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Standards Navigator

Standards Navigator Monthly Report

2-January-2012

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 – December 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 ***The draft guidance document can be found on the SoftwareCPR Standards Navigator web page.***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	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 60601-1-8 NEW	*Medical electrical equipment – Part 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 – Amendment 1* The CDV for the first amendment of IEC 60601-1-8 has been approved. However, over 200 comments were made – more than typically seen on a CDV.
ISO 13485 NEW	Medical devices – Quality management systems – Requirements for regulatory purposes ISO has approved a revision of ISO 13485. As part of the ISO requirements for new or modified management system standards, a justification for the revision must be produced. A justification has been developed and is currently being voted on. ***The justification document can be found on the SoftwareCPR Standards Navigator web page.***

NWIP NEW	Medical devices - Selection and use of standards in support of recognized essential principles of safety and performance of medical devices This Standard identifies significant standards and guides that can be used in the assessment of conformity of medical devices with recognized essential principles of safety and performance. It also provides guidance in the use of standards and their application in conformity assessment. This proposed third edition of ISO Technical Report 16142 will be developed as an international standard and is intended to identify additional links between existing international standards and the revised and updated Global Harmonization Task Force Essential Principles. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***
IEC 62366	Application of usability engineering to medical devices A proposal to split the usability standard into two parts is planned. 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.

MEDICAL IT NETWORKS

IEC TR 80001-2-1	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	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	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

ISO/IEC 29119-2 NEW	Software Testing — Part 2: Test Process This DIS has been circulated in JTC1 with the ballot closing on May 9, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 8, 2012.***
ISO/IEC 29119-3 NEW	Software Testing — Part 3: Test Documentation This DIS has been circulated in JTC1 with the ballot closing on May 9, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 8, 2012.***
ISO/IEC 20000-3 NEW	Information technology – Service management – Part 3: Guidance on scope definition and applicability of ISO/IEC 20000-1 This DIS has been circulated in JTC1 with the ballot closing on May 3, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 2, 2012.***