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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 – June 2011

HEALTH SECTOR SOFTWARE STANDARDS

IEC 82304	A revised NWIP was circulated in ISO on July 2. The ballot will close on October 2. Since this has already been approved in IEC, work will begin on it at the October 10-11 meeting of JWG7 whether it is approved in ISO or not.
NWIP 62A/754/NP	The New Work Item proposal on Validation of software for regulated processes was approved in IEC and ISO. This NWIP will be joint work between ISO TC 210 and IEC SC 62A with ISO lead. The project has been assigned to IEC/ISO JWG3. Work on this technical report will begin at the October 13-14 meeting of JWG3. This activity was requested by the GHTF on the recommendation of its software ad hoc committee.

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.***
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes, 3rd edition A NWIP for a revision of ISO 13485 has been circulated in TC 210. Purpose and justification

	This proposed Standard is intended to replace ISO 13485:2003 in order to better reflect changes in regulatory requirements and expectations, current practices employed by medical device providers (e.g., manufacturers, distributors, and service providers) to ensure safe and effective medical devices that meet customer requirements. The revised standard also will reflect changes to the ISO 9001 standard on which this Standard is based. Changes that have occurred internationally since the publication of the ISO 13485:2003 Standard include: • Revisions to the EU Medical Devices Directive and Active Implantable Medical Devices Directive, including changes to the conformity assessment annexes for which EN ISO 13485 is the harmonized European standard. • The publication of several relevant Global Harmonization Task Force (GHTF) and the Asian Harmonization Working Party (AHWP) guidance documents that reflect current expectations of regulators around the world (e.g., Risk Management, Control of Suppliers, Process Validation, and Corrective and Preventive Actions). • Format and content changes made to the ISO 9001 standard published in 2008. • The adoption and/or amendment of medical device quality system regulatory requirements in countries and regions around the world (e.g., Gulf Cooperation Council (GCC), Association of Southeast Asian Nation (ASEAN), Brazil, India, Russia, and China). • Formal objection in 2011 from the Swedish competent authority to the European Union harmonization of the EN ISO 13485:2003 Standard. • The implications for EN ISO 13485 of the European Commission formal objection in 2010 to the harmonization of a series of medical devices standards, including EN ISO 14791:2009. • A formal request from the GHTF Steering Committee in 2011 for ISO/TC 210 to initiate a revision of the ISO 13485:2003 In order to meet the needs of the medical device industry and related regulatory authorities, as determined by ISO/TC210/WG1 and the GHTF SG3, this revised standard will contain additional and/or revised requirements related to risk management, outsourcing of product and services, software validation, post commercialization information gathering, clinical investigations, and relationships with regulatory documentation requirements, among others. This NWIP ballot will close on August 4. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page until August 4, 2011.***

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.

	The first meeting of the task group developing this recommended practice will be on August 25.

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.***
IEC 62673	Methodology for communication network dependability assessment and assurance A second committee draft has been circulated for comment. The comment period closes on September 16. ***The draft CD can be found on the SoftwareCPR Standards Navigator web page until September 16, 2011.***
ISO/IEC 29119-1	Software Testing — Part 1: Concepts and Definitions A committee draft is currently being prepared.
ISO/IEC 29119-2	Software Testing — Part 2: Test Process A committee draft has been circulated for comment. The comment period closes on October 15. ***The draft CD can be found on the SoftwareCPR Standards Navigator web page until October 15, 2011.***
ISO/IEC 29119-3	Software Testing — Part 3: Test Documentation A committee draft has been circulated for comment. The comment period closes on October 15. ***The draft CD can be found on the SoftwareCPR Standards Navigator web page until October 15, 2011.***