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Standards Navigator

Standards Navigator Monthly Report

6-March-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

February 2014 Standards Navigator Overview

Medical device software

- The IMDRF has completed a draft recommendation for the classification and regulation of Software as a Medical Device. The recommendation will be circulated for public comment following the IMDRF steering committee meeting in late March. The report provides a common approach to:
    - Identify essential information for describing the SaMD in terms of the medical purpose, context of use, and core functionality
    - Characterize types of SaMDs, based on the essential information, similarity in risk profile and the hazards associated with SaMD.
    - Identify measures considered appropriate for assuring reasonable safety and effectiveness.

  The draft is available on the SoftwareCPR Standards Navigator web page.
- The IMDRF work group that developed the Software as a Medical Device recommendation also requested that a new work item be started to develop a separate document on detailed guidance on application of quality management systems to SaMD. This request will be considered by the IMDRF steering committee at its March meeting.

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

Medical Devices

- There is a new draft for vote of *ISO 13485 Medical Devices – Quality Management systems – Requirements for regulatory purposes*. This version updates the references to ISO 9001 to the 2008 version. Some new requirements include:
    - A requirement for a risk management process has been added in the product realization phase and ISO 14971 and IEC 62304 have been referenced for guidance.
    - The organization also now has to define a method for protecting confidential health information that may be provided as part of the requirements related to the product or as customer feedback or post-market surveillance.
    - If required by regulation, the organization shall establish and maintain a system to assign a UDI to the device.
    - A new requirement for documenting procedures for the validation of the application of computer software used in the quality management system, including production and service provision, has been added.

  The draft contains tables that show the differences between the new version of ISO 13485 and the 2008 version of ISO 9001 and the differences between the new version of ISO 13485 and the 2003 version of ISO 13485.

  The draft is available on the SoftwareCPR Standards Navigator web page.
- A new committee draft of *IEC/TR 60878: Graphical symbols for electrical equipment in medical practice* is available for comment. This update to IEC/TR 60878 contains new or revised symbols and safety signs that have been developed or revised since the publication of the second edition in 2003. Most of the text was taken from the ISO/IEC Symbols database.

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

Health IT and mobile health regulation

- The Office of National Coordinator for Health Information Technology published a proposed rule for Voluntary 2015 Edition Electronic Health Record Certification Criteria; Interoperability Updates and Regulatory Improvements. The proposed rule eliminates the "complete EHR" designation, separates the content and transport certification criteria and announces a more frequent certification rule making process. The proposed rule also fixes a number of issues in the 2014 edition with changes to Computerized Provider Order Entry, Clinical decision support, uses of UDI data and many others.

  The Microsoft Word version of the proposed rule and the document that can be used for providing comments can be found on ONC's Web site (http://www.healthit.gov).

Security

- The final version of the NIST Framework for critical infrastructure cybersecurity has been published. Healthcare and public health have been designated as critical infrastructure. In its introduction, the framework states "Due to the increasing pressures from external and internal threats, organizations responsible for critical infrastructure need to have a consistent and iterative approach to identifying, assessing, and managing cybersecurity risk. This approach is necessary regardless of an organization's size, threat exposure, or cybersecurity sophistication today." The framework is voluntary and not industry specific. It takes a risk-based approach to managing cybersecurity risk in an enterprise. While the framework is voluntary, it seems likely that regulation, litigation and insurance will consider it the minimum expectation for managing cybersecurity risks in an enterprise.

  The Framework and related documentation can be found on http://www.nist.gov/cyberframework/.

Software Engineering

- A draft for vote of *ISO/IEC 29119-4 Software and Systems Engineering — Software Testing — Part 4: Test Techniques* has been circulated for ballot. ISO/IEC/IEEE 29119 consists of the following standards, under the general title Software and Systems Engineering — Software Testing:

  - Part 1: Concepts and Definitions
  - Part 2: Test Processes
  - Part 3: Test Documentation
  - Part 4: Test Techniques

  Part 4 defines software test design techniques (also known as test case design techniques or test methods) that can be used during the test design and implementation process that is defined in ISO/IEC/IEEE 29119-2 Test Processes. ISO/IEC/IEEE 29119-4 does not prescribe a process for test design and implementation; instead, it describes a set of techniques that can be used within ISO/IEC/IEEE 29119-2. The intent is to describe a series of techniques that have wide acceptance in the software testing industry.

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

- A draft for vote of *ISO/IEC 29169 Information technology — Process assessment — The application of conformity assessment methodology to the assessment of process quality characteristics and organizational maturity* has been circulated for ballot. The scope of this work is to define the application of a conformity assessment methodology, based on the existing published ISO/IEC standards and guides, to the process assessment of process quality characteristics and organizational process maturity, performed according to the requirements of the ISO/IEC 33001-33099 series of process assessment standards, and supporting the use of other international standards including ISO/IEC 29110 and ISO/IEC 30105, in order to support an environment which encourages worldwide recognition of conformity assessment results.

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

- A draft for comment of *ISO/IEC 25066 Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) - Common industry Format for Usability — Evaluation Report* has been circulated. This standard provides a framework and consistent terminology for describing the evaluation report of an interactive system based on the human-centred design approach of ISO 9241-210. It is intended to assist developers in documenting and communicating usability-related information as part of the system development life-cycle. This standard provides specifications for the contents of evaluation reports, as well as definitions and the relationship of elements. The intended users of the Evaluation Report are identified, as well as the situations in which the evaluation report can be applied. The documentation elements are intended to be used as part of system-level documentation resulting from development processes such as those in ISO 9241-210 and ISO/IEC JTC 1/SC 7 process standards.

