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Standards Navigator

Standards Navigator Monthly Report

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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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Standards Activity Status – October 2012

HEALTH SECTOR REPORTS & REGULATIONS

FDA to require safety cases for more device types **(NEW)**	FDA staff have indicated in a meeting with AdvaMed and at an AAMI course that they have concluded that the pilot use of safety cases for pre-market review of infusion pumps has been successful and will be asking for safety cases during pre-market review of other device types in the future. While the device types that will be included have not yet been determined, the criteria will likely be that they are life-critical and the device type has a history of many recalls. FDA has not indicated when they will begin asking for safety cases for additional device types. They will continue to require a safety case for infusion pumps.
EU MDD and IVDD recast	The European Union has released a draft revised Medical Device Directive and In vitro Diagnostic Directive for public consultation. These are not amendments to the existing directives, but entire new documents. The existing Implantable Medical Device Directive is incorporated into the new MDD. Changes in both the MDD and IVDD relating to software include: Extending the PEMS requirement in the old MDD to apply to standalone software that is a medical device in the new MDD. Changing the requirement for "software must be validated according to the state of the art" in the old MDD to "software shall be developed and manufactured according to the state of the art" in the new MDD. Adds a new requirement for Software in mobile computing platforms. This new requirement states that software intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise). Software is also mentioned in the requirement for Interaction of devices with their environment. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate • (b) the risk of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used; • (e) the risk associated with the possible negative interaction between software and the environment within which it operates and interacts; ***The draft directives can be found on the SoftwareCPR Standards Navigator web page.***

US Congress requires a study on how Health IT should be regulated **(NEW information)**	As part of the renewal of the medical device user fee legislation, Congress inserted language requiring a study and report on how to regulate Health IT. Specifically, they said **SEC. 618. HEALTH INFORMATION TECHNOLOGY.** (a) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, and in consultation with the National Coordinator for Health Information Technology and the Chairman of the Federal Communications Commission, shall post on the Internet Web sites of the Food and Drug Administration, the Federal Communications Commission, and the Office of the National Coordinator for Health Information Technology, a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. The FDA, ONC and FCC have started meeting regarding this study. The target date for the release of the report is January 2014. FDA staff has indicated that they expect this report to be at a very high level and to not include any specific regulatory requirements. FDA is planning to hold a public meeting to gather input for this study in January, 2013.

GAO report on FDA's handling of medical device security **(New additional information)**	The General Accounting Office does investigations for the US Congress. In this report they reviewed how FDA reviewed implanted medical devices that used wireless communications for security vulnerabilities that could cause safety concerns. They looked at two devices that researchers had shown could be controlled by use of off-the-shelf radio devices. In their findings, they criticized FDA for not reviewing security capabilities in these devices, even though they determined that FDA had the authority to do so. This will certainly result in FDA increasing their scrutiny of security for these type of devices. Since a security vulnerability in a device that is wirelessly communicating over a network seems to surely pose a risk as well, it is likely that FDA will also increase security scrutiny of all devices that use wireless communications. Dr. Kevin Fu testified to the National Institute of Standards and Technology Information Security & Privacy Advisory Board that "Conventional malware is rampant in hospitals because of medical devices using unpatched operating systems. There's little recourse for hospitals when a manufacturer refuses to allow OS updates or security patches." A report of the meeting can be found in the MIT Technology Review http://www.technologyreview.com/news/429616/computer-viruses-are-rampant-on-medical-devices-in-hospitals/ The article states that "In September, the Government Accountability Office issued a report warning that computerized medical devices could be vulnerable to hacking, posing a safety threat, and asked the FDA to address the issue. The GAO report focused mostly on the threat to two kinds of wireless implanted devices: implanted defibrillators and insulin pumps. The vulnerability of these devices has received widespread press attention (see "Personal Security" and "Keeping Pacemakers Safe from Hackers"), but no actual attacks on them have been reported. Fu, who is a leader in researching the risks described in the GAO report, said those two classes of device are "a drop in the bucket": thousands of other network-connected devices used for patient care are also vulnerable to infection. "These are life-saving devices. Patients are overwhelmingly safer with them than without them. But cracks are showing," he said. (Fu was *Technology Review's* Innovator of the Year in 2009.)" One of Dr. Fu's collaborators in research that showed an implanted defibrillator could be hacked was Dr. William Maisel who is now the Deputy Director for Science at CDRH. FDA staff has indicated that they are in the process of revising the FDA Cybersecurity Guidance. This guidance will likely include recommendations for manufacturer's security programs for devices and additional recommendations for security information to be provided during pre-market review of devices that are intended for use on a network. Another interesting bit of information in this report was the FDA response that they had hired a consultant (later determined to be McKinsey) to assess how they review software and make suggestions for improvements. This assessment is supposed to be completed by the end of 2012. ***The GAO report can be found on the SoftwareCPR Standards Navigator web page.***

