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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

December 2013 Standards Navigator Overview

Medical device software

- A draft technical report containing a process reference model (PRM) for IEC 62304 has been distributed for vote. IEC/TR 80002-3: Medical device software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304). The process descriptions in the PRM incorporate a statement of the purpose of the process which describes at a high level the overall objectives of performing the process, together with the set of outcomes which demonstrate the successful achievement of the process purpose.

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

Health IT and mobile health regulation

- A committee draft for guidance on the application of risk management for distributed alarm systems has been circulated for comment. 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 first describes distributed alarm systems in general, defining and describing the main components, communication paths, and features associated with them. It then offers guidance on application of risk management to distributed alarm systems in a framework that follows the risk management process as defined by the IEC 80001-1 standard. It suggests causes and risk control methods that should be considered when developing, configuring, and maintaining a distributed alarm system. Technical, clinical, and procedural causes and risk control methods are considered. Finally, the technical report offers some rules for general classification of types of distributed alarm systems as well as an overview of the scalability of multiple distributed alarm systems to aid in application of risk management.

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

- The International Telecommunication Union (ITU) has adopted the Continua Design Guidelines (CDG) that contain specifications to ensure the interoperability of devices used for applications monitoring personal health as Recommendation ITU-T H.810 Interoperability design guidelines for personal health systems. These guidelines focus on the following interfaces:
  - TAN-IF – Interface between touch area network (TAN) health devices and application hosting devices (AHDs)
  - PAN-IF – Interface between personal area network (PAN) health devices and AHDs
  - LAN-IF – Interface between local area network (LAN) health devices and AHDs
  - WAN-IF – Interface between AHDs and wide area network (WAN) health devices
  - HRN-IF – Interface between WAN health devices and Health Record Network health devices.

  ITU-T H.810 is available at http://www.itu.int/rec/T-REC-H.810-201312-I

- The Office of the National Coordinator for Health IT has issued a report entitled “How to Identify and Address Unsafe Conditions Associated with Health IT”. The report was prepared by ECRI Institute. ECRI evaluated more than 170 health IT related events reported by 36 healthcare organizations over a nine-week period and identified the top five categories of events. Three of the five categories—system interface, system/software configuration, and software function—are considered computer-related events that occur, for example, as a result of design issues (e.g., difficult-to-read screen displays) or software interfaces that jeopardize the exchange of data between separate health IT systems.

The report is available at http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/guide-identify-address-unsafe-conditions-health/

Usability

- ISO 62366 is being divided into two parts for the second edition, Part 1 which is requirements and Part 2 which is recommended practices. A committee draft for vote of ISO 62366-1 has been circulated for review. This part describes a usability engineering process to provide acceptable risk related to usability of a medical device. The usability engineering process is intended to identify and minimize use errors and thereby reduce use-associated risks.

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

Security

- NIST has made the Preliminary Cybersecurity Framework for improving critical infrastructure cybersecurity available for review. This framework has been developed under Executive Order 13636 issued on February 12, 2013. It calls for the development of a voluntary Cybersecurity Framework that provides a "prioritized, flexible, repeatable, performance-based, and cost-68 effective approach" for assisting organizations responsible for critical infrastructure services to manage cybersecurity risk. Critical infrastructure is systems vital to the United States and includes the healthcare and public health sector. While this framework is identified as voluntary, it's high level of visibility will likely result in it becoming the expected level of security in regulatory and legal proceedings.

  The draft framework is available at http://www.nist.gov/itl/upload/preliminary-cybersecurity-framework.pdf

- A new project proposal has been issued by IEC TC 65 for industrial communication networks security. The new proposed standard is IEC/NP 62443-4-1 Industrial communication networks – Network and system security – Part 4-1: Product development requirements. It is based on ISA-62443-04-01, Draft 1, Edit 9, April 2013. This proposed standard addresses security aspects of individual hardware and software components of industrial automation and control systems (IACS), including security aspects of the construction of those components and their maintenance while in operation.

  Other standards in the IEC 62443 series have been recognized by FDA as being useful for medical device security.

  The draft proposed new standard is available at the SoftwareCPR Standards Navigator web site.

