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Standards Navigator

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Standards Activity Status – November 2010

MEDICAL DEVICE STANDARDS

ISO 13485	The ISO Technical Management Board (TMB) is considering a proposal that all management systems standards such as ISO 13485, *Medical devices - Quality management systems - Requirements for regulatory purposes*, follow a specified template. This change, if adopted, could mean that future editions of ISO 13485 would need to be restructured, as well as being required to include certain "mandated requirements", some of which are beyond the regulatory requirements for medical devices. This could possibly also impact ISO 14971. ISO TC 210, which maintains ISO 13485 and ISO 14971 has objected to this proposal and has asked countries that are members of TC 215 to support their position. The objection is based on these points: • the content of voluntary standards used to verify compliance with regulations must be left up to the sector that is directly affected by the standard • The template for Management System Standards includes mandatory text for things that are not verifiable in a regulatory context such as continual improvement and motivating personnel. • ISO 13485 and 14971 are tools to assist manufacturers in the production of devices that achieve a consistent level of performance and to use risk management information to reduce any unforeseen hazards, i.e., these documents are focused on patient and operator safety (safe products). Patient and operator safety are also the focus of the national and regional medical device regulations that ISO 13485 and ISO 14971 support. Mandatory text in the template for integration into business processes and strategic direction of the organization are laudable goals. Nonetheless, neither industry nor regulators want decisions intended to strengthen a company's performance (i.e., ISO 9001) intermingled with decisions intended to ensure product safety and regulatory compliance (i.e., ISO 13485, ISO 14971). • The development of a standard such as ISO 13485 to support regulatory requirements must be based on consensus agreement between regulators, industry, and other directly affected interests in the specific document being developed. • The ISO voting process would have little meaning if some text is required to be included in the requirements and guidance sections of all MSS documents. For example, if a sector-specific MSS was voted down based on inclusion of mandated text from the template, what would ISO's response be? • The proposed template will introduce significant change in the content, format and principles of ISO 9001, which if implemented in ISO 13485 will cause significant regulatory and financial problems for device manufacturers and regulatory authorities alike. The ISO TMB will discuss the proposal at their next meeting on February 23-24, 2011.
ISO 14971	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. The European Medical Device Standards committees and the international committees responsible for ISO 14971 (ISO TC 210 and IEC TC 62) will be able to provide comments on the objection before the committee addresses it. The formal objection refers to Directive: **93/42/EEC, 90/385/EEC and 98/79/EC** 1. The standard is based upon a concept of risk management which is partly incompatible with the risk management requirements contained in the ER 1 to 6 of Directive 93/42/EEC and ER 1 to 5 of Directive 90/385/EEC and of Directive 98/79/EC. Whereas the ER require the manufacturer: - to reduce as much as possible the risks, and - to weigh the remaining risks individually and all together against the medical benefit, the standard gives the manufacturer a discretionary power to fix, in the risk management plan, the "acceptable risk". Such discretionary power is not foreseen in the ER 1 to 6 of Directive 93/42/EEC and ER 1 to 5 of Directive 90/385/EEC and of Directive 98/79/EC. 2. A risk-benefit analysis is unconditionally required by ER 6 of Directive 93/42/EEC and ER 5 of Directive 90/385/EEC and of Directive 98/79/EC. However the standard foresees the risk-benefit analysis only to take place when the risk has been judged as "unacceptable" in accordance with the discretionarily established risk-management plan.