The US Federal Communications Commission report on recommendation for mHealth	The FCC created an independent mHealth Task Force, to research the barriers to rapid deployment of mHealth technology and develop recommendations to government and industry to address those barriers. This report documents the task force recommendations for achieving 5 goals: Goal 1: FCC should continue to play a leadership role in advancing mobile health adoption. Goal 2: Federal agencies should increase collaboration to promote innovation, protect patient safety, and avoid regulatory duplication. Goal 3: The FCC should build on existing programs and link programs where possible in order to expand broadband access for healthcare. Goal 4: The FCC should continue efforts to increase capacity, reliability, interoperability and RF safety of mHealth technologies. Goal 5: Industry should support continued investment, innovation, and job creation in the growing mobile health sector. Recommendations include: • greater collaboration with other US Federal agencies • promoting the availability of broadband for healthcare • harmonizing spectrum allocations for healthcare internationally • industry use of standards based technologies for transmitting authenticated messages and encrypted health information ***The FCC report can be found on the SoftwareCPR Standards Navigator web page.***
US Institute of Medicine report on Best Care at Lower Cost	*Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* presents a vision of what is possible if the nation applies the resources and tools at hand by marshaling science, information technology, incentives, and care culture to transform the effectiveness and efficiency of care—to produce high-quality health care that continuously learns to be better. This report identifies the digital infrastructure (computing, internet and mobile technologies) and data utility as the foundational elements to improving care and lowering cost. It recommends that these be improved and provides strategies for progress toward that goal. These strategies do not get as specific as recommending standards based approaches, but it is hard to see how the strategies could be achieved without standards. ***The IOM report can be found on the SoftwareCPR Standards Navigator web page.***

IOM Workshop on Digital Data	Digital Data Improvement Priorities for Continuous Learning in Health and Health Care: Workshop Summary The workshop task was to identify and characterize the current deficiencies in the reliability, availability, and usability of digital health data and consider strategies, priorities, and responsibilities to address such deficiencies. Objectives of the workshop 1. Discuss the current quality status of digital health data. 2. Explore challenges, and identify key questions related to data quality in the use of EHRs, patient registries, administrative data, and public health sources for learning—continuous and episodic—and for system operational and improvement purposes. 3. Engage individuals and organizations leading the way in improving the reliability, availability, and usability of digital health data for real-time knowledge generation and health improvement in a continuously learning health system. 4. Identify and characterize the current deficiencies and consider strategies, priorities, and responsibilities to address the deficiencies. 5. Initiate the development of a strategic framework for integrated and networked stewardship of efforts to continuously increase digital data utility. ***The IOM workshop summary can be found on the SoftwareCPR Standards Navigator web page.***
IOM Discussion Paper on how user experience of Health IT products could be reported	Comparative User Experiences of Health IT Products: How User Experiences Would Be Reported and Used In its report *Health IT and Patient Safety: Building Safer Systems for Better Care*, released in November 2011, the IOM recommended that comparative user experiences be collected and made publicly available. The IOM held a workshop in which participants were asked to discuss three components of Recommendation 3 from *Health IT and Patient Safety*: (1) identify the metrics needed and who should develop and maintain the metrics; (2) develop a plan to re-port comparative user experiences; and (3) consider the feasibility of reporting and guidelines for product identification. This discussion paper provides the views of a number of the participants of that workshop on how to develop recommendations regarding how comparative user experience data could be formatted, housed, and reported. This is a discussion paper that has not been subject to the review procedures of the IOM and is not a formal report of the IOM. ***The IOM discussion paper can be found on the SoftwareCPR Standards Navigator web page.***
Institute of Medicine report – Health IT and patient safety	The Institute of Medicine produced a report on the impact of Health IT on patient safety. The report had a number of recommendations for the Secretary of HHS. ***A presentation on the recommendations and the entire report are available at the SoftwareCPR Standards Navigator web page.***
ASEAN draft medical device directive	The Association of Southeast Asian Nations (ASEAN) has released a draft medical device directive for comment. Software appears to be treated similarly to how it is treated in the current EU MDD. ***The ASEAN draft document can be found on the SoftwareCPR Standards Navigator web page.***

