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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 – December 2012

HEALTH SECTOR REPORTS & REGULATIONS

Finland proposed legislation **(NEW)**	The Finnish Government has drafted legislation regulating Health IT and EMRs. The proposal has been circulated for a public consultation period, after which it will revised and submitted to Parliament. The legislation has various deadlines and is intended to be fully in force by 2015. The draft is in Finnish, but a partial English translation is available. ***The partial English translation can be found on the SoftwareCPR Standards Navigator web page.***
Sweden revision of guidance on classification of software information systems **(NEW)**	The Swedish report on guidelines for classification of software based information systems used in health care was published in 2009 and was a starting point for the EU MEDDEV 2.1/6. The report has been revised in 2012. It is currently only available in Swedish, but an English translation is expected early in 2013.
Revision of MedDev 2.1/6 planned **(NEW)**	The EU Medical Device Expert Group software working group is expected to convene in 2013 to consider revisions to the MEDDEV 2.1/6 Qualification and Classification of standalone software.

MEDICAL DEVICE STANDARDS & GUIDANCE

IEC 62366-1 CD	A Committee Draft for comment of IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices has been circulated. IEC 62366 is being divided into two parts. The new part 1 will contain updated normative requirements for the application of usability engineering to medical devices. A new part 2 which is also under development will contain guidance on the application of usability engineering. These activities are separate from the amendment to 62366 that is currently under development. ***The CD can be found on the SoftwareCPR Standards Navigator web page.*** ***The comment period ends on 1 March 2013.***
AAMI WD TIR Infusion Pump Safety Assurance Case Report	A working draft of the Infusion Devices: Assurance Case Report Guidance has been circulated to the working group for comment. This technical information report will provide guidance on how to complete an Assurance Case Report in order to comply with the new additional FDA pre-market requirements for infusion pumps. This TIR will include a detailed but strictly hypothetical example from the medical device domain. ***The draft technical information report can be found on the SoftwareCPR Standards Navigator web page. Comments on the draft are due by 31 January 2013.***
IEC 62304 edition 2 CD1	The first committee draft of the second edition of IEC 62304 *Medical device software life cycle processes* has been circulated for comments. Major changes include a revision of how software safety class is determined, new requirements for legacy software and an informative process reference model. Other changes have been made to align with ISO 14971:2007 and to clarify and improve particular requirements. A question to National Committees is whether to expand the scope of 62304 to include health software that is not a medical device. A second CD for comments is planned before a draft for vote will be circulated. Comments on CD1 due by January 11, 2013. ***The CD can be found on the SoftwareCPR Standards Navigator web page.***
IEC 82304-1 CD1	The first CD of 82304-1 *Health Software – Part 1: General Requirements for product safety* has been circulated for comment. At the IEC/TC 62 meeting in Brussels in 2009, a concern was raised that software standards for Health IT /Standalone Software may use a different risk model to ISO 14971 and that manufacturers might in the future be required to follow two different risk models and development processes for the same software. At the Brussels meeting, the IEC/TC 62 CAG tasked Chuck Sidebottom to convene a small group to investigate extending the scope of IEC 60601-1 to include standalone software. The extension to 60601-1 developed by the small group was opposed by the majority of the National Committees, but most of them agreed that standalone software should be covered by a new IEC standard. The IEC 60601-1 Amendment Project Management Team (A1PMT) asked IEC/SC 62A MT 31 (PEMS) for a recommendation on how to proceed. The MT 31 recommendation was to create a new product level standard for standalone software and reuse IEC 62304 in respect of software development processes. During the discussion in the CAG meetings, it was strongly suggested that the new standard not be constrained to software that meets the strict definition of a regulated medical device. This proposed new standard consequently addresses HEALTH SOFTWARE and includes requirements that would be sufficient for software that is a medical device, while not constraining its scope to only those software products that are

	regulated as medical devices. The new work was approved as a joint project between IEC SC 62A and ISO TC 215. A second CD for comments is planned before a draft for vote will be circulated. Comments on CD1 due by January 11, 2013. ***The CD can be found on the SoftwareCPR Standards Navigator web page.***
ISO DTR 24971	ISO/TR 24971 *Guidance on the application of ISO 14971* has been circulated for vote. This Technical Report provides guidance to assist in the development, implementation and maintenance of risk management for medical devices that aims to meet the requirements of ISO 14971. This Technical Report is not intended to be an overall guidance document on the implementation of ISO 14971 for organizations. It supplements the guidance contained in the informative annexes of ISO 14971 related to the following areas. – The role of international product safety standards and process standards in risk management – Guidance on formulation of a risk management policy – Guidance on how the production and post-production feedback loop can work – Guidance on the differentiation of information for safety as a risk control measure and disclosure of residual risk – Guidance on the evaluation of overall residual risk This ballot closes on January 11, 2013. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***
IEC 62366 Amendment 1 CDV	Amendment 1 to IEC 62366: Medical devices - Application of usability engineering to medical devices Amendment 1 updates the standard to add requirements to deal with legacy devices where the USER INTERFACE design is of unknown provenance. It defines the term USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) and adds a normative annex on how to evaluate a UOUP relying wherever possible on existing documentation that should have been created during the development of legacy medical devices. This is the last opportunity to provide comments on the technical requirements. The CDV closes on January 11, 2013. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
IEC 60601-1-9 Amendment 1 CDV	Amendment 1 to IEC 60601-1-9: Requirements for environmentally conscious design The first edition of IEC 60601-1-9 was published in 2007. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012 and to make a few minor editorial updates. This amendment does not add or change requirements in 60601-1-9. This is the last opportunity to provide comments on the technical requirements. The CDV closes on January 11, 2013. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***

IEC 60601-1-10 Amendment 1 CDV	Amendment 1to IEC 60601-1-10: Requirements for the development of physiologic closed-loop controllers The first edition of IEC 60601-1-10 was published in 2007. This amendment updates the references to IEC 60601-1 and other collateral 60601-1 standards to include amendments made since 2007. It also removes the normative reference to IEC 62304 since Amendment 1 of IEC 60601-1 now includes a normative reference to IEC 62304. This is the last opportunity to provide comments on the technical requirements. The CDV closes on January 11, 2013. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***

MEDICAL IT NETWORKS

NWIP IEC 80001-2-x Guidance for Responsibility Agreements	A new work item proposal has been circulated for ISO 80001-2-x: Application of risk management for IT-networks incorporating medical devices – Part 2-x Guidance for responsibility agreements. This Technical Report provides guidance on implementing RESPONSIBILITY AGREEMENTS, which are required in ISO/IEC 80001-1 for the purpose of defining the roles and responsibilities of all relevant stakeholders in the MEDICAL IT-NETWORK. ***The NWIP and draft TR can be found on the SoftwareCPR Standards Navigator web site.***