

Standards Navigator

Standards Navigator Monthly Report

5-August-2013

SoftwareCPR Standards Navigator provides information and tools related to standards that play a significant role in health software and software intensive medical devices. In addition to information on existing standards, SoftwareCPR Standards Navigator keeps you up to date on new standards activity and gives you expert insight into future changes to existing standards.

<http://www.softwarecpr.com/topicsframepage.htm>

July 2013 Standards Navigator Overview

Medical device software

- The ISO TC 210 officers have proposed that the second edition of IEC 62304 be moved to the joint working group between IEC 62A and ISO TC 215 (JWG7) to bring it into the same working group as IEC 82304-1. The second edition of 62304 will expand the scope of the standard from medical device software to health software. The leadership believes that TC 215 would be a better committee to address this broader scope than TC 210. The national member bodies of TC 210 have been asked if they have any objections to this change. If the change is made, TC 210 would remain in close liaison with the work, but TC 215 would become the ISO voting committee for the second edition of IEC 62304.
- MEDDEV 2.6/1 on Qualification and Classification of standalone software is under revision. Minor changes are expected to be made in early 2014, with a more extensive revision following. Since the IMDRF has taken up this topic, it is not clear whether Europe will complete a major revision and use it as input into the IMDRF work or wait for the IMDRF to complete before making a significant revision to the MEDDEV. This MEDDEV was created following work done in Sweden on software classification. The Swedish report was revised in January of 2013 and a revision of the MEDDEV was initiated. An approximate timeline looks like this: 2008 Sweden publishes report, January 2012 MEDDEV 2.6/1 published, January 2013 Sweden publishes revised report, March 2013 IMDRF adds standalone software as a work item, April 2013 MDEG software group meets to discuss revision of MEDDEV. The next meeting of the MDEG software group is planned for January 2014. The person in common with all this activity is Mats Olson from the Swedish Competent Authority.

Health IT and mobile health regulation

- The FDA Safety and Innovation Act (FDASIA) workgroup is completing its work and is expected to make public its recommendations in the areas of taxonomy, risk assessment and innovation, and regulations on August 13. A draft report from the three agencies involved (FDA, ONC and FCC) is expected by the end of September. The agencies have also requested input from other parties in addition to the work group. The agencies have until January to complete the report.
- A draft TR of ISO 80001-2-6 Guidance for responsibility agreements has been circulated for vote. This technical report provides practical guidance to responsible organizations on establishing responsibility agreements between all stakeholders involved, namely the responsible organization, the medical device manufacturers and the IT technology suppliers.

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 revised second committee draft (revised because of an error in creating the original pdf file) of ISO 62366-1 has been circulated for review. The revised version is now available on the Standards Navigator web site. The date for comments did not change.
- An FDIS of the amendment to the first edition ISO 62366 has been circulated for an up or down vote. This amendment adds requirements for legacy products that were created prior to the adoption of ISO 62366. Work on the second edition of 62366 continues in parallel.
- An FDIS of an amendment to IEC 60601-1-6 has been circulated for an up or down vote. The third edition of IEC 60601-1-6 was published in 2010. The third edition created a bridge that enables a manufacturer to conform to the requirements in IEC 60601-1 that make normative reference to IEC 60601-1-6 by employing a usability engineering process complying with IEC 62366:2007. However, IEC 62366 contains certain life-cycle process elements that are inconsistent with a type test.

This amendment is intended to clarify the elements of the usability engineering process that are required for compliance with the IEC 60601 series. This amendment is a bridge to use of ISO 62366 for the third edition of IEC 60601-1.

Interoperability

- FDA has recognized a total of 25 standards on medical device interoperability and cyber security. These standards can be categorized into 3 groups:
 - Risk management standards for a connected and networked environment (IEC 80001 series and ASTM F2761-09);

- Interoperability standards that establish nomenclature, frameworks and medical device specific communications and including system and software lifecycle processes (ISO/IEEE 11073 series and ISO/IEC 15026-4);
- Cyber security standards from the industrial control area most relevant to medical devices (IEC 62443 series).