Chinese guidance for software	The SFDA has issued a guidance document for software in an application for medical device registration. The guidance is based largely off IEC 62304 and requires different documentation for different software safety classes as defined in IEC 62304. ***The SFDA guidance document can be found on the SoftwareCPR Standards Navigator web page.***
Japan standalone software device regulation	Japan has adopted IEC 62304 as a Japan Industry Standard (T 2304 published March 1, 2012). Legislation is expected to be introduced in 2013 to amend the PAL to include standalone software as a medical device.
CEN TC 251 newsletter	CEN TC 251 is the EU standards organization for Health Informatics. It works closely with ISO TC 215, HL7 and other standards organizations on standards related to EMRs, interoperability and other areas. This is their first newsletter and it contains information on their strategy and initiatives. ***The Newsletter can be found on the SoftwareCPR Standards Navigator web page.***
ITU Report	E-health Standards and Interoperability This is the second report from the ITU related to E-Health standards. The reports can be found at http://www.itu.int/techwatch.
UK NHS Policy document on information technology	**The power of information:** Putting all of us in control of the health and care information we need This policy document lays out a ten-year strategy for information for health and care with the intention of using modern technology to make health and care services more convenient, accessible and efficient. It recognizes the need for national information standards and interoperable systems. “Minimum ‘standards’ will be systematically adopted; a shared language to allow systems to talk to each other, phased over ten years.” ***The paper can be found on the SoftwareCPR Standards Navigator web page.***
	The EU Medical Device Experts Group has approved guidelines for the boundaries of what software products are considered medical devices in the EU. This document has just been published as a MEDDEV. ***The MEDDEV document can be found on the SoftwareCPR Standards Navigator web page.***

MEDICAL DEVICE STANDARDS & GUIDANCE

IEC 62304 edition 2 CD1 **(NEW)**	The first committee draft of the second edition of IEC 62304 *Medical device software life cycle processes* has been circulated for comments. Major changes include a revision of how software safety class is determined, new requirements for legacy software and an informative process reference model. Other changes have been made to align with ISO 14971:2007 and to clarify and improve particular requirements. A question to National Committees is whether to expand the scope of 62304 to include health software that is not a medical device. A second CD for comments is planned before a draft for vote will be circulated. Comments on CD1 due by January 11, 2013. ***The CD can be found on the SoftwareCPR Standards Navigator web page.***
IEC 82304-1 CD1 **(NEW)**	The first CD of 82304-1 *Health Software – Part 1: General Requirements for product safety* has been circulated for comment. At the IEC/TC 62 meeting in Brussels in 2009, a concern was raised that software standards for Health IT /Standalone Software may use a different risk model to ISO 14971 and that manufacturers might in the future be required to follow two different risk models and development processes for the same software. At the Brussels meeting, the IEC/TC 62 CAG tasked Chuck Sidebottom to convene a small group to investigate extending the scope of IEC 60601-1 to include standalone software. The extension to 60601-1 developed by the small group was opposed by the majority of the National Committees, but most of them agreed that standalone software should be covered by a new IEC standard. The IEC 60601-1 Amendment Project Management Team (A1PMT) asked IEC/SC 62A MT 31 (PEMS) for a recommendation on how to proceed. The MT 31 recommendation was to create a new product level standard for standalone software and reuse IEC 62304 in respect of software development processes. During the discussion in the CAG meetings, it was strongly suggested that the new standard not be constrained to software that meets the strict definition of a regulated medical device. This proposed new standard consequently addresses HEALTH SOFTWARE and includes requirements that would be sufficient for software that is a medical device, while not constraining its scope to only those software products that are regulated as medical devices. The new work was approved as a joint project between IEC SC 62A and ISO TC 215. A second CD for comments is planned before a draft for vote will be circulated. Comments on CD1 due by January 11, 2013. ***The CD can be found on the SoftwareCPR Standards Navigator web page.***

