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Standards Navigator

Standards Navigator Monthly Report

29-November-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.

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

Standards Activity Status – September 2011

HEALTH SECTOR SOFTWARE STANDARDS

	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 ***The draft guidance document can be found on the SoftwareCPR Standards Navigator web page.***
ISO TR 17791 NEW	Guidance on Standards for Enabling Safety in Health Software This new work item has been approved in ISO/TC 215. 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. Discussion is continuing between IEC TC 62 and ISO TC 215 regarding how to collaborate on this work.

MEDICAL DEVICE STANDARDS

IEC 60601-1	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	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	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 CDV for the amendment to IEC 60601-1-8 has been approved.

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 TR was approved in IEC. It has been circulated in ISO with the ballot closing on February 4, 2012. ***The draft TR can be found on the SoftwareCPR Standards Navigator web page until February 4, 2012.***
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 TR was approved in IEC. It has been circulated in ISO with the ballot closing on February 4, 2012. ***The draft TR can be found on the SoftwareCPR Standards Navigator web page until February 4, 2012.***
IEC TR 80001-2-3 NEW	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks This TR was approved in IEC. It has been circulated in ISO with the ballot closing on February 4, 2012. ***The draft TR can be found on the SoftwareCPR Standards Navigator web page until February 4, 2012.***

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.***