

Standards Navigator

Standards Navigator Monthly Report

16-February-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 – January 2011

MEDICAL DEVICE STANDARDS

<p>Proposal for a new Joint Working Group on medical robots</p>	<p>Proposal from ISO/TC 184/SC 2, <i>Robots and robotic devices</i> to establish a new Joint Working Group on <i>Safety for medical devices using robotic technology</i>.</p> <p>ISO/TC 184/SC 2 is proposing the formation of a JWG with IEC/SC 62A under IEC administrative lead to develop a new work item proposal for a Collateral Standard in the IEC 60601 family. The scope of this work would be:</p> <p>Establish basic safety and essential performance requirements for medical electrical equipment and systems employing robotic technology (i.e., medical robots). The work would encompass medical applications (including aids for the disabled) covering invasive and noninvasive procedures such as surgery, rehabilitation therapy, imaging and other robots for medical diagnosis and treatment.</p> <p>The current working definition of a robot is an “actuated mechanism programmable in more than one axis with a degree of autonomy, moving within its environment, to perform intended tasks”. Autonomy is currently defined as the “ability to control movement and communication to perform intended tasks without human intervention”. Before a meaningful new work item proposal can be circulated, the proposed JWG will need to refine these definitions so as to establish the appropriate boundaries for this work.</p>
<h3>SOFTWARE STANDARDS</h3>	
<p>IEC 62628</p>	<p>A committee draft of a new standard on Guidance on Software Aspects of Dependability has been distributed for comment.</p> <p>The draft standard can be found on the SoftwareCPR Standards Navigator web page until March 11, 2011.</p>
<p>IEC 62673</p>	<p>A committee draft of a new standard on Methodology for communication network dependability assessment and assurance has been distributed for comment.</p> <p>The draft standard can be found on the SoftwareCPR Standards Navigator web page until March 11, 2011.</p>
<p>ISO 90003</p>	<p>A Preliminary Draft Technical Report on Guidelines for the application of ISO 9001:2008 to computer software has been distributed for comment.</p> <p>The draft technical report can be found on the SoftwareCPR Standards Navigator web page until April 18, 2011.</p>