ISO DTR 24971 **(NEW)**	ISO/TR 24971 *Guidance on the application of ISO 14971* has been circulated for vote. This Technical Report provides guidance to assist in the development, implementation and maintenance of risk management for medical devices that aims to meet the requirements of ISO 14971. This Technical Report is not intended to be an overall guidance document on the implementation of ISO 14971 for organizations. It supplements the guidance contained in the informative annexes of ISO 14971 related to the following areas. – The role of international product safety standards and process standards in risk management – Guidance on formulation of a risk management policy – Guidance on how the production and post-production feedback loop can work – Guidance on the differentiation of information for safety as a risk control measure and disclosure of residual risk – Guidance on the evaluation of overall residual risk This ballot closes on January 11, 2013. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***
EN 14971:2012	A new version of EN 14971 was published and harmonized in the Official Journal of the EU. The effective date was immediate, August 30, 2012. This version only changed the annexes that relate the standard to the EU Directives, Annex ZA (Relationship between the standard and the MDD), ANNEX ZB (Relationship between the standard and the AIMDD) and ZC (Relationship between the standard and the IVDD). **The essence of this change is that conformity with the EU Essential Requirements is no longer entirely achieved by complying only with the requirements of ISO 14971. Specific content deviations between the standard and the ERs include:** **Content deviations** The following aspects have been identified where the standard deviates or might be understood as deviating from the Essential Requirements: **1. Treatment of negligible risks:** a) According to standard ISO 14971, the manufacturer may discard negligible risks. b) However, Sections 1 and 2 of Annex I to Directive 93/42/EEC require that all risks, regardless of their dimension, need to be reduced as much as possible and need to be balanced, together with all other risks, against the benefit of the device. c) Accordingly, the manufacturer must take all risks into account when assessing Sections 1 and 2 of Annex I to Directive 93/42/EEC. **2. Discretionary power of manufacturers as to the acceptability of risks:** a) ISO 14971 seems to imply that manufacturers have the freedom to decide upon the threshold for risk acceptability and that only non-acceptable risks have to be integrated into the overall risk-benefit analysis. b) However, Sections 1 and 2 of Annex I to Directive 93/42/EEC require that all risks have to be reduced as far as possible and that all risks combined, regardless of any "acceptability" assessment, need to be balanced, together with all other risks, against the benefit of the device. c) Accordingly, the manufacturer may not apply any criteria of risk acceptability prior to applying Sections 1 and 2 of Annex I to Directive 93/42/EEC. **3. Risk reduction "as far as possible" versus "as low as reasonably practicable":** a) Annex D.8 to ISO 14971, referred to in 3.4, contains the concept of reducing risks "as low as reasonably practicable" (ALARP concept). The ALARP concept contains an element of economic consideration. b) However, the first indent of Section 2 of Annex I to Directive 93/42/EEC and various particular Essential Requirements require risks to be reduced "as far as possible" without

there being room for economic considerations.
c) Accordingly, manufacturers and Notified Bodies may not apply the ALARP concept with regard to economic considerations.

4. Discretion as to whether a risk-benefit analysis needs to take place:

a) 6.5 of ISO 14971 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." Clause 7 of ISO 14971 says: "If the overall residual risk is not judged acceptable using the criteria established in the risk management plan, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the overall residual risk." Both quotes imply that an overall risk-benefit analysis does not need to take place if the overall residual risk is judged acceptable when using the criteria established in the risk management plan. Equally, D.6.1 says: "A risk/benefit analysis is not required by this International Standard for every risk."
b) According to Section 1 of Annex I to Directive 93/42/EEC, an overall risk-benefit analysis must take place in any case, regardless of the application of criteria established in the management plan of the manufacturer. Furthermore, Section 6 of Annex I to Directive 93/42/EEC requires undesirable side effects to "constitute an acceptable risk when weighed against the performance intended".
c) Accordingly, the manufacturer must undertake the risk-benefit analysis for the individual risk and the overall risk-benefit analysis (weighing all risks combined against the benefit) in all cases.

