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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.

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

Standards Activity Status – June 2012

HEALTH SECTOR SOFTWARE STANDARDS

ISO 17791 Document for Comment **(NEW)**	ISO/TR 17791, Health informatics - Guidance on standards for enabling safety in health software This current working draft has been circulated to IEC 62A national committees for comment. The comment period closes on July 27. ***The Draft can be found on the SoftwareCPR Standards Navigator web page.***
MDICC Draft concept paper **(NEW)**	Medical Device Interoperability Coordinating Council The FDA has been putting a lot of resources into this effort to encourage interoperability between medical devices. The group has had two face-to-face meetings and numerous teleconferences. It is planning to present its work at an FDA/AAMI Summit on Medical Device Interoperability to be held in October 2012. ***The draft concept paper can be found on the SoftwareCPR Standards Navigator web page.***
ITU Report **(NEW)**	E-health Standards and Interoperability This is the second report from the ITU related to E-Health standards. The reports can be found at http://www.itu.int/techwatch.
UK NHS Policy document on information technology **(NEW)**	**The power of information:** Putting all of us in control of the health and care information we need This policy document lays out a ten-year strategy for information for health and care with the intention of using modern technology to make health and care services more convenient, accessible and efficient. It recognizes the need for national information standards and interoperable systems. “Minimum ‘standards’ will be systematically adopted; a shared language to allow systems to talk to each other, phased over ten years.” ***The paper can be found on the SoftwareCPR Standards Navigator web page.***
NWIP	AAMI Technical Report - Guidance on the application of quality management principles to health software This TIR will provide recommendations for using quality management principles for health software to improve patient safety. It will also interpret requirements of FDA regulations and international standards when these are required for regulated software. This NWIP was discussed at the AAMI Software Committee meeting on June 1-2. Work will begin following approval by the AAMI Standards Board. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***

NWIP	AAMI Technical Report - Guidance on Health software safety and assurance This technical report will provide recommendations for how to achieve safety in health software and how to demonstrate assurance that health software is safe by organizing the evidence in an assurance case. This NWIP was discussed at the AAMI Software Committee meeting on June 1-2. Work will begin following approval by the AAMI Standards Board. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***
NWIP	AAMI Standard - Classification of defects contributing to unacceptable risk in health software In order to gather useful data on the causes of safety related software failures, there needs to be a common way of identifying and reporting the software defects that lead to the failures. Classifying and reporting defect types will provide input for developers to create evidence to demonstrate that these types of defects have been addressed in their software. This NWIP was discussed at the AAMI Software Committee meeting on June 1-2. Work will begin following approval by the AAMI Standards Board. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***
	The EU Medical Device Experts Group has approved guidelines for the boundaries of what software products are considered medical devices in the EU. This document has just been published as a MEDDEV. ***The MEDDEV document can be found on the SoftwareCPR Standards Navigator web page.***
Institute of Medicine report – Health IT and patient safety	The Institute of Medicine produced a report on the impact of Health IT on patient safety. The report had a number of recommendations for the Secretary of HHS. ***A presentation on the recommendations and the entire report are available at the SoftwareCPR Standards Navigator web page.***

MEDICAL DEVICE STANDARDS

IEC 60601-1-6 Amendment 1 Committee Draft for Vote **(NEW)**	IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability The third edition of IEC 60601-1-6 was published in 2010. The third edition created a bridge that enables a MANUFACTURER to conform to the requirements in IEC 60601-1 that make normative reference to IEC 60601-1-6 by employing a USABILITY ENGINEERING PROCESS complying with IEC 62366:2007. However, IEC 62366 contains certain life-cycle process elements that are inconsistent with a type examination. This amendment is intended to clarify the elements of the USABILITY ENGINEERING PROCESS that are required for compliance with IEC 66001-1 series. This Committee Draft for Vote is the last opportunity to make technical comments. The ballot will close on October 26. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
IEC 60601-1-12 CDV report of voting **(NEW)**	IEC 60601-1-12: Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment The draft of this standard was approved in ISO, but rejected in IEC. The main objections appear to be the definition of emergency medical services environment and that this draft standard changes requirements found in IEC 60601-1 and its other collateral standards. The Joint Working Group developing this standard will review the voting results and comments at a meeting in September. It is expected that a second CDV will be created with the comments addressed.
IEC 60601-1-2 CDV	IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests This Committee Draft for Vote is the last opportunity to make technical comments. The ballot will close on August 17. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
New scope for IEC 62	This new scope adds software and broadens the purpose from just medical devices to healthcare. "To prepare international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment. NOTE: This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will contribute to regulatory frameworks. Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living)."

China software guidance	The SFDA is working on a software guidance document for regulatory purposes in China. This guidance will be for all medical device software including standalone software devices. At this time a public draft is not available, but from preliminary discussions it appears the new document will be based on IEC 62304 with some additional requirements specific to China.
Japan standalone software device regulation	Japan has adopted IEC 62304 as a Japan Industry Standard (T 2304 published March 1, 2012). Legislation will be introduced this year to amend the PAL to include standalone software as a medical device.
ISO 13485	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.***

MEDICAL IT NETWORKS

IEC/TR 80001-2-4 Draft Technical Report **(NEW)**	IEC/TR 80001-2-4: Application of risk management for IT-networks incorporating medical devices – Part 2-4: General implementation guidance for Healthcare Delivery Organizations This draft technical report has been circulated for voting. The ballot closes on August 8. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***
IEC 80001-2-x New Work Item Proposal **(NEW)**	Application of risk management for IT-networks incorporating medical devices – Part 2-x: Guidance on distributed alarm systems This new work proposal is out for ballot. A draft is included. Voting closes on September 9. ***The NWIP draft can be found on the SoftwareCPR Standards Navigator web page.***

GENERAL SOFTWARE STANDARDS

IEC 62628 Final Draft International Standard **(NEW)**	IEC 62628/Ed1: Guidance on Software Aspects of Dependability This final draft standard has been circulated for an up or down vote. The ballot closes on July 20. ***The FDIS draft can be found on the SoftwareCPR Standards Navigator web page.***