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Standards Navigator

Standards Navigator Monthly Report

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

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

July 2015 Standards Navigator Overview

Medical device software

The draft for ballot (CDV/DIS) of *IEC 82304-1 Health Software: General requirements for safety* has been circulated. This International Standard applies to the safety of health software products designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware, and its primary focus is on the requirements for manufacturers. This standard will be voted on concurrently by CENELEC and is expected to become a harmonized EN document. Conformance to this standard is expected to provide assumption of conformity to the software validation portion of the MDD essential requirement on software for those products that are only software.

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

Medical Devices

- A draft of *IEC/TR 60601-4-1: Medical electrical equipment – Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy* has been circulated for comments.
  This Technical Report is intended to help a manufacturer through the key decisions and steps required to perform a detailed risk management process and usability engineering processes of medical electric equipment or a medical electric system employing a degree of autonomy. This draft has developed out of the convergence of robots for personal care and medical electrical equipment that has properties and capabilities of autonomy (monitoring, generating, selecting, and executing without operator intervention).

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

Health IT and mobile health applications

- Report on the EU Rolling Plan for ICT Standardisation that applies to health and healthcare systems. This draft report identifies the need for better interoperability between eHealth systems and for adoption of common standards in eHealth systems.

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

Security

- No new documents this month

Software Engineering and Information Technology

- A final draft for vote (FDIS) of *ISO/IEC/ 15026-3 Systems and software engineering — Systems and software assurance — Part 3: System integrity levels* has been circulated.

  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 corresponding integrity level requirements. It covers systems, software products, and their elements, as well as relevant external dependences.

  The draft is available on the SoftwareCPR Standards Navigator web page

- A second draft for vote (DIS) of *ISO/IEC 25022 Systems and software Engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – Measurement of quality in use* has been circulated.

  This International Standard contains:

  - a basic set of measures for each quality in use characteristic;
  - an explanation of how quality in use is measured.

  This International Standard provides a suggested set of quality in use measures to be used with the quality in use model in ISO/IEC 25010. They are not intended to be an exhaustive set. The proposed quality in use measures are primarily intended to be used for quality assurance and management of systems and software products based on their effects when actually used. The quality measures address quality characteristics of effectiveness, efficiency, satisfaction, freedom from risk and context coverage. The main users of the measurement results are people managing development, acquisition, evaluation or maintenance of software and systems.

  The draft is available on the SoftwareCPR Standards Navigator web page

- A draft for vote (DIS) of *ISO/IEC/IEEE 20246 Systems and Software Engineering - Work product reviews* has been circulated.

  The purpose of ISO/IEC/IEEE 20246 Work Product Reviews is to provide an International Standard that defines work product reviews that can be used at any stage of the software and systems life cycle. It can be used to review any system and software work product. ISO/IEC/IEEE 20246 defines a generic process for work product reviews that can be configured based on the purpose of the review and the constraints of the reviewing organization. The intent is to describe a generic process that can be applied both efficiently and effectively by any organization to any work product.

  The draft is available on the SoftwareCPR Standards Navigator web page

- A draft for comment (CD) of *ISO/IEC/IEEE 26513 Software and Systems Engineering — Requirements for testers and reviewers of user documentation* has been circulated.

  This standard supports the interest of software users in receiving consistent, complete, accurate, and usable documentation and specifies processes for use in testing and reviewing of user documentation. It is not limited to the test and review stage of the life cycle, but includes activities throughout the information management and documentation management process.

  This standard is intended for use in all types of organizations, whether or not a dedicated documentation department is present. In all cases, it may be used as a basis for local standards and procedures. Readers are assumed to have experience or general knowledge of testing or reviewing processes.

  This standard deals with the evaluation of end-user content only, and not with the evaluation of the software it supports.

  The draft is available on the SoftwareCPR Standards Navigator web page

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

These draft documents can be found on the SoftwareCPR Standards Navigator until their review period completes.

	Topic	Use / Users	Description
ISO/IEC/IEEE 12207 DIS	Software Engineering	Manufacturers	*ISO/IEC 12207 - Systems and software engineering — Software life cycle processes* Draft for vote. 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.
IEC 80001-2-8 DTR	Security	Manufacturers	*IEC 80001-2-8: Application of risk management for IT networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2* Draft for vote. This technical report provides additional guidance in relation to how security capabilities might be referenced (disclosed and discussed) in both the risk management process and stakeholder communications and agreements. This technical report provides guidance for the establishment of each of the security capabilities presented in IEC 80001-2-2.

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	Topic	Use / Users	Description
IEC 80002-2 CD	Quality	Manufacturers	*ISO TR 80002-2: Medical device software - Part 2: Validation of software for regulated processes* Draft for comment This technical report has been developed to assist readers in determining appropriate activities for the validation of process software used in medical device quality systems using a risk-based approach that applies critical thinking. The intention of this document is to help stakeholders, including manufacturers, auditors and regulators, to understand and apply the requirement for software validation included in ISO 13485.
ISO 24748-4 FDIS	Software Engineering	Manufacturers	*ISO 24748-4 System and software engineering – Life cycle processes – System engineering planning* Final draft for vote ISO 24748 specifies the technical management processes from ISO/IEC/IEEE 15288 that are required to be implemented for planning a systems engineering project. This is a final draft for approval.
ISO 24748-5 CD3	Software engineering	Manufacturers	*ISO 24748-5 System and software engineering – Life cycle processes –Software development planning* Draft for comment ISO 24748-5 provides a common framework for planning and controlling the technical processes and activities to produce and sustain software products.

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	Topic	Use / Users	Description
IEC 62366-2 DTR	Usability	Manufacturers	*IEC TR 62366-2: Medical devices - Part 2: Guidance on the application of usability engineering to medical devices* *Draft for vote.* IEC 62366-2 provides medical device manufacturers with guidance on how to integrate usability principles and user interface design practices into their overall medical device development processes.

REFERENCE LIBRARY

	Topic	Use / Users	Description
ONC 10-Year Vision	Health IT	Health IT infrastructure	*ONC 10-Year Vision to Achieve an Interoperable Health IT Infrastructure* The document can be found on the SoftwareCPR Standards Navigator web page or at http://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf

BSI white paper	Medical devices	Manufacturers	*"The proposed EU regulations for medical and in vitro diagnostic devices"* The white paper can be found on the SoftwareCPR Standards Navigator web page
EC green paper	Health IT	Manufacturers	*"Green Paper on mobile Health (mHealth)"* The green paper can be found on the SoftwareCPR Standards Navigator web page
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 2013. ***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 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.
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

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.

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 Edition 2	Software Life Cycle	Health Software Vendors including medical device manufacturers	The second edition expands the scope of 62304 from medical device software to health software. Health software is any software that is developed with an intended purpose of being used for health services. This includes software developed for medical devices. Current status: An initial committee draft is being developed. Next step: A draft is expected to be circulated in October 2015. Expected completion: 2018
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: CDV has been circulated and is currently out for vote. Next step: Resolution of comments on the CDV. Expected completion: 2016

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: Second DIS was approved in ISO but not in CEN. Next step: FDIS to be circulated in ISO. Expected completion: 2016