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Security

- FDA announced that it has created a cybersecurity laboratory and would be acquiring fuzzing tools from Codenomicon. This will be similar to their laboratory that acquired and used software static analysis tools to find software defects. It is expected that FDA will use these tools on medical devices that have had a report of a security vulnerability. It is also expected that pre-market reviewers may ask manufacturers if they have tested their devices with this type of tool if they have data communication capabilities.
- The AAMI medical device security working group has a preliminary working draft of a new work item proposal for a TIR on device security principles and practices. The new work item and an outline of the proposed TIR will be the topic of a meeting of the group in Washington, D.C. on July 13. The draft of the TIR is expected to be developed for review at the AAMI standards week in early December.

Quality

- A second committee draft of ISO/IEC 29169 on the application of conformity assessment methodology to the assessment of process quality characteristics and organizational process maturity has been circulated for comment. 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. While not directed at medical devices, this standard may provide the basis for future assessment of medical device process standards such as 62304 and 62366.
- The AAMI TIR on safety assurance case reports has been circulated to the Infusion Device Committee for vote.

Medical Devices

- An FDIS of an amendment of IEC 60601-1-10 on Requirements for the development of physiologic closed-loop controllers has been circulated for an up or down vote. This amendment updates the references to other parts of 60601 and removes the normative reference to IEC 62304 since 60601-1 now has a normative reference to 62304.
- South Korea has announced that beginning June 2014 the third edition of IEC 60601-1 with amendments will be required. This means that medical electrical equipment that includes software will have to comply with IEC 62304 since the 2012 amendment to IEC 60601-1 requires 62304 for software. South Korea also said that safety requirements for software would be coming. This is expected to require software medical devices that are not covered by 60601-1 to comply with 62304. No date for the new software requirements was given.

Software Engineering

- A committee draft of ISO/IEC 30130 Software engineering – Capabilities of Software Testing Tools has been circulated for comment. This Technical Report covers the capabilities of software testing tools for being used by any project for software testing.
- A second committee draft of ISO/IEC 16350 Information Technology – Application Management has been circulated for comment. This standard addresses the stage of the life cycle after the application is placed into service. This stage of usage is called service delivery (or: service management and maintenance). During this stage, supporting the application and adapting based on changing demands or based on quality improvements (fixes, patches, releases) are the primary activities. While not directed at health applications, this standard addresses an area where there is a gap in current health software standards according to ISO 17791.

Activity – July 2013

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO 62366-1 CD2	Usability	Manufacturers	<p>Second edition of ISO 62366. Part 1 is requirements for usability. This CD has been reissued because of an error in the settings used to generate the pdf file when it was issued in June.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>
ISO 62366:2010 Amendment 1 FDIS	Usability	Manufacturers	<p>Final draft of an amendment to the first edition of 62366 that adds requirements for legacy products that were developed before 62366 was completed.</p> <p><i>The draft amendment can be found on the SoftwareCPR Standards Navigator web page.</i></p>
IEC 60601-1-6 Amendment 1 FDIS	Usability	Manufacturers	<p>Final draft of an amendment to the third edition of IEC 60601-1-6:2010. This amendment clarifies that post-production monitoring required in ISO 62366 is not required for compliance to IEC 60601-1-6.</p> <p><i>The draft amendment can be found on the SoftwareCPR Standards Navigator web page.</i></p>
IEC 60601-1-10 FDIS	Closed-loop controllers	Manufacturers	<p>Final draft of an amendment to IEC 60601-1-10 updates references to include the 2012 amendment to IEC 60601-1. Changes the usability requirement from IEC 60601-1-6 to IEC 62366 and removes the requirement for 62304 since it is now required by 60601-1.</p> <p><i>The draft amendment can be found on the SoftwareCPR Standards Navigator web page.</i></p>

