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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 – August 2012

HEALTH SECTOR SOFTWARE STANDARDS

MDICC Draft concept paper	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 October 2-3, 2012. This work is expected to be brought under a new public/private partnership formed by the FDA and medical device industry. (See the Medical Device Innovation Consortium entry below). ***The draft concept paper can be found on the SoftwareCPR Standards Navigator web page.***
CEN TC 251 newsletter	CEN TC 251 is the EU standards organization for Health Informatics. It works closely with ISO TC 215, HL7 and other standards organizations on standards related to EMRs, interoperability and other areas. This is their first newsletter and it contains information on their strategy and initiatives. ***The Newsletter can be found on the SoftwareCPR Standards Navigator web page.***
ITU Report	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	**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 has been approved by the AAMI Standards Board. Work will begin this fall. ***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 has been approved by the AAMI Standards Board. Work will begin this fall. ***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 has been approved by the AAMI Standards Board. Work will begin this fall. ***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

ASEAN draft medical device directive **(NEW)**	The Association of Southeast Asian Nations (ASEAN) has released a draft medical device directive for comment. Software appears to be treated similarly to how it is treated in the current EU MDD. ***The ASEAN draft document can be found on the SoftwareCPR Standards Navigator web page.***
ISO 13485 Working draft **(NEW)**	A working draft of the revision of ISO 13485 has been circulated for comment. Comments are due by September, 10. ***The working draft (redlined version) can be found on the SoftwareCPR Standards Navigator web page.***
ISO 13485 draft Revision design specification **(NEW)**	ISO Guide 72 on justification and development of management system standards recommends that a design specification be developed and approved prior to drafting a standard or revision. This draft design specification translates the results of a justification study into requirements for revising ISO 13485. This draft document has been circulated for comments prior to circulating it for ballot. Comments are due by September 10. ***The draft revision design specification can be found on the SoftwareCPR Standards Navigator web page.***
IEC60601-1-8 Amendment 1 FDIS **(NEW)**	The second edition of IEC 60601-1-8 was published in 2006. 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. This amendment addresses these issues. This Final Draft allows for editorial comments only. The ballot will close on September 28. ***The FDIS can be found on the SoftwareCPR Standards Navigator web page.***
Medical Device Innovation Consortium **(NEW)**	FDA has been working with Life Science Alley in the Twin Cities to establish a public/private partnership to jointly work on pre-competitive areas of regulatory science. Following a recent meeting with FDA Commissioner Hamburg, they have now announced that a US non-profit organization will be formed to carry out this work. Medtronic has loaned an executive to help get the organization started. As a non-profit, this organization can accept tax-deductible funding from businesses as well as funding from public entities. The initial areas expected to be addressed include modeling and simulation as a replacement for human clinical studies, educational needs for the medical area and interoperability of medical devices. The work being done by MDICC (see above) is expected to be incorporated into this new organization.
Draft revision to IEC Guide 51, Safety Aspects **(NEW)**	A draft revision of ISO/IEC Guide 51, Safety Aspects – Guidelines for their inclusion in standards has been circulated for comments. This third edition cancels and replaces the second edition (ISO/IEC Guide 51:1999) which has been technically revised. The main changes with respect to the previous edition are as follows: 1) Strengthened focus on risk reduction in the overall risk assessment process (see improved figure 2), 2) The term “harmful event” has been replaced by “hazardous event”, 3) Updated use of terms in the context of consumer safety ,

	4) The risk reduction steps in figure 3 are specified in more detail, 5) A new introduction giving additional background has been added, 6) Specific provisions and references to vulnerable persons have been added, 7) References have been re-allocated between the Normative References and the Bibliography, 8) Content in Clauses 6 and 7, "Achieving tolerable risk" and "Safety aspects in standards" has been reorganized and consolidated. Comments are due by October 5. ***The draft Guide 51 guidance document can be found on the SoftwareCPR Standards Navigator web page.***
Chinese guidance for software	The SFDA has issued a guidance document for software in an application for medical device registration. The guidance is based largely off IEC 62304 and requires different documentation for different software safety classes as defined in IEC 62304. ***The SFDA guidance document can be found on the SoftwareCPR Standards Navigator web page.***
IEC 60601-1-6 Amendment 1 Committee Draft for Vote	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.***
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)."
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.

MEDICAL IT NETWORKS

ISO/IEC 90006 Draft TR **(NEW)**	ISO/IEC 90006 - Guidelines for the application of ISO 9001:2008 to IT service management and its integration with ISO/IEC 20000-1:2011. This document establishes a comparison of the commonalities and differences between the requirements of ISO 9001 and ISO/IEC 20000-1. This should support enterprise adoption and audit of management systems developed following the requirements of ISO 9001 alone or of an integrated management system for both ISO 9001 and ISO/IEC 20000-1. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 20000-5 Preliminary Draft TR **(NEW)**	Revision of ISO/IEC TR 20000-5: 2010: Information technology – Service management – Part 5: An exemplar implementation plan for ISO/IEC 20000-1:2011 This preliminary draft TR has been circulated for comments. Comments are due by November 2. ***The PDTR can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 20000-11 Preliminary Draft TR **(NEW)**	ISO/IEC 20000 - Part 11: Guidance on the relationship between ISO/IEC 20000-1:2011 and related frameworks: ITIL® This preliminary draft TR has been circulated for comments. Comments are due by November 1. ***The PDTR can be found on the SoftwareCPR Standards Navigator web page.***
IEC/TR 80001-2-1 IEC/TR 80001-2-2 IEC/TR 80001-2-3	- IEC 80001-2-1 TR Ed.1.0 - "Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks - Practical applications and examples " - IEC 80001-2-2 TR Ed.1.0 - "Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls" - IEC 80001-2-3 TR Ed.1.0 - "Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks" Have been published by IEC. AAMI is adopting these as TRs and will publish them soon. Publication by AAMI is expected in September.
IEC 80001-2-x New Work Item Proposal	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

Draft Publically available specification IEC/PAS 62814	IEC/PAS 62814 Dependability of Software Products Containing Reusable Components – Guidance for Functionality and Tests This draft specification has been circulated for an up or down vote. The ballot closes on September 19. ***The PAS draft can be found on the SoftwareCPR Standards Navigator web page.***