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Standards Navigator

Standards Navigator Monthly Report

5-June-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.

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May 2013 Standards Navigator Overview

Health IT and mobile health regulation

- The FDA Safety and Innovation Act (FDASIA) workgroup has been meeting online. They have created three sub-groups to look at the specific areas of taxonomy, risk assessment and innovation, and regulations. The risk assessment and innovation sub-group is looking at both safety and risk to innovation. There will be a face-to-face meeting of the entire workgroup in Washington on May 30-31 to review the work to date and set the outline of the workgroup report. The workgroup plans to complete its input by the end of July and a draft report is expected by the end of September. The agencies have until January to complete the report.
- The International Medical Device Regulators Forum work item on the international harmonization of the approach to standalone medical device software has started working. Their first task is the definition of common data elements describing medical devices through the regulatory lifecycle. Draft definitions are expected in July, with finalization in November. A draft description of how risk is determined for standalone medical device software is planned for November with final version in March, 2013. A draft of how to determine appropriate regulatory requirements is planned for March 2013 with a final version ready by September, 2013.
- The EU Medical Software experts group met April 17. They are reviewing MedDev 2.1/6 Qualification and Classification of standalone software to determine if revisions are needed.
- FDA is currently working on a draft guidance document for medical device clinical decision support systems. It is unclear when (or if) this guidance will be released. The draft document reportedly takes a similar approach that FDA has taken with mobile medical apps, with only a small number of decision support systems requiring regulatory pre-market review.
- ISO TR 17791 Health informatics Guidance on standards for enabling safety in health software was approved. It will be published later this year.

Quality management and risk management

- Team NB, a group of EU notified bodies, have issued a position paper on using EN ISO 14971:2012 for compliance with the essential requirements of the MDD relating to risk management. The position paper notes the Z annexes of EN ISO 14971:2012 describe where EN ISO 14971:2012 does not fully meet the requirements and identifies questions a notified body assessor will ask to determine if the requirements have been met. The position paper also states that future assessments will expect to see that EN ISO 14971:2012 has been considered in the risk management for new products and that a plan has been established for evaluating and addressing the impact of EN ISO 14971:2012 on older devices.
- A first committee draft of the revision of ISO 13485 has been circulated for comment. This third edition will replace the previous 2003 version. This edition of ISO 13485 is based on and follows the format of ISO 9001:2008. Annex A in the draft details the differences between this draft version of ISO 13485 and ISO 9001:2008. Annex B in the committee draft details the differences between the 2003 version of ISO 13485 and this current draft.
- ISO TR 24971 has been approved. This technical report provides guidance for ISO 14971:2007 in several areas, but does not address the issues of whether ISO 14971:2007 satisfies the MDD essential requirements. Areas addressed in this guidance are:
    - Use & application of 14971 in product and process standards
    - Risk-management policy and acceptability criteria
    - Incorporating production and post-production information
    - “Information for safety” vs. “disclosure of residual risk”
    - Evaluating overall residual risk
- AAMI has begun work on two technical reports. One is TIR47 Guidance on the application of quality management principles to health software. The second is TIR46 Guidance on health software safety and assurance. The tasks groups for these guidance documents met at the end of May to begin work developing the documents.

Information Security

- FDA has created a draft guidance document for submission of security information for pre-market review. The draft guidance is expected to be released this year.

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- FDA has been revising its cybersecurity guidance document. The revision is reported to have criteria for when a medical device security vulnerability should be reported to FDA, when a security vulnerability would result in an MDR, and when a security vulnerability would necessitate a recall of the device.
- ISO TS 14441Health informatics — Security and privacy requirements of EHR systems for use in conformity assessment was approved. It will be published later this year.
- A new AAMI working group has been initiated on Medical Device Security. The first meeting of the group was held on May 31. No work item has been approved yet, but an area of interest is guidance on the use of the ISO 14971 risk management process to manage the risk from security threats.

