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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

Standards Activity Status – September 2011

HEALTH SECTOR SOFTWARE STANDARDS

NEW	IEC Technical Committee 62 established a Software and Network Advisory Group at its meeting in September. The purpose of this group is to advise the TC Chairman and other TC and Sub Committee officers on the needs for software standards for medical devices and when joint work with other standards developing organizations is appropriate. Sherman Eagles of SoftwareCPR was named chair of this 7 member international advisory group.
NEW	The AAMI software committee is reviewing a draft Technical Information Report on "Guidance on the use of agile practices in the development of medical device software" Comments on the draft are due by November 9. ***The draft TIR can be found on the SoftwareCPR Standards Navigator web page until November 9, 2011.***
NEW	The committee developing guidelines for the boundaries of what software products are considered medical devices in the EU has released a new draft document. As they have only asked for editorial comments, this is expected to be the final draft before the document is approved. Approval is expected in December. ***The draft guidance document can be found on the SoftwareCPR Standards Navigator web page.***
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. At its meeting in September, IEC TC 62 requested that this be done as joint work between the two committees.

MEDICAL DEVICE STANDARDS

IEC 60601-1 NEW	The schedule for Amendment 1 of IEC 60601-1 is for an FDIS to be circulated in April, 2012 and for the Amendment to be published in June, 2012. Standards in the IEC 60601-2-x series will then need to be revised if they make a dated normative reference to IEC 60601-1.

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 were discussed at a meeting held on Oct 17-19, 2011. Some 17 topics will be considered for revision or enhancement, including incorporating risk management into the quality management system. A New Work Item Proposal is to be circulated along with a user survey on possible changes.
IEC 62366 NEW	Application of usability engineering to medical devices A proposal to split the usability standard into two parts is planned for December. This would result in a small normative standard (Part 1) and a larger guidance technical report (Part 2). The expected publication date for IEC 62366 Ed. 2 is August, 2015.
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 80001-2-1 NEW	Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples This draft TR was circulated for ballot. The ballot closes on November 25. ***The draft TR can be found on the SoftwareCPR Standards Navigator web page until November 25, 2011.***
IEC TR 80001-2-2 NEW	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls This draft TR has been circulated for ballot. The ballot closes on November 25. ***The draft TR can be found on the SoftwareCPR Standards Navigator web page until November 25, 2011.***

IEC TR 80001-2-3 NEW	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks This draft TR has been circulated for ballot. The ballot closes on November 25. ***The draft TR can be found on the SoftwareCPR Standards Navigator web page until November 25, 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 NEW	Software Testing — Part 1: Concepts and Definitions A committee draft has been circulated for comment. The comment period closes November 27. ***The draft CD can be found on the SoftwareCPR Standards Navigator web page until November 27, 2011.***
ISO/IEC 29119-4 NEW	Software Testing – Part 4: Test Techniques A committee draft has been circulated for comment. The comment period closes on November 27. ***The draft CD can be found on the SoftwareCPR Standards Navigator web page until November 27, 2011.***