to those persons in Health Organisations who are responsible for ensuring clinical safety in the deployment of Health IT Systems through the application of clinical risk management. It includes many of the risk management requirements of IEC 80001-1. ***The standard can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
UK NHS Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems – Implementation Guidance	Guidance on how to implement clinical risk management in deployment and use of Health IT systems	Network integrators and operators	This guidance document provides additional information for the ISB 0160 standard on implementing the requirements of the standard. ***The Guidance can be found on the SoftwareCPR Standards Navigator web page.***
UK NHS ISB 0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems	Risk management for the development and modification of Health IT systems	Software developers	The purpose of this standard is to promote and ensure that effective clinical risk management is carried out by organisations that are responsible for developing and modifying Health IT Systems. This purpose is achieved through the presentation of a set of requirements similar to ISO 14971:2009. The standard requires in addition a safety case report at each lifecycle phase identified in the risk management plan. ***The standard can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
UK NHS Clinical Risk Management: its Application in the Manufacture of Health IT Systems – Implementation Guidance	Guidance on how to implement the requirements for risk management for the development and modification of Health IT systems	Software developers	This guidance document provides additional information for the ISB 0129 standard on implementing the requirements of the standard. ***The Guidance can be found on the SoftwareCPR Standards Navigator web page.***
Sweden Medical Information Systems – guidance for qualification and classification of standalone software with a medical purpose	Classifying standalone software as a medical device	Manufacturers, Notified bodies	The purpose of the guideline is: To clarify the relevant criteria for qualification of standalone software that is a medical device, and the application of classification criteria for such software • To help manufacturers, health care providers and other interested parties to better understand what determines a standalone software a medical device • To clarify the Medical Products Agency's expectations on the manufacturers • To harmonise the interpretation of the regulatory requirements for standalone software. ***The Guidance can be found on the SoftwareCPR Standards Navigator web page.***
IMDRF software work item	Determining when standalone software is a medical device	Regulators, manufacturers	The International Medical Device Regulators Forum (IMDRF) has accepted a new work item for harmonizing how standalone software is determined to be a medical device. ***The work item can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
Members of the FDASIA workgroup	Health IT policy	Manufacturers, regulators	The Food and Drug Administration Safety and Innovation Act (FDASIA) directed the HHS Secretary, acting through the Commissioner of the U.S. Food and Drug Administration (FDA), and in consultation with ONC and the Chairman of the FCC, to develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT, including medical mobile applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. This workgroup will advise the agencies regarding this regulatory framework. ***The press release naming the members of the workgroup can be found on the SoftwareCPR Standards Navigator web page.***
Draft guidance using EN 14971:2012 to meet essential requirements	Risk management	Manufacturers, Notified bodies	This draft guidance provides a rationale for why using EN 14971:2012 along with other additional requirements from other sources can be used to demonstrate compliance with the essential requirements related to risk management. ***The Guidance can be found on the SoftwareCPR Standards Navigator web page.***
Report to ISO/IEC JWG1 on the official objection to EN ISO 14971 and the revised Z annexes.	Risk management	Manufacturers, Notified bodies	Discussion regarding the application of the revised annexes in EN 14971:2012. ***The report can be found on the SoftwareCPR Standards Navigator web page.***
Transatlantic eHealth/health IT Cooperation Roadmap	Health IT interoperability	Public, academic, and private stakeholders in Health IT	Lays out plans to advance cooperation around health related information and communication technology between the US and the EU. ***The roadmap can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
Report on cost savings available with medical device interoperability	Interoperability	Manufacturers, hospitals	This report by West Health Institute suggests that an annual savings in excess of $30 billion can be achieved through adoption of functional interoperability for medical devices. The savings would result from the elimination of waste in health care. ***The report can be found on the SoftwareCPR Standards Navigator web page.***
FDIS IEC 60601-1-9	Medical electrical equipment	Manufacturers, Notified bodies	Final draft of an amendment to IEC 60601-1-9 General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design This minor amendment updates references to the 2012 version of IEC 60601-1 and makes editorial changes. The ballot end on 24 May. ***The FDIS can be found on the SoftwareCPR Standards Navigator web page.***
CDV IEC 60601-1-12	Medical electrical equipment	Manufacturers, Notified bodies	The second Committee Draft for Vote of IEC 60601-1-12 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 This new collateral standard specifies requirements for safety in an emergency medical services environment. The ballot ends on 28 June. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

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.***
CDV ISO/IEC 15026-1	Assurance	Manufacturers, regulators	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.***

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 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: 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: Comments have been received on the first CD. Next step: Resolution of comments received on the first CD. Expected completion: 2015