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Standards Navigator

Standards Navigator Monthly Report

5-April-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

March 2014 Standards Navigator Overview

Medical device software

- The IMDRF draft recommendation for the classification and regulation of Software as a Medical Device has been published for public comment. 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.

  Comments will be accepted until May 31.

  The draft recommendations can be found at http://www.imdrf.org/consultations/cons-smd-samd.asp
- The new work item proposal from the IMDRF work group that developed the Software as a Medical Device recommendation for a separate document on detailed guidance on application of quality management systems to SaMD was not approved by the IMDRF steering committee at its March meeting. Instead they decided to wait until comments had been received on the draft recommendations before initiating additional work. The request will be considered again at the September meeting of the IMDRF steering committee.

Medical Devices

- There is a final draft for vote of *IEC 60601-1-12: Medical electrical equipment – 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 is an up or down vote on the standard and no comments except editorial corrections will be allowed. The standard applies to electrical medical equipment used in an emergency medical services environment, that includes:
  - responding to and providing life support at the scene of an emergency to a PATIENT reported experiencing injury or illness in a pre-hospital setting, and transporting the PATIENT, while continuing such life support care, to an appropriate professional healthcare facility for further care.
  - providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

  The draft is available on the SoftwareCPR Standards Navigator web page.
- A committee draft for vote (CDV) of *IEC 60601-1-11: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* is available for comment and vote. The standard applies to electrical medical equipment that are intended for use in the home healthcare environment, regardless of whether the equipment is intended for use by a lay operator or by trained healthcare personnel. The home healthcare environment includes:
  - The dwelling place in which a patient lives.
  - Other places where patients are present, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present.

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

Health IT and mobile health regulation

- The FDA, Office of the National Coordinator for Health IT (ONC) and the FCC released the draft FDASIA Health IT Report, Proposed Strategy and Recommendations for a Risk-Based Framework. The report recommended no new or additional areas of FDA oversight. The proposed strategy and recommendations are based on the premise that risk and controls should focus on functionality, not on the platform or product name and description. The strategy identifies three categories of health IT: 1) administrative health IT functions, 2) health management health IT functions and 3) medical device health IT functions. The report recommends no oversight for administrative health IT functions. For health management health IT functions, the report recommends viewing safety within the full healthcare sociotechnical system and across the entire life cycle of the health IT. This would be accomplished by a limited, narrowly-tailored approach that primarily relies on ONC-coordinated activities and private sector capabilities. Four priority areas would be focused on: 1) Promoting the use of quality management principles, 2) identify, develop, and adopt standards and best practices, 3) leverage conformity assessment tools and 4) create an environment of learning and continual improvement. FDA would not focus its regulatory oversight on health management health IT even if the health IT meets the statutory definition of a medical device. FDA currently provides oversight for health IT with medical device functionality and will continue to focus on this type of health IT.

  The report also recommends creation of a Health IT Safety Center that includes broad representation from public and private sector stakeholders to establish a governance structure for the creation of a sustainable, integrated health IT learning system that avoids regulatory duplication and leverages and complements existing and ongoing efforts. The purpose of this center would be to develop a culture of safety, transparency, learning, continual improvement, and shared responsibility with better-defined accountability. This public-private entity would be created by ONC. ONC stated in the report that it expects to launch the Health IT Safety Center in 2014.

  The agencies will accept comments for 90 days. They also will hold a public meeting to gather input during the 90 day period.

  The report can be found at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm390588.htm

Security

Software Engineering

- A draft of *ISO/IEC/IEEE 12207 Systems and software engineering — Software life cycle processes* has been circulated for comment. This standard replaces ISO/IEC/IEEE Std 12207™-2008, Systems Engineering—Software Life Cycle Processes. That standard replaced a three-part modified adoption of ISO/IEC 12207:1995.

  This new revision of ISO/IEC/IEEE 12207 is the product of a coordinated effort by IEEE and ISO/IEC JTC 1/SC 7 to completely harmonize life cycle process standards for systems and for software. The new editions of ISO/IEC/IEEE 12207 and ISO/IEC/IEEE 15288 will provide a single, shared baseline of systems and software life cycle processes applicable to both ISO/IEC and the IEEE standards collections.

