Standards Navigator

Standards Navigator Monthly Report

12-April-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

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Standards Activity Status – March 2011

HEALTH SECTOR SOFTWARE STANDARDS

IEC 82304	The NWIP for a standard for Healthcare Software Systems - Part 1: General requirements was approved in IEC. This activity has been assigned to IEC/ISO JWG7 and Patty Krantz, Medtronic, ISO TC 215 WG7 and Peter Linders, Philips, IEC SC 62A, and CENELEC TC 62, have been appointed as project leaders. A committee draft is being prepared for circulation as a NWIP in ISO following the May TC 215 meeting. This CD will also be circulated in IEC for comments. This standard is intended to be harmonized under the EU MDD for standalone software medical devices, but is also intended to be useful for other healthcare software.
NWIP 62A/754/NP	New Work Item proposal on Validation of software for regulated processes. This NWIP is expected to be joint work between ISO TC 210 and IEC SC 62A with ISO lead. The project is expected to be assigned to IEC/ISO JWG3. This activity was requested by the GHTF on the recommendation of its software ad hoc committee. The NWIP ballot will close on July 1, 2011. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page until July 1, 2011.***

MEDICAL DEVICE STANDARDS

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance The CDV for the first amendment to IEC 60601-1:2005 has been circulated for vote with a closing date of August 12, 2011. This amendment includes changes to the PEMS section of the standard. ***The draft CDV can be found on the SoftwareCPR Standards Navigator web page until August 12, 2011.***
ISO/TS 24971	Guidance on the application of ISO 14971. This new work item was approved in ISO.

MEDICAL IT NETWORKS

AAMI proposed NWIP	A proposal for a guidance document on Applying the Quality System to Medical Device Data Systems has been submitted to AAMI by the FDA. The work is expected to be done by the AAMI software committee and the AAMI Quality Management committee.

GENERAL SOFTWARE STANDARDS