

Standards Navigator

Standards Navigator Monthly Report

7-January-2011

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 – November 2010

MEDICAL DEVICE STANDARDS

ISO 14971	<p>The European Commission has formally objected to the harmonization of ISO 14971 for certain Essential Requirements in the MDD. The objection was sent to a committee that deals with harmonization issues and may take up to 12 months to resolve. The Medical Device Experts Group (MDEG) has asked for input from EU member states and industry groups by January 15, 2011. ISO TC 210 and CEN have already provided input. Industry groups Eucomed, Euromcontact, Edma and COCIR are working together and have been meeting with the EC. They will provide written input by January 15.</p> <p>The formal objection from the EC, and the responses from ISO and CEN can be found on the SoftwareCPR Standards Navigator web page.</p>
IEC 60601-1	<p>A committee draft for vote (CDV) of the 60601-1 amendment was been sent to the French national committee for translation. The French national committee has indicated that it will provide a translation by March 1. The CDV will be circulated for vote by mid-March, 2011. The CDV will include a normative reference to IEC 62304 (62304 will be required to comply with 60601-1) and revisions to the accompanying documentation required if a medical device is intended to be used on a network. The documentation requirements align with requirements included in IEC 80001-1.</p>

SOFTWARE STANDARDS

New proposed standard on health care software systems	<p>An NWIP for this new standard was circulated in IEC 62A on December 10, 2010. The ballot will close on March 11, 2011. If approved, work will begin in June 2011. A final standard will not be completed until the end of 2014.</p> <p>The intention is to have a standard that can be harmonized for use by regulated medical devices that are standalone software and also used voluntarily by health software that is safety critical but is not regulated.</p> <p>The NWIP and draft standard can be found on the SoftwareCPR Standards Navigator web page until March 11, 2011.</p>
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