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO 80001-2-6 DTR	Medical devices on networks	Hospitals and manufacturers	Draft for vote on guidance for responsibility agreements between hospitals and manufacturers. <i>The draft technical report can be found on the SoftwareCPR Standards Navigator web page.</i>
AAMI TIR 38 CDV	Assurance	Manufacturers	Draft for vote on safety assurance case reports. <i>The draft TIR can be found on the SoftwareCPR Standards Navigator web page.</i>
AAMI Device security TIR WD	Security	Manufacturers	Working draft of a new TIR work item for device security. The draft will be discussed at a meeting of the AAMI device security working group in Washington, D.C. on August 13. Approval of the NWIP by the AAMI standards board should occur prior to the AAMI standards week meetings in December. <i>The draft TIR NWIP can be found on the SoftwareCPR Standards Navigator web page.</i>
ISO/IEC 29169 CD2	Quality	Inspection bodies and manufacturers	Committee draft on the application of conformity assessment of process assessment of process quality characteristics and organizational process maturity. <i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i>
ISO/IEC 16350 CD2	Software	Developers, maintainers, users	Committee draft on the processes necessary for communication between parties involved in application management after the application has been developed. This includes integration, configuration, maintenance and user support. <i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i>

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO/IEC 30130 CD	Software	Developers	<p>Committee draft on the capabilities of software testing tools. This standard provides an object model of dynamic and static testing and test management. The objective is establishing a basis for common understanding of the tools needed for an effective testing environment for a particular software application.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

ISO 13485 edition 3 – CD	Quality management systems	Manufacturers	<p>This new edition of ISO 13485 is based off ISO 9001:2008.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>
IEC 62304 Amendment 1 CD	Medical device software	Manufacturers	<p>Revision of IEC 62304 has been divided into two parts, an amendment and a second edition. The amendment includes a revision to how software safety classification is determined and new requirements for legacy software that was developed prior to 62304, as well as a few other new requirements and clarification of existing requirements. A committee draft of the amendment has been circulated for comment. The second edition of 62304 will extend the scope to health software. Work on the second edition will begin later this year.</p> <p><i>The draft amendment can be found on the SoftwareCPR Standards Navigator web page.</i></p>
ISO 17522 DTR	Mobile Devices	Manufacturers	<p>This technical report describes the status and requirements of health applications and services on smart devices platforms and suggests the reference architecture for these.</p>

			<i>The draft technical report can be found on the SoftwareCPR Standards Navigator web page.</i>
IEC NP	Medical electrical equipment and medical electrical systems employing a degree of autonomy	Manufacturers	<p>This Technical Report is intended to help a MANUFACTURER through the key decisions and steps required to perform a detailed RISK ASSESSMENT of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM, hereafter referred to as ME EQUIPMENT or ME SYSTEM, which employs a degree of autonomy.</p> <p>This Technical Report provides guidance on:</p> <ul style="list-style-type: none"> • defining DEGREE OF AUTONOMY and by way of example give guidance on how this can affect the RISK ASSESSMENT; • methodologies for assessing the change to the RISK, and RISK reduction suggestion; and • BASIC SAFETY consideration in relation to IEC 60601-1. <p>This is the first document created by a joint working group of IEC SC 62A – medical electrical equipment, and ISO/TC 184/SC 2 - Automation systems and integration - Robots and robotic devices.</p> <p><i>The draft technical report can be found on the SoftwareCPR Standards Navigator web page until September 6, 2013</i></p>
ISO 33001 DIS	Process assessment	Manufacturers	<p>ISO IEC 33001 DIS Information technology — Process assessment — Concepts and terminology</p> <p>This International Standard provides a glossary of terms related to the performance of process assessment, together with an overall introduction to the concepts and standards framework for process assessment. The Standard identifies the principal components supporting the performance of process assessment, describes the results of process assessment, and gives an overview of the ways in which the results of assessment can be applied.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>
ISO 33002 DIS	Process assessment	Manufacturers	<p>ISO IEC 33002 DIS Information Technology — Process Assessment — Requirements for performing process assessment</p> <p>This International Standard defines the minimum set of requirements for performing an assessment that will ensure assessment results are objective, consistent, repeatable and representative of the assessed processes. The requirements help to ensure that the assessment output is self-consistent and to provide evidence to substantiate the ratings and to verify compliance with the requirements.</p>

