

## **Standards Navigator**

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### **Standards Navigator Monthly Report**

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**20-March-2011**

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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.

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<http://www.softwarecpr.com/topicsframepage.htm>

## Standards Activity Status – February 2011

### REGULATORY ACTIONS REGARDING STANDARDS

Formal Objection to ISO 13485	<p>The Swedish Competent Authority has requested a formal objection be raised by the European Commission to the harmonization of ISO 13485. The Swedish object on several grounds, including that a quality system is not an essential requirement of the MDD and therefore cannot have a harmonized standard, that the standard claims to cover essential requirements that it does not cover, and that in some points the standard is less precise than the directive.</p> <p>The letter sent by the Swedish authority to the EC, and a response from European medical device industry groups are both available on the SoftwareCPR Standards Navigator web page.</p>
Formal Objection to ISO 14971	<p>A decision on the formal objection to the harmonization of ISO 14971 has been delayed for one year. A task force has recently begun meeting to address the issues that were raised by the EC.</p>

### MEDICAL DEVICE STANDARDS

IEC 60601-1-12	<p>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 used in the emergency medical services environment.</p> <p>The NWIP for this new collateral standard was approved in both IEC and ISO. A Committee Draft has been circulated for comments with a closing date of June 24, 2011. The draft CD can be found on the SoftwareCPR Standards Navigator web page until June 24, 2011.</p>
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### MEDICAL IT NETWORKS

IEC 80001-2-x	<p>Three technical report NWIPs were approved in both IEC and ISO. These are:</p> <ul style="list-style-type: none"> <li>IEC 80001-2-x Step by Step Risk Management of Medical IT-NETWORKS; Practical Applications and Examples</li> <li>IEC 80001-2-x Guidance for the communication of medical device security needs, risks and controls</li> <li>IEC 80001-2-x Guidance for wireless networks</li> </ul> <p>Drafts for ballot are expected to be circulated by September.</p>
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