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Standards Navigator

Standards Navigator Monthly Report

21-September-2011

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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Standards Activity Status – August 2011

HEALTH SECTOR SOFTWARE STANDARDS

NEW	FDA hosted a meeting to discuss standards needs related to medical device interoperability. Representatives of Standards developing organizations were invited. FDA does not have the resources to participate in duplicate efforts, so they are hoping for a coordinated approach among SDOs. There was general agreement that a general architecture or infrastructure was needed and could help to facilitate future standards development. One key component to determining the direction forward focused on the needs of the FDA. It was generally agreed that interoperability matters to the Agency and there is current interest in moving forward with building the foundation and thinking through the complex issues imbedded in the subject. Actions for attendees out of the meeting: • Develop use cases for device interfaces • Identify existing standards for interoperability and determine if additional standards are required for medical device interoperability • Identify scope and 'how used' of those standards (use, adoption, which devices specific to, etc) • Categorize standards based on use environments and technologies (EHR/EMR, Point of Care, Image Exchange, etc.) • Identify clusters of use cases and technology, rank /prioritize, and identify roadmap to create interoperability for those clusters • Each group to propose strategy and tactics, including roles and responsibilities for addressing interoperability within the scope of specific use cases • Each association group interoperability standards (new or proposed) based on clinical and patient use cases relevant to their respective association • Propose multi-generational approach to development of new standards • Establish rules of engagement / conduct / commitment to solve interoperability puzzle • Agree on standardized communication protocol(s)within specific clinical and patient use cases • Each association propose strategy and tactics to accomplish action • Define specific interoperability need(s) and use cases, where interoperability can be improved/created, so we don't duplicate what's already been done by all the organizations out there which are now working, or have worked, on some aspect of the interoperability space Key Considerations: • Consider safety implications looking inward, not just outward • Ensure safety through essential principles • Solution(s) should be flexible enough to accommodate emerging technologies In review of these identified needs and considerations, the assignment is to: 1. Rank the need from 1 (highest) to 12 (lowest); 2. Determine what dysfunction from the list of interoperability dysfunctions (below) does each need address; and 3. Can a standard help to solve the dysfunction/problem? If so, how?

	 The need for a next meeting will be determined at a future time.
ISO TR 80002-2	Validation of software for regulated processes This project was approved in IEC and ISO. This TR will be joint work between ISO TC 210 and IEC SC 62A with ISO lead. The project has been assigned to IEC/ISO JWG3. Work on this technical report will begin at the October 13-14 meeting of JWG3. This activity was requested by the GHTF on the recommendation of its software ad hoc committee.
NP TC 215	Guidance on Standards for Enabling Safety in Health Software ISO/TC 215 has circulated for ballot a new work item for a technical report that focuses on the identification of a coherent set of international standards needed for the patient-safe (safer) development, implementation and use of health software. The intent of this work item is to identify and assemble a globally-accepted “package” of standards that will provide guidance to countries, health software developers, implementers and end users to ensure that health software appropriately protects the safety of patients. The voting on this ISO proposal closes on 30 September 2011. ***The draft TR can be found on the SoftwareCPR Standards Navigator web page until September 30, 2011.***

MEDICAL DEVICE STANDARDS

ISO 13485 NEW	Medical devices – Quality management systems – Requirements for regulatory purposes ISO has approved a revision of ISO 13485. The plans and next steps for revising the standard will be discussed at a meeting to be held on Oct 17-19, 2011.