Medical Devices

- IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) has published Document OD-2044 Ed. 2.2, Evaluation of Risks Management in medical electrical equipment according to the IEC 60601-1 and IEC/ISO 80601-1 Series of Standards.

  The scope of this procedure is intended to provide a uniform approach to the Certification Body Testing Laboratory and Manufacturer on how to assess and document compliance with the relevant clauses of IEC 60601 standard series related to the standard ISO 14971. The document has been prepared by the IECEE Risk Management Task Force chaired by Alf Dolan, the convener of the ISO 14971 working group. The TF's goal is not to demand more or less than the standard requires but to help ensure that all those in the CB scheme take a common approach to assessing compliance to the standard's risk management aspects.

  This document is available at http://www.iecee.org/Operational_documents/iecee_documents/od-2044_ed.2.2.pdf

- A committee draft of a technical report on unclear or unaddressed safety aspects in IEC 60601-1 has been circulated. This document has been circulated for comment. This document is for informational purposes only. It contains a number of issues that have been reviewed by a working group of IEC 62A and their recommendation or interpretation of how the issue can be addressed. Most of the issues relate to electrical hazards, with a few relating to other types of hazards identified in IEC 60601-1.

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

Software Engineering

- A draft technical report, ISO/IEC TR 30103 Software and Systems Engineering — Lifecycle Processes — Framework for Product Quality Achievement, has been circulated for vote. This Technical Report provides guidance on the application of **ISO/IEC/IEEE 15288:2008 life cycle processes** with specific reference to addressing quality in projects that deliver systems and software products and services. It focuses on a systematic approach to achieving quality, involving the development of certain information items, the inter-relationships between these information items and the maintenance and mutual consistency management of these information items. In particular, it describes how to develop detailed specifications of the collection of process instances need to produce a specific product or system and achieve its quality goals.

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

- A committee draft for vote (DIS) of **ISO/IEC 16350 Systems and Software Engineering - Application Management** has been circulated. This standard addresses the actions, responsibilities, activities and tasks required to support use and operation of an application that is in production use. The major actions required are supporting use and operation of the application and adapting it, based on changing demands or based on quality improvements. This standard establishes a common framework for application management processes, with well-defined terminology. It contains processes, activities and tasks that apply during the in-production stage, from the point of view of the supplier organization that enhances, maintains and renews the application software and the software-related products such as data structures, architecture, designs and other documentation.

  The DIS is available on the SoftwareCPR Standards Navigator web page. 5/29

- A committee draft for vote (DIS) of **ISO/IEC/IEEE 26531 Systems and software engineering — Content management for product life-cycle, user, and service management documentation** has been circulated. This standard provides requirements for the management of the content used in product life cycle, software, and service management system documentation. Content management allows an organization to control the storage and retrieval of content objects, track content revisions, maintain a content audit trail, and enable a collaborative environment.

  The DIS is available on the SoftwareCPR Standards Navigator web page. 5/21

- A committee draft for vote (DIS) of **ISO/IEC/IEEE 23026 Systems and software engineering — Engineering and management of websites for systems, software, and services information** has been circulated. 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 goal of this standard is to improve the usability of informational websites and ease of maintenance of managed Web operations in terms of locating relevant and timely information, applying information security management, facilitating ease of use, and providing for consistent and efficient development and maintenance practices.

