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Standards Navigator

Standards Navigator Monthly Report

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Standards Activity Status – October 2010

MEDICAL DEVICE STANDARDS

IEC 60601-1	The proposal for adding medical software systems was rejected by the national committees in a question included in the committee draft of the first amendment to IEC 60601-1:2005. The requirements for medical software systems have been removed and a new standard on health care software systems has been proposed (see item under software standards). A committee draft for vote (CDV) of the 60601-1 amendment will be circulated in January 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.

SOFTWARE STANDARDS

IEC 62304	Work began on the second edition of IEC 62304 Medical device software life cycle processes in October. Some of the changes being considered include: • Changing software safety class to include a risk element and to align class A with FDA's minor level of concern • Adding guidance on software vendor selection and management • Adding guidance on how to address legacy products that are being enhanced • Recognize the benefits of some modern development tools • Adding guidance for artifacts created using agile methods • Clarifying that integration occurs at multiple levels • Clarifying that integration planning is really the approach and not details of exact order and series of integrations • For integration testing, including the types of things that you would be testing for during this type of testing, similar to types of requirements list (use "as appropriate") • The requirement that every unit must have a detailed design for Class C is too prescriptive • There are known types of defects that should be addressed in implementation (and known approaches to detecting them that should be mentioned as guidance) • Harmonize risk terminology with ISO 14971:2007 • Improve the discussion of probability to take into account what is in IEC 80002-1 • Include appropriate requirements for use of medical device software on networks (align with IEC 80001-1) • Consider adding guidance for higher level languages such as JAVA, .NET, etc. • Consider including safety assurance case guidance Some additional questions raised for discussion: • Should there be a clause for software validation? • ISO 12207 has been updated – should 62304 align with this revision? • Should 62304 be less prescriptive and more goal based? • This may be where safety assurance cases could come in • Should there be better guidance for integration of S/W development process with quality system procedures? • Should there be guidance for small companies? A first committee draft of the 2nd edition is expected in the fall of 2011. Final approval will probably not occur before 2014.
AAMI TIR on using Agile Practices in	Work is continuing on this technical information report. The first draft should be available by mid 2011.

development of medical device software	
New proposed standard on health care software systems	At the IEC 62A meeting in Seattle in October, the subcommittee approved issuing a NWIP for standalone health care software systems. This new proposed work is the result of the national committees desire to separate this activity from the IEC 60601-1 standard. The draft standard will be based on the proposed medical software systems addition that was in the 60601-1 amendment CD, but has been removed from the amendment CDV. This new work has been proposed to be assigned to JWG7, the joint working group between IEC 62A and ISO 215 on risk management of IT-networks incorporating medical devices. The NWIP will be circulated in December 2010. If approved, work will begin in June 2011. A final standard will not be completed until the end of 2014. 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.
New proposed TR on gaps in standards for health software	A proposed new ISO technical report on the currently existing standards, the gaps and how to address these gaps in standards for enabling safe health software is being discussed at a meeting in London in December. If work moves forward this would be addressed in ISO TC 215.
New proposed TR on validation of software for production and service provision	The GHTF steering committee has requested that ISO 210 (in collaboration with IEC 62A) develop a technical report giving guidance for validation of the application of computer software for production and service provision. (ISO 13485 7.5.2.1.) A NWIP is being prepared and is expected to be considered at the ISO 210 meeting in May 2011. If approved, the work is expected to be assigned to JWG3 Medical device software.
NETWORK STANDARDS	
IEC 80001 series	IEC 80001-1 has been approved by IEC and ISO on September 24 and published on October 27. The IEC published a bilingual (English and French) version for Three technical report NWIPs were circulated on October 1 These are: IEC 80001-2-x Step by Step Risk Management of Medical IT-NETWORKS; Practical Applications and Examples IEC 80001-2-x Guidance for the communication of medical device security needs, risks and controls IEC 80001-2-x Guidance for wireless networks The NWIP for IEC 80001-2-x Health Delivery Organization Implementation Guidance will be circulated when issues regarding copyright are resolved between NHS, BSI and IEC. The draft has been prepared, but circulation is on hold until the copyright issues are resolved.

	At the IEC 62A meeting in October, three additional preliminary work items were approved. JWG7 will begin preparing NWIPs and draft TRs for these items at its spring meeting. The three preliminary work items are: The relationship of IEC 80001-1 to ISO 20000 Guidance for self-audit of healthcare organizations implementing IEC 80001-1 Guidance for integrated alarm systems This means that there are 7 work items currently at the preliminary stage in JWG7 with 3 of them currently out for ballot as new work item proposals. I expect these to proceed to approved new work items and to technical reports. It is almost certain that additional work items will be proposed as 80001-1 begins to be implemented. The next full meeting of JWG7 is expected to be in early 2011 in Europe. No date or venue has been set. The primary agenda items for JWG7 will be addressing comments received on the CDs circulated with the NWIPs for the new TRs and beginning work on the new preliminary items.