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

- A preliminary draft technical report of *ISO/IEC TR 12182 Systems and software engineering — Framework for categorization of IT systems and software, and guide for applying it* has been circulated for comment. This technical report specifies the manner in which categorizations of IT systems and software are organized and expressed. It describes the framework for describing categorizations, and provides a guide for applying it. This allows any community to define the system scope of their interest by using their own categorization.

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

- Draft versions of three standards intended to measure product quality have been circulated for comment. These standards identify quality characteristics and provide measures and measurement methods for these characteristics. The three draft standards are:
  - *ISO/IEC 25022 – Measurement of quality in use*: provides measures, including associated measurement methods and QMEs for the quality characteristics in the quality in use model.
  - *ISO/IEC 25023 – Measurement of system and software product quality*: provides measures, including associated measurement methods and QMEs for the quality characteristics in the product quality model.
  - *ISO/IEC 25024 – Measurement of data quality*: provides measures, including associated measurement methods and QMEs for the quality characteristics in the data quality model.

  The drafts are available on the SoftwareCPR Standards Navigator web page.

Activity – February 2014

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
IMDRF draft recommendation	Medical device software	Manufacturers	*Software as a Medical Device: Framework for Risk Categorization and Corresponding Controls* ***The draft recommendation can be found on the SoftwareCPR Standards Navigator web page.***
IMDRF proposed NWIP	Medical device software	Manufacturers	*Quality Management Systems for Software as a Medical Device* ***The draft new work item can be found on the SoftwareCPR Standards Navigator web page.***
ISO 13485 DIS	QMS	Manufacturers	*ISO 13485 Medical Devices – Quality Management systems – Requirements for regulatory purposes*. Committee draft for vote. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends May 22.***
IEC 60878 CD	Medical Devices	Manufacturers	*IEC/TR 60878: Graphical symbols for electrical equipment in medical practice* Includes new symbols created since the previous version in 2003. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 29119-4 DIS			*ISO/IEC 29119-4 Software and Systems Engineering — Software Testing — Part 4: Test Techniques* Part 4 defines software test design techniques (also known as test case design techniques or test methods) ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends July.***
ISO/IEC 29169 DIS			*ISO/IEC 29169 Information technology — Process assessment — The application of conformity assessment methodology to the assessment of process quality characteristics and organizational maturity* Defines the application of a conformity assessment methodology to the process assessment of process quality characteristics and organizational process maturity. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. Ballot ends July.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO/IEC 25066 CD	Usability	Manufacturers	*ISO/IEC 25066 Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) - Common industry Format for Usability — Evaluation Report* A framework and consistent terminology for describing the evaluation report of an interactive system based on the human-centred design approach. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC TR 12182 pDTR	Software engineering	Manufacturers	*ISO/IEC TR 12182 Systems and software engineering — Framework for categorization of IT systems and software, and guide for applying it* Specifies the manner in which categorizations of IT systems and software are organized and expressed. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 25022 CD	Software engineering	Manufacturers	*ISO/IEC 25022 Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of quality in use* Provides measures and measurement methods for quality characteristics of quality in use. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 25023 CD	Software engineering	Manufacturers	*ISO/IEC 25023 Systems and software engineering - Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of system and software product quality* Provides measures and measurement methods for quality characteristics of product quality. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 25024 CD	Software engineering	Manufacturers	*ISO/IEC 25024 Systems and software engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of data quality* Provides measures and measurement methods for the quality characteristics of data quality. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

ISO/TR 80001-2-7 CD	Medical IT-networks	Hospitals	*ISO/TR 80001-2-7: Application of risk management for IT-networks incorporating medical devices — Application guidance — Part 2-7: Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1.* This document 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 can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on March 21, 2014.***
ISO/TR 19231 DTR	mHealth		*ISO DTR 19231 Health informatics — Survey of mHealth Projects in Low to Middle Income Countries (LMIC).* This TR surveys on-going national mHealth projects in LMIC and possible mHealth frameworks that might be used. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on April 6, 2014.***

ISO/IEC 19793 DAM	Open Distributed Processing	Manufacturers	*ISO/IEC 19793: Information technology — Open distributed processing — Use of UML for ODP system specifications* This International Standard defines: – use of the viewpoints prescribed by the RM-ODP to structure UML system specifications; – rules for expressing RM-ODP viewpoint languages and specifications with UML and UML extensions (e.g. UML profiles). The amendment incorporates notation for representing obligations and policies. ***The draft standard including the amendment can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC/IEEE 15288 DIS	System Engineering	Manufacturers	*ISO/IEC/IEEE DIS 15288:201x(E) Systems and software engineering — System life cycle processes* This International Standard establishes a common process framework for describing the full life cycle of man-made systems from conception through retirement. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 33063 DIS	Process	Manufacturers	*ISO/IEC 33063 Information technology — Process assessment — Process assessment model for software testing* A process assessment model comprises a set of indicators of process performance and process capability. The indicators are used as a basis for collecting the objective evidence that enables an assessor to assign ratings. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
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.***

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. The ballot closes on April 8, 2014.***
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.***

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