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Standards Navigator

Standards Navigator Monthly Report

20-May-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 – May 2012

HEALTH SECTOR SOFTWARE STANDARDS

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 will be discussed at the AAMI Software Committee meeting on June 1-2. ***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 will be discussed at the AAMI Software Committee meeting on June 1-2. ***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 will be discussed at the AAMI Software Committee meeting on June 1-2. ***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 Amendment FDIS (NEW)	The final draft of the first amendment to IEC 60601-1:2005 is out for an up or down vote. No technical comments are accepted on this final ballot. The ballot closes on June 29. This amendment is being concurrently voted on by CENELEC, and following its adoption, the amended version is expected to replace the 2005 version as a harmonized standard in the EU. Since the second edition (1990 version) of 60601-1 is just being withdrawn on June 1, it is likely that there will be an extended transition period before the new amended version is required. This date will be announced after the amended version is listed as a harmonized standard. The amendment primarily makes corrections and clarifications to the 2005 version. One new item for software is a requirement to comply with IEC 62304 if the medical electrical equipment is programmable. ***The FDIS can be found on the SoftwareCPR Standards Navigator web page.***
IEC 60601-1-2 CDV (NEW)	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.***
ISO/TR 24971 CD (NEW)	Guidance on the application of ISO 14971. First committee draft of a new guidance document for ISO 14971. This document includes guidance on determining criteria for risk acceptability, feedback loop, differentiation of information for safety and disclosure of residual risk, and evaluation of overall residual risk. The comment period closes on August 17. ***The CD 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.
IEC 60601-1-12	*IEC 60601-1-12 Ed. 1.0 : 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* A Committee draft for vote (CDV) for this new standard has been circulated. The ballot will close on June 15, 2012. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
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

	No new documents

GENERAL SOFTWARE STANDARDS

	No new documents