Medical device software

- FDA stated in the GAO report calling for expanded consideration of information security that it was planning to have a review of its approach to evaluating software used in medical devices. Officials said the review of its approach would be conducted by a contractor and would involve an analysis of how the agency considers software in medical devices during premarket reviews. The consultant report on FDA's pre-market review of software has been completed and FDA is considering how to address its findings. FDA has not made the report or its considerations public, but some things under consideration may include:
    - Need for a consistent, transparent review process with clear stages
    - Need for a formal training program for software reviewers
    - Need to collaborate with industry for continuous improvement of software
    - Need for a governance structure that provides focus to software
        - This may include consolidating all software activities in one office

Activity – May 2013

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO 13485 edition 3 – CD	Quality management systems	Manufacturers	This new edition of ISO 13485 is based off ISO 9001:2008. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
IEC NP	Medical electrical equipment and medical electrical systems employing a degree of autonomy	Manufacturers	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. This Technical Report provides guidance on: • 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. 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. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page until September 6, 2013***

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NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
IEC 62657-2 Ed 1.0 - FDIS	Wireless communication networks - Coexistence management	Hospitals, manufacturers	IEC 62657-2: Industrial communication networks - Wireless communication networks - Part 2: Coexistence management 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. 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. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page until July 19, 2013.***
ISO/IEC 29119-4 - DIS	Software testing – test techniques	manufacturers	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. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***

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NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
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.***

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STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

CDV IEC 60601-1-12	Medical electrical equipment	Manufacturers, Notified bodies	The second Committee Draft for Vote of IEC 60601-1-12 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment This new collateral standard specifies requirements for safety in an emergency medical services environment. The ballot ends on 28 June. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
CDV ISO/IEC 15026-1	Assurance	Manufacturers, regulators	ISO/IEC 15026-1 System and software assurance – concepts and vocabulary Software and systems assurance and closely related fields share concepts but have differing vocabularies and perspectives. This International Standard provides a unifying set of underlying concepts and an unambiguous use of terminology across these various fields. It provides a basis for elaboration, discussion, and recording agreement and rationale regarding concepts and the vocabulary used uniformly across all parts of ISO/IEC 15026. ***The CDV can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on 18 June.***

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REFERENCES

	Topic	Use / Users	Description
Report	Interoperability	Medical device manufacturers, Hospitals, Regulators	AAMI/FDA Interoperability Summit report An AAMI/FDA sponsored summit meeting on medical device interoperability was held in late 2012. This report documents the discussion and identifies themes from the summit. This report can be found at http://www.aami.org/interoperability/Interoperability_Summit_publication.pdf
Report	Wireless	Hospitals, Medical device manufacturers	AAMI Wireless Workshop report A workshop with approximately 80 invited medical wireless experts was held in late 2012. This report documents the discussion and outcomes of this workshop. A follow-up meeting is planned for March 2013. This report can be found at http://www.aami.org/wireless/2012_Wireless_Workshop_publication.pdf
Presentation	Research	Medical device manufacturers	Medical Device Innovation Consortium (MDIC) Presentation from FDA and MDIC FDA and Life Science Alley have been collaborating on establishing a public-private partnership for research into regulatory science. A non-profit organization called the Medical Device Innovation Consortium has been created. This presentation by the FDA and the temporary director of the non-profit describes the need and the plans for this organization. ***This presentation can be found on the Standards Navigator web page.***

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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

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			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

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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.***

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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

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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	Amendment to the Medical Device Software Life Cycle standard. This standard is harmonized in the EU. The amendment addresses software safety classification and how to be compliant with legacy software. Current status: Comments received on the first CD are being resolved. Next step: Second CD or CDV will be circulated. Expected completion: January 2014
IEC 82304-1	Health Software	Medical device manufacturers, Regulators	New standard on Health Software: General Requirements. This standard is intended to be for standalone software products and to cover the product level requirements such as product validation, labeling, documents to be provided to the user, etc. Current status: Comments received on the first CD are being resolved. Major issues are scope and terminology. Next step: Second CD will be circulated. Expected completion: 2015

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IEC 62366-1	Medical devices	Medical device manufacturers, Regulators	The standard on human factors engineering is being revised and divided into two documents. The first is a standard that includes requirements for the process. The second will be a technical report providing information about good practices for implementing the human factors process. This document is the first part. Current status: Comments have been received on the first CD. Next step: Resolution of comments received on the first CD. Expected completion: 2015

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