  This International Standard was developed with the following goals:

  - provide a common terminology between the revision of ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207
  - where applicable, provide common process names and process structure between the revision of ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207

- enable the user community to evolve towards fully harmonized standards, while maximizing backward compatibility

This revision is intended to achieve a fully harmonized view of the system and software life cycle processes.

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

- A draft of *ISO/IEC 15026-3 Systems and software engineering —Systems and software assurance — Part 3: Systems integrity levels* has been circulated for comment. This part of ISO/IEC 15026 specifies the concept of integrity levels with corresponding integrity level requirements that are required to be met in order to show the achievement of the integrity level. It places requirements on and recommends methods for defining and using integrity levels and their integrity level requirements. It does not prescribe a specific set of integrity levels or their integrity level requirements. One important use of integrity levels could be by suppliers and acquirers in agreements; for example, to aid in assuring safety, economic, or security characteristics of a delivered system or product.

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

- A draft of *ISO/IEC 29119-5 Software and Systems Engineering — Software Testing — Part 5: Keyword-Driven Testing* has been circulated for comment. 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 5: Keyword-Driven Testing

  Part 5 defines an established approach of describing test cases in a modular way. This standard will explain the main concepts and application of Keyword-Driven Testing and define attributes of frameworks which are designed to support Keyword-Driven Testing.

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

- A draft of *ISO/IEC 25011 Information technology — Service Quality Requirement and Evaluation (SQuaRE) – Service Quality Model* has been circulated for comment. This standard defines a general service product quality model that is applicable to the design, transition, delivery and improvement of IT services.

  The scope of this International Standard is the quality of the services that make use of software and IT systems. Examples include:

  - Services that use IT as tools to support the customers and business;
  - Design, development, testing, integration and maintenance of software products and software-intensive systems;
  - Support of IT infrastructure, software and IT systems.

  The quality characteristics and sub-characteristics, which are defined in the quality model, provide a consistent terminology for specifying, measuring and evaluating IT service quality.

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

Activity – March 2014

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
IMDRF draft recommendation for comment	Medical device software	Manufacturers	*Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Controls* ***The draft recommendation can be found on the SoftwareCPR Standards Navigator web page.***
FDASIA Health IT Report	Health IT	Manufacturers	*Proposed Strategy and Recommendations for a Risk-Based Framework* **The draft proposal can be found on the SoftwareCPR Standards Navigator web page.**
IEC 60601-1-12 FDIS	Medical devices	Manufacturers	*IEC 60601-1-12: Medical electrical equipment – 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*. **The FDIS can be found on the SoftwareCPR Standards Navigator web page**
IEC 60601-1-11 CDV	Medical devices	Manufacturers	*IEC 60601-1-11: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* **The CDV can be found on the SoftwareCPR Standards Navigator web page**

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO/IEC/IEEE 12207 CD	Software engineering	Manufacturers	*ISO/IEC/IEEE 12207 Systems and software engineering — Software life cycle processes* **The CD can be found on the SoftwareCPR Standards Navigator web page**
ISO/IEC 15026-3 CD	Software engineering	Purchasers and Manufacturers	*ISO/IEC 15026-3 Systems and software engineering —Systems and software assurance — Part 3: Systems integrity levels* **The CD can be found on the SoftwareCPR Standards Navigator web page**
ISO/IEC 29119-5 CD	Software engineering	Manufacturers	*ISO/IEC 29119-5 Software and Systems Engineering — Software Testing — Part 5: Keyword-Driven Testing* **The CD can be found on the SoftwareCPR Standards Navigator web page**
ISO/IEC 25011 CD	Information Technology	Service procurers and providers	*ISO/IEC 25011 Information technology — Service Quality Requirement and Evaluation (SQuaRE) – Service Quality Model* **The CD can be found on the SoftwareCPR Standards Navigator web page**

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

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. Review ends May 23.***
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 May 27.***
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 May 27.***
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. Ballot ends May 27.***

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. Ballot ends May 18.***
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. Ballot ends May 18.***
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. Ballot ends May 18.***
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. Ballot ends June 27.***
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. Ballot ends May 5.***

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