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Standards Navigator

Standards Navigator Monthly Report

20-March-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.

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Standards Activity Status – February/March 2012

HEALTH SECTOR SOFTWARE STANDARDS

NEW	The FDA has invited numerous standards developing organizations and a few other stakeholders to meet for the purpose of coordinating standards activities related to medical device interoperability. The first face-to-face meeting of this group was held at FDA on March 9. The group is organizing and discussing governance and work plans. It is currently being identified as the Medical Device Interoperability Coordinating Council. ***Unofficial brief notes are available at the SoftwareCPR Standards Navigator web page.***
NWIP NEW	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. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***
NWIP NEW	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. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***
NWIP NEW	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. ***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.***
ISO TR 17791	Guidance on Standards for Enabling Safety in Health Software ISO/TC 215 has agreed that this work should be done as a joint project with IEC/TC 62. A new work item has been circulated in IEC and, if approved, will be assigned to JWG7 with an ISO project lead. The new work item has already been approved in ISO/TC 215. The

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	intent of this work item is to identify and assemble a globally-accepted "package" of standards that will provide guidance to countries, health software developers, implementers and end users to ensure that health software appropriately protects the safety of patients. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page until April 5.***
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.***

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MEDICAL DEVICE STANDARDS

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 NEW	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 NEW	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 62366 NEW	Proposal to initiate a fast-track amendment to IEC 62366:2007 Medical devices - Application of usability engineering to medical devices. This proposal introduces the concept of UOUP, User Interface of Unknown Provenance, and describes how to utilize it with legacy products developed before IEC 62366. ***This proposal can be found on the SoftwareCPR Standards Navigator web page.***
IEC 60601-1-6	*Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability – Amendment 1* A Committee Draft for the first amendment of IEC 60601-1-6 has been circulated. 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. ***The CD can be found on the SoftwareCPR Standards Navigator web page.***

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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.***
NWIP	Medical devices - Selection and use of standards in support of recognized essential principles of safety and performance of medical devices This Standard identifies significant standards and guides that can be used in the assessment of conformity of medical devices with recognized essential principles of safety and performance. It also provides guidance in the use of standards and their application in conformity assessment. This proposed third edition of ISO Technical Report 16142 will be developed as an international standard and is intended to identify additional links between existing international standards and the revised and updated Global Harmonization Task Force Essential Principles. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***

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MEDICAL IT NETWORKS

PDTR 90006 NEW	Information technology — Guideline on the application of ISO 9001 to service management This draft technical report has been circulated in JTC1 with the ballot closing on May 8. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 7, 2012.***
PDTR 20000-10 NEW	Information technology — Service management — Concepts and terminology This draft technical report has been circulated in JTC1 with the ballot closing on May 8. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 7, 2012.***
NWIP (with draft) NEW	Information technology – Service management – Part 7: Guidance on the application of ISO/IEC 20000-1 to the cloud ***The NWIP & draft can be found on the SoftwareCPR Standards Navigator web page until May 7, 2012.***
PDTR 20000-5 NEW	Information technology — Service management — Part 5: Exemplar implementation plan for ISO/IEC 20000-1 This draft technical report has been circulated in JTC1 with the ballot closing on May 8. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 7, 2012.***
ISO/IEC 20000-3	Information technology – Service management – Part 3: Guidance on scope definition and applicability of ISO/IEC 20000-1 This DIS has been circulated in JTC1 with the ballot closing on May 3, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 2, 2012.***

GENERAL SOFTWARE STANDARDS

ISO/IEC 29119-1 NEW	Software Testing — Part 1: Concepts and Definitions This Committee Draft has been circulated in JTC1 with the ballot closing on May 7, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 6, 2012.***
ISO/IEC 29119-4 NEW	Software Testing — Part 4: Test Techniques This Committee Draft has been circulated in JTC1 with the ballot closing on May 7, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 6, 2012.***

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ISO/IEC 29119-2	Software Testing — Part 2: Test Process This DIS has been circulated in JTC1 with the ballot closing on May 9, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 8, 2012.***
ISO/IEC 29119-3	Software Testing — Part 3: Test Documentation This DIS has been circulated in JTC1 with the ballot closing on May 9, 2012. ***The draft can be found on the SoftwareCPR Standards Navigator web page until May 8, 2012.***
NWIP - Capabilities of software testing tools ISO/IEC JTC1/SC7	The scope of this work is to define the capabilities of tools that make it possible to fully or partially automate the software testing. ***The draft NWIP can be found on the SoftwareCPR Standards Navigator web page until April 28, 2012.***

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