5. Discretion as to the risk control options/measures:

a) 6.2 of ISO 14971 obliges the manufacturer to "use one or more of the following risk control options in the priority order listed: (a) inherent safety by design; (b) protective measures in the medical device itself or in the manufacturing process; (c) information for safety" and leaves a discretion as to the application of these three options: shall the second or third control option still be used when the first was used? 6.4 indicates that further risk control measures do not need to be taken if, after applying one of the control options, the risk is judged acceptable according to the criteria of the risk management plan.
b) However, the second sentence of Section 2 of Annex I to Directive 93/42/EEC requests "to conform to safety principles, taking account of the generally acknowledged state of the art" and "to select the most appropriate solutions" by applying *cumulatively* what has been called "control options" or "control mechanisms" in the standard.
c) Accordingly, the manufacturer must apply all the "control options" and may not stop his endeavours if the first or the second control option has reduced the risk to an "acceptable level" (unless the additional control option(s) do(es) not improve the safety).

6. Deviation as to the first risk control option:

a) 6.2 of ISO 14971 obliges the manufacturer to "use one or more of the following risk control options in the priority order listed: (a) inherent safety by design …" without determining what is meant by this term.
b) However, the first indent of the second sentence of Section 2 of Annex I to Directive 93/42/EEC requires to "eliminate or reduce risks as far as possible (inherently safe design and construction)".
c) Accordingly, as the Directive is more precise than the standard, manufacturers must apply the former and cannot rely purely on the application of the standard.

7. Information of the users influencing the residual risk:

a) The residual risk is in 2.15 and in 6.4 of ISO 14971 defined as the risk remaining after application of the risk control measures. 6.2 of ISO 14971 regards "information for safety" to be a control option.
b) However, the last indent of Section 2 of Annex I to Directive 93/42/EEC says that users shall be informed about the residual risks. This indicates that, according to Annex I to Directive 93/42/EEC and contrary to the concept of the standard, the information given to the users does not reduce the (residual) risk any further.
c) Accordingly, manufacturers shall not attribute any additional risk reduction to the information given to the users.
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AAMI TIR45:2012 on Agile Practices published	AAMI has announced that **Technical Information Report AAMI TIR45: 2012 Guidance on the use of AGILE practices in the development of medical device software** has been published. This TIR provides recommendations for complying with IEC 62304 and FDA guidance documents when using agile practices to develop medical device software. Three FDA software experts contributed to this technical report which was led by Patty Krantz who is also convening the work on the second edition of IEC 62304. Brian Pate of SoftwareCPR was a member of the working group that developed this technical report.
IEC 62366 Amendment 1 CDV	Amendment 1 to IEC 62366: Medical devices - Application of usability engineering to medical devices Amendment 1 updates the standard to add requirements to deal with legacy devices where the USER INTERFACE design is of unknown provenance. It defines the term USER INTERFACE OF UNKNOWN PROVENANCE (UOUP) and adds a normative annex on how to evaluate a UOUP relying wherever possible on existing documentation that should have been created during the development of legacy medical devices. This is the last opportunity to provide comments on the technical requirements. The CDV closes on January 11, 2013. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
IEC 60601-1-9 Amendment 1 CDV	Amendment 1 to IEC 60601-1-9: Requirements for environmentally conscious design The first edition of IEC 60601-1-9 was published in 2007. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012 and to make a few minor editorial updates. This amendment does not add or change requirements in 60601-1-9. This is the last opportunity to provide comments on the technical requirements. The CDV closes on January 11, 2013. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***
IEC 60601-1-10 Amendment 1 CDV	Amendment 1to IEC 60601-1-10: Requirements for the development of physiologic closed-loop controllers The first edition of IEC 60601-1-10 was published in 2007. This amendment updates the references to IEC 60601-1 and other collateral 60601-1 standards to include amendments made since 2007. It also removes the normative reference to IEC 62304 since Amendment 1 of IEC 60601-1 now includes a normative reference to IEC 62304. This is the last opportunity to provide comments on the technical requirements. The CDV closes on January 11, 2013. ***The CDV can be found on the SoftwareCPR Standards Navigator web page.***