  The DIS is available on the SoftwareCPR Standards Navigator web page. 5/25

Activity – December 2013

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
IEC/TR 80002-3 DTR	Medical device software	Manufacturers	*IEC/TR 80002-3: Medical device software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304)* A draft technical report containing a process reference model (PRM) for IEC 62304. The process descriptions in the PRM incorporate a statement of the purpose of the process which describes at a high level the overall objectives of performing the process, together with the set of outcomes which demonstrate the successful achievement of the process purpose. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 14, 2014.***
IEC/TR 80001-2-5 CD	Alarm systems	Manufacturers, Hospitals	*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.* Guidance on application of risk management to distributed alarm systems including causes and risk control methods that should be considered when developing, configuring, and maintaining a distributed alarm system. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 14, 2014.***
ISO 62366-1 DIS	Usability	Manufacturers	*IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices* A usability engineering process to provide acceptable risk related to usability of a medical device. This standard defines the requirements of the usability engineering process that a manufacturer will be required to meet. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on March 21, 2014.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
IEC 62443-4-1 NP	Security	Manufacturers	*IEC/NP 62443-4-1 Industrial communication networks – Network and system security – Part 4-1: Product development requirements* Security aspects of the construction of industrial automation and control systems (IACS) components and their maintenance while in operation. Although not specific for medical devices, the FDA has recognized other parts of the 62443 series as useful for medical devices. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on January 17, 2014.***
IEC/TR 60601-4-3 CD	Medical electrical equipment	Manufacturers	*IEC/TR 60601-4-3: Medical electrical equipment – Part 4-3: Guidance and interpretation – Considerations of unclear or unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements* This draft TR contains a number of issues that have been reviewed by a working group of IEC 62A and their recommendation or interpretation of how the issue can be addressed. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on March 21, 2014.***
ISO/IEC TR 30103 DTR	Quality	Manufacturers	*ISO/IEC TR 30103 Software and Systems Engineering — Lifecycle Processes — Framework for Product Quality Achievement* Guidance on the application of *ISO/IEC/IEEE 15288:2008 life cycle processes* with specific reference to addressing quality in projects that deliver systems and software products and services. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO/IEC 16350 DIS	Software products	Manufacturers	*ISO/IEC 16350 Systems and Software Engineering - Application Management* This standard addresses the actions, responsibilities, activities and tasks required to support use and operation of an application that is in production use. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 29, 2014.***
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.***

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

IEC 60601-1-2 FDIS	Medical devices	Manufacturers	*IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests* This revised standard will replace the edition of 2007. It includes technical changes such as: • specification of immunity test levels according to the environments of intended use, categorized according to locations that are harmonized with iec 60601-1-11: the professional healthcare facility environment, the home healthcare environment and special environments; • specification of tests and test levels to improve the safety of medical electrical equipment and medical electrical systems when portable rf communications equipment is used closer to the medical electrical equipment than was recommended based on the immunity test levels that were specified in the third edition; • specification of immunity tests and immunity test levels according to the ports of the medical electrical equipment or medical electrical system; • specification of immunity test levels based on the reasonably foreseeable maximum level of electromagnetic disturbances in the environments of intended use, resulting in some immunity test levels that are higher than in the previous edition; and • better harmonization with the risk concepts of basic safety and essential performance, including deletion of the defined term “life-supporting”; ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on January 31, 2014.***
IEC 82304-1 CD2	Software products	Manufacturers	*IEC 82304-1: Health Software - Part 1: General requirements for product safety.* This standard is intended to provide requirements for health software products. These are product requirements, and 82304-1 refers to 62304 for software process requirements. This standard is expected to cover the EU essential requirement for software validation when the product is only software (this essential requirement is covered by IEC 60601-1-1 for software that is a part of medical electrical equipment.) ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 28, 2014.***

IEC 80001-2-x NP	Security	Manufacturers	*IEC 80001-2-x, Application of risk management for IT networks incorporating medical devices - Part 2-X: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2* This proposed technical report maps applicable requirements in six security standards to the security capabilities identified in IEC 80001-2-2. This provides guidance to medical device manufacturers as to which security standards and requirements are possibly useful in achieving the security capabilities. A supplemental document is provided to assist reviewers in assessing the appropriateness of the identified security requirements. ***The draft standard and supplemental document can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 28, 2014.***
IEC 62368 FDIS	Audio/Video and ICT equipment	Manufacturers	IEC 62368-1 *Audio/video, information and communication technology equipment - Part 1: Safety requirements*. This standard replaces IEC 60065 *Audio, video and similar electronic apparatus - Safety requirements* and IEC 60950-1 *Information technology equipment - Safety - Part 1: General requirements.* The safety requirements of these two standards are merged into a single standard as these types of equipment are merging. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on January 10, 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. This is a draft for comment. Comments should be submitted before September 13.
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