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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.

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Standards Activity Status – May 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 revised NWIP is being circulated in ISO in July. This revised NWIP will also be circulated in IEC for comments. The revision includes "safety" in the title so that it is clear that the standard only applies to general requirements for safety aspects. Some changes to make the scope less "medical device" like have also been proposed. 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.***
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.***

JWG9	IEC/SC 62A – ISO/TC 184/SC 2 JWG 9, Medical electrical equipment and systems using robotic technology. This new JWG has been approved and will begin meeting in June. Its task is to develop general requirements and guidance related to the safety of medical electrical equipment and systems that utilize robotic technology. (i.e., medical robots). The work would encompass medical applications (including aids for the disabled) covering invasive and non-invasive procedures such as surgery, rehabilitation therapy, imaging and other robots for medical diagnosis and treatment.

MEDICAL IT NETWORKS

NWIP 62A/760/NP IEC TR 80001-2-x	Application of risk management for IT-networks incorporating medical devices – Part 2-x: General implementation guidance for Healthcare Delivery Organizations 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. The NWIP ballot will close on September 16, 2011. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page until September 16, 2011.***
AAMI proposed NWIP AAMI SW87	Recommended Practice AAMI SW87, Application of the Quality System to Medical Device Data Systems (MDDS). The proposal for a recommended practice document on Applying the Quality System to Medical Device Data Systems has been approved for work by the AAMI standards committee. The work will be done by the AAMI software committee with additional experts from the AAMI Quality Management committee and from healthcare facilities.

GENERAL SOFTWARE STANDARDS