IEC 60601-1 NEW	IEC 60601-1:2005/A1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance, Amendment 1 The committee draft for vote was approved. Comment resolution is under way and an FDIS is expected early in 2012.
ISO 14971	Application of risk management to medical devices Update on European Commission objection to harmonization of ISO 14971. A special task force was established with representatives from the European Commission (DG SANCO and DG Enterprise), the CEN consultants and representatives from the CEN/CLC Technical Committees involved. This task force developed a new outline for the various "Z" annexes that is much more detailed than the previous template. It was also agreed that for EN/ISO 14971 the "Z" annexes would not attempt to map the clauses of the standard to specific Essential Requirements. Having gathered input from a number of sources, the Chair and Secretary of CEN/CLC TC 3 prepared a draft proposal (CEN/CLC TC 3 N134), which was submitted to the Commission through the CEN/CLC Management Center. The commission is not as yet satisfied with the rewrite of the "Z" annexes for EN/ISO 14971:2009. A further high-level meeting of stakeholders is being planned for late June or early July to discuss the Commission's objections.
ISO TR 24971	Guidance on the application of ISO 14971 The systematic review of ISO 14971 identified six areas in the application of Risk Management System that could benefit from additional guidance. They are: 1) The role of product and process standards in the RM process 2) The policy for determining the criteria for risk acceptability 3) Production and post-production feedback loop 4) Differentiation of information for safety and disclosure of residual risk 5) Guidance on determining overall residual risk 6) Relation between clinical decision making and risk/benefit analysis During the discussion, a seventh topic was suggested: 7) Safety cases For the time being, the JWG decided to combine 5) and 6) into one discussion. The JWG also decided not to immediately tackle safety cases as considerable work is going on in other venues to refine the concept of applying safety cases to medical devices. It was decided to let that work mature a bit more before talking on this subject. Work has begun on content of the working draft. A committee draft is scheduled to be available about the end of 2011. Final approval and publishing is planned for spring 2013.

IEC 60601-1-8:	General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. The second edition of IEC 60601-1-8 was published in 2005. Since its publication, an issue has been identified with respect to pulse and burst testing. In addition, issues have been raised by IEC/62D/MT 22, Electromedical diagnostic and patient monitoring equipment, during implementation of alarm system requirements in particular standards within their scope of work. At the Brussels meeting, IEC/SC 62A accepted a proposal, based on ISO/TC 121/SC 3 Resolution Orebro 6, to develop the 1st amendment to IEC 60601-1-8:2006 to address the issues identified above. IEC/SC 62A – ISO/TC 121/SC 3 Joint Working Group 2, Alarms, was reactivated as a maintenance team to develop this amendment. The CDV for the amendment to IEC 60601-1-8 has been circulated for vote with a closing date of November 18, 2011. ***The draft CDV can be found on the SoftwareCPR Standards Navigator web page until November 18, 2011.***

MEDICAL IT NETWORKS

IEC TR 80001-2-4 NEW	Application of risk management for IT-networks incorporating medical devices – Part 2-4: General implementation guidance for Healthcare Delivery Organizations The new work item proposal has been approved in IEC. Comments received on the draft and next steps will be discussed at a meeting in Brussels on Oct 10-11. This Technical Report helps a RESPONSIBLE ORGANIZATION through the key decisions and steps required to establish a RISK MANAGEMENT framework, before the organization embarks on a detailed RISK ASSESSMENT of an individual instance of a MEDICAL IT-NETWORK.
AAMI SW87 NEW	Recommended Practice for application of the Quality System to Medical Device Data Systems (MDDS). The first meeting of the task group developing this recommended practice was on August 25. A small drafting team met on September 12-13. A working draft is expected to be available by October 2011 and a draft for ballot by January 2012.
AAMI New work item	The AAMI SW87 task group will propose an additional technical information report on guidance on the application of ISO 13485 and FDA Quality System Regulation to Health IT software. This proposal will be made to the AAMI standards board before the end of 2011.

GENERAL SOFTWARE STANDARDS

IEC 62638	Guidance on Software Aspects of Dependability A committee draft for vote has been circulated. The ballot period will close on December 16. ***The draft CDV can be found on the SoftwareCPR Standards Navigator web page until December 16, 2011.***
ISO/IEC 29119-1	Software Testing — Part 1: Concepts and Definitions A committee draft is currently being prepared.
ISO/IEC 29119-2	Software Testing — Part 2: Test Process A committee draft has been circulated for comment. The comment period closes on October 15. ***The draft CD can be found on the SoftwareCPR Standards Navigator web page until October 15, 2011.***
ISO/IEC 29119-3	Software Testing — Part 3: Test Documentation A committee draft has been circulated for comment. The comment period closes on October 15. ***The draft CD can be found on the SoftwareCPR Standards Navigator web page until October 15, 2011.***