			<i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i>
ISO 33003 DIS	Process assessment	Manufacturers	<p>ISO IEC 33003 DIS Information technology — Process assessment — Requirements for process measurement frameworks</p> <p>This International Standard provides requirements for process measurement frameworks that support and enable the assessment of process quality characteristics, from conceptualization to empirical validation.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>
ISO 33004 DIS	Process assessment	Manufacturers	<p>ISO IEC 33004 DIS Information technology — Process assessment — Requirements for process reference, process assessment and maturity models</p> <p>This International Standard provides requirements for the construction and verification of process reference models, process assessment models and maturity models.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>
ISO 33020 DIS	Process assessment	Manufacturers	<p>ISO IEC 33020 DIS Information technology — Process assessment — Process measurement framework for assessment of process capability</p> <p>This International Standard defines a process measurement framework conformant to the requirements defined in ISO/IEC 33003 for the process quality characteristic of process capability. The process measurement framework in this international standard conforms to the requirements of ISO 33003 and is applicable to any domain.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>

IEC 62657-2 Ed 1.0 - FDIS	Wireless communication networks - Coexistence management	Hospitals, manufacturers	<p>IEC 62657-2: Industrial communication networks - Wireless communication networks - Part 2: Coexistence management</p> <p>Wireless communication interfaces can interfere with others on the same premises or environment, disturbing each other. Therefore, without a predictable assuredness of coexistence, it could be problematic to have multiple wireless communication networks in the same facility or environment, especially because the time-criticality, the safety and the security of the operation may not be ensured in such an environment.</p> <p>This part of the IEC 62657 addresses the coexistence management for a predictable assuredness of coexistence. While this standard addresses industrial automation, the concerns are also applicable to healthcare delivery organizations.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page until July 19, 2013.</i></p>
ISO/IEC 29119-4 - DIS	Software testing – test techniques	manufacturers	<p>ISO/IEC 29119-4 Software and Systems Engineering — Software Testing — Part 4: Test Techniques describes a set of techniques that have wide acceptance in the software testing industry. It is intended to be used during the test design and implementation process that is defined in ISO/IEC 29119-2 Test Processes. Risk-based testing can be used to determine the set of techniques that are applicable in specific situations.</p> <p><i>The draft standard can be found on the SoftwareCPR Standards Navigator web page.</i></p>

REFERENCES

	Topic	Use / Users	Description
IMDRF draft document on Standalone Medical Device Software: Key Definitions	Medical device software	Manufacturers	The International Medical Device Regulators Forum believes that existing regulations do not readily address the unique public health risks posed by standalone software nor assure an appropriate balance between patient/consumer protection and promoting public health by facilitating innovation. The IMDRF has undertaken an effort to facilitate international regulatory convergence towards a smart, balanced regulatory approach that provides an optimal level of patient safety while fostering innovation and provides patient and providers with continued access to advanced health care technology that is safe. This draft document is the first of several documents intended to achieve these objectives. It identifies and defines key terms needed for regulation of standalone medical device software.
FDA draft premarket cybersecurity guidance	Security	Manufacturers	<p>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.</p> <p>This is a draft for comment. Comments should be submitted before September 13.</p>
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	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

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regarding medical devices with hard-coded passwords			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.
<i>ONC contract with the Joint Commission to investigate health IT-related safety events</i>	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	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

for critical infrastructure			and subcategories. References such as existing standards, guidelines and practices will be provided for each subcategory. A draft of the framework will be released in October.
TEAM-NB position paper on use of ISO 14971:2012	Risk management	Manufacturers	<p>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.</p> <p><i>The position paper can be found on the SoftwareCPR Standards Navigator web page.</i></p>
TEAM-NB "Vision on Revision"	Regulation	Regulators, Manufacturers, Notified bodies	<p>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.</p> <p><i>The report can be found on the SoftwareCPR Standards Navigator web page.</i></p>
Report	Interoperability	Medical device manufacturers, Hospitals, Regulators	<p>AAMI/FDA Interoperability Summit report</p> <p>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.</p> <p>This report can be found at http://www.aami.org/interoperability/Interoperability_Summit_publication.pdf</p>
Report	Wireless	Hospitals, Medical device manufacturers	<p>AAMI Wireless Workshop report</p> <p>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.</p> <p>This report can be found at http://www.aami.org/wireless/2012_Wireless_Workshop_publication.pdf</p>