	Moreover, the standard uses erroneously the word "may". The standard says: "If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to 6.6. For risks that are demonstrated to be outweighed by the benefits, the manufacturer shall decide which information for safety is necessary to disclose the residual risk." 3. Finally, the standard deviates from the ER 1 of Directive 93/42/EEC and of Directive 98/79/EC in as much as it does not require that all risks combined are weighed against the medical benefit, in addition to the weighing of individual risks. 4. The foreword of the harmonised standard contains a disclaimer-like reference to some of the ER that are not fulfilled according to the previous paragraphs. However, this reference is incomplete in as much as it does not refer to all the ER which are not fulfilled. Furthermore, such a disclaimer will not be noticed by all the readers. It is even questionable whether most readers take account of the disclaimer.
ISO 14971	ISO TC 210 plans to reaffirm ISO 14971 for another 5 years without change at their next meeting on April 15 in Tokyo. However, this will be an opportunity to initiate a revision of ISO 14971 if satisfactory resolution to the EC objection is not possible.
NWIP for TR on Guidance on the application of ISO 14971	ISO TC 210 has circulated a NWIP for at technical report on guidance on the application of ISO 14971. The closing date for the vote on whether to create this new TR is March 14, 2011. This Technical Report will provide guidance that addresses specific areas that experience has shown are problematic for those implementing a risk management system. This guidance would not require any change to existing implementations of ISO 14971. The proposed document would not be a general guidance on implementation of risk management. Such documents already exist from various sources. Rather the document envisioned would focus on expectations in certain critical areas such as those listed below. During the systematic review of ISO 14971, a number of areas were identified where additional guidance on the application of standard would be useful. Areas that could be addressed include: • Guidance on formulation of a risk management policy • The role of product and process standards in the risk management process • Guidance on how the feedback loop can work • Guidance on the differentiation of information for safety as a risk control measure and disclosure of residual risk • An expansion of the discussion of overall residual risk
IEC 62366	The joint working group responsible for maintaining IEC 62366 has proposed that a project be initiated to revise the standard. The national members of IEC 62A and ISO TC 210 have been asked if they support revising the standard. The closing of the vote will be February 18, 2011. The following areas have been identified as in need of updating. – More detail about how a Validation or Summative Usability Test should be conducted: - Sample size - Acceptance criteria - Reporting – More detail about Use Error Risk Analysis and how it relates to Usability Testing - Task Selection - Determining safety critical tasks - Analysis of Observed task failures in a usability test – Clarify what is expected in a the submission of human factors work for regulatory review - Points to consider and document – Add or modify informative annexes - Clarify expectations about Usability Goals and Acceptance criteria - Add example of a regulatory submission package covering human factors
IEC 60601-1	A committee draft for vote (CDV) of the 60601-1 amendment will be sent to the French national committee for translation in December. It will be circulated for vote two months later or as soon as the French translation is available. 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.
IEC NWIP for emergency environment	A new work item has been proposed for a collateral standard to IEC 60601-1 for Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment. The vote on starting this new project will close on February 11, 2011. A draft of the proposed standard is available for comment.
IEC 60601-1-8	An amendment to the Collateral Standard on alarm systems has been initiated. A committee draft is available and comments are due before February 4, 2011.
IEC 60601-2-66 Hearing instruments and hearing systems – General requirements for basic safety and essential performance	A NWIP for the preparation of a product safety standard for hearing aids in view of the foreseen publication of revised generic medical safety standards, containing also a complete first draft, doc. 29/722/NP, was approved and allocated to IEC/TC 29/WG 13. The project number originally allocated by the IEC/CO to this item was IEC 62712. Subsequently, it has, however, been decided that the document should become a part of the IEC 60601-2-x series and it has been re-numbered IEC 60601-2-66. A committee draft is available. Comments are due by March 11, 2011.
AAMI NWIP for Assurance Case Reports	AAMI has approved a new work item for Assurance case reports. This work is being done by a task group under the AAMI infusion pump device committee. An outline has been created and the first conference call for the task group has been scheduled.
AAMI NWIP for insulin pumps	A proposal for a new technical report on infusion pumps has been circulated by the AAMI infusion device committee. This technical information report will provide guidance on how to evaluate insulin infusion pumps in order to comply with the revised FDA pre-market requirements. A preliminary outline of the proposed TIR is available. Comments are requested by January 4, 2011.

SOFTWARE STANDARDS

Health Canada Software Classification Rule	Health Canada has issued a clarification and a Q&A document on the classification of software applications. If software applications meet the definition of medical device, they are classified into either Class I or Class II. The documents are available on the SoftwareCPR web site or the Health Canada web site.
AAMI NWIP for Human factors engineering design processes for medical software not considered a medical device	This process standard will provide human factors engineering based guidance on the structured design and evaluation processes of the user interface components of software platforms used in healthcare. This guidance applies to all healthcare-related software that is not part of a medical device and thus is currently not subject to federal regulation for safety and efficacy. Thus, this standard would apply to healthcare software (henceforth called healthcare information technology or HIT) that is used to create, view, and analyze patient data in clinical components of health information management systems. These software systems include but are not limited to patient records, computerized physician order entry systems, clinical imaging information systems, pharmacy management systems, medication administration systems, laboratory analysis and reporting software, clinical decision support, informed consent software, vital signs measurement and recording, and nursing documentation. Many current national and international standards (e.g., IEC/ISO 62366) have applicability and value to the design of HIT. However, many HIT manufacturers have not developed their products in a regulated environment and will not immediately see the applicability of standards that use the term “medical device” particularly when the examples provided in the standards are not readily applicable to HIT applications. We propose to create a national process standard specifically for this audience. An outline is available and comments are requested by February 15, 2011.
IEC 62304	Work began on the second edition of IEC 62304 Medical device software life cycle processes in October. The next meeting of the working group will be in March, 2011. 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	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 was discussed at a meeting in London in December. A call for participation was sent to ISO TC 215 following that meeting. The next meeting for this preliminary activity will be in February in Orlando, FL. The item is proposed to be presented at the ISO TC 215 meeting in May 2011.
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 is now available from AAMI - $50 for members, $100 for non-members. The three technical report NWIPs that were circulated on October 1 will be discussed at the next JWG7 meeting to be held in Best, NL on March 14-15, 2011. 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 continues to wait for resolution of issues regarding copyright. Three additional preliminary work items will be discussed at the next JWG7 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 The next meeting of JWG7 is March 14-15 in Best, NL. The primary agenda items for JWG7 will be addressing comments received on the CDs circulated with the NWIPs for the new TRs, reviewing the results of the NWIP on Healthcare Software Systems, and beginning work on the new preliminary items.