Presentation	Research	Medical device manufacturers	<p>Medical Device Innovation Consortium (MDIC) Presentation from FDA and MDIC</p> <p>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.</p> <p><i>This presentation can be found on the Standards Navigator web page.</i></p>
Announcement	Interoperability	Medical device manufacturers, Hospitals, Regulators	<p>AAMI/UL collaboration on interoperability standards</p> <p>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.</p> <p>This announcement can be found at http://www.aami.org/news/2012/091712_press_AAMI_UL_Interoperability.pdf</p>
Report	Security	Medical device manufacturers, Regulators	<p>GAO report on FDA review of certain medical devices</p> <p>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.</p> <p>Dr. Kevin Fu testified to the National Institute of Standards and Technology <u>Information Security & Privacy Advisory Board</u> 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."</p> <p>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/</p>

			<p>The article states that “In September, the Government Accountability Office issued a <u>report</u> 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 "<u>Personal Security</u>" and "<u>Keeping Pacemakers Safe from Hackers</u>"), but no actual attacks on them have been reported.</p> <p>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 <i>Technology Review's</i> <u>Innovator of the Year</u> in 2009.)”</p> <p>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.</p> <p>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.</p> <p>This report can be found at http://www.gao.gov/products/GAO-12-816</p>
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Report	Mobile medical devices	Medical devices manufacturers, Hospitals, Regulators	<p>FCC report on Mobile Medical Devices</p> <p>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:</p> <p>Goal 1: FCC should continue to play a leadership role in advancing mobile health adoption.</p> <p>Goal 2: Federal agencies should increase collaboration to promote innovation, protect patient safety, and avoid regulatory duplication.</p> <p>Goal 3: The FCC should build on existing programs and link programs where possible in order to expand broadband access for healthcare.</p> <p>Goal 4: The FCC should continue efforts to increase capacity, reliability, interoperability and RF safety of mHealth technologies.</p> <p>Goal 5: Industry should support continued investment, innovation, and job creation in the growing mobile health sector.</p> <p>Recommendations include:</p> <ul style="list-style-type: none"> • 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 <p><i>This report can be found on the Standards Navigator web page</i></p>
Report	Health IT	Hospitals, EHR vendors, MD manufacturers	<p>Institute of Medicine report – Health IT and patient safety</p> <p>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.</p> <p><i>A presentation on the recommendations and the entire report are available at the SoftwareCPR Standards Navigator web page.</i></p>

Regulation	Regulation	Medical device manufacturers, IVD manufacturers	<p>EU draft proposed new Medical Device Regulation and In-Vitro Device Regulation</p> <p>These draft regulations can be found at</p> <p>http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf - medical devices</p> <p>http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf - In-vitro devices</p>
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STANDARDS CURRENTLY UNDER DEVELOPMENT OR REVISION

	Topic	Use / Users	Description
IEC 62304 Amendment 1	Software Life Cycle	Medical Device manufacturers, Regulators	<p>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.</p> <p>Current status: Comments received on the first CD are being resolved.</p> <p>Next step: Second CD or CDV will be circulated.</p> <p>Expected completion: January 2014</p>
IEC 82304-1	Health Software	Medical device manufacturers, Regulators	<p>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.</p> <p>Current status: Comments received on the first CD are being resolved. Major issues are scope and terminology.</p> <p>Next step: Second CD will be circulated.</p> <p>Expected completion: 2015</p>

IEC 62366-1	Medical devices	Medical device manufacturers, Regulators	<p>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.</p> <p>Current status: Comments have been resolved on the first CD and a second CD circulated.</p> <p>Next step: Comments received on the second CD.</p> <p>Expected completion: 2015</p>
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