MEDICAL IT NETWORKS

ISO/IEC 90006 Draft TR	ISO/IEC 90006 - Guidelines for the application of ISO 9001:2008 to IT service management and its integration with ISO/IEC 20000-1:2011. This document establishes a comparison of the commonalities and differences between the requirements of ISO 9001 and ISO/IEC 20000-1. This should support enterprise adoption and audit of management systems developed following the requirements of ISO 9001 alone or of an integrated management system for both ISO 9001 and ISO/IEC 20000-1. Comments are due by November 10. ***The DTR can be found on the SoftwareCPR Standards Navigator web page.***
IEC/TR 80001-2-1 IEC/TR 80001-2-2 IEC/TR 80001-2-3 (New AAMI publication dates)	- IEC 80001-2-1 TR Ed.1.0 - "Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks - Practical applications and examples ". Now available from AAMI. - IEC 80001-2-2 TR Ed.1.0 - "Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls". AAMI expected publication date is November 30. - IEC 80001-2-3 TR Ed.1.0 - "Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks". Now available from AAMI. These TRs have been published by IEC and ISO. AAMI is adopting these as TIRs and will publish them in late 2012.

INTEROPERABILITY

MDICC Draft concept paper	Medical Device Interoperability Coordinating Council The FDA has been putting a lot of resources into this effort to encourage interoperability between medical devices. The group has had two face-to-face meetings and numerous teleconferences. It is planning to present its work at an FDA/AAMI Summit on Medical Device Interoperability to be held October 2-3, 2012. This work is expected to be brought under a new public/private partnership formed by the FDA and medical device industry. (See the Medical Device Innovation Consortium entry below). ***The draft concept paper can be found on the SoftwareCPR Standards Navigator web page.***
Medical Device Innovation Consortium	FDA has been working with Life Science Alley in the Twin Cities to establish a public/private partnership to jointly work on **pre-competitive areas of regulatory science**. Following a recent meeting with FDA Commissioner Hamburg, they have now agreed that a US non-profit organization will be formed to carry out this work. Medtronic has loaned an executive to help get the organization started. As a non-profit, this organization can accept tax-deductible funding from businesses as well as funding from public entities. The initial areas expected to be addressed include modeling and simulation as a replacement for human clinical studies, educational needs for the medical area and interoperability of medical devices. The work being done by MDICC (see above) is expected to be incorporated into this new organization. Informal discussion with AdvaMed indicates that medical device manufacturers are being asked to pay $200,000 each to join this consortium.
AAMI Interoperability White Paper	AAMI created an ad hoc group on Health Information Technology and Interoperability to determine whether and how it should be involved in interoperability of medical devices. Their conclusion is that AAMI should develop standards for individual clinical scenarios that define specific clinical functional requirements and non-functional requirements, such as QoS, quality of measurement (precision and accuracy), and, most importantly safety. These standards would describe the essential performance requirements for such a composite system. The first standard being developed is for a Patient Controlled Analgesic system (see below). ***The AAMI Interoperability white paper can be found on the SoftwareCPR Standards Navigator web page.***
AAMI NWIP on Integrated Clinical System: Patient Controlled Analgesia (PCA)	The first of an anticipated series of clinical scenario standards that describe the essential performance characteristics of multi-vendor composite integrated interoperable systems. This NWIP is being reviewed by AAMI standards committees prior to being submitted for approval by the AAMI Standards Board. The review period ends November 4. ***The AAMI PCA NWIP can be found on the SoftwareCPR Standards Navigator web page.***

AAMI/UL collaboration on interoperability standards	AAMI and Underwriters Laboratory have announced they will collaborate on development of a suite of standards on medical device interoperability. These standards will be designated the AAMI/UL 28000 series and aims to map existing implementation practices into a risk management framework and to address further safety issues where applicable. ***The AAMI/UL press release can be found on the SoftwareCPR Standards Navigator web page.*** ***A technical brief for the 2800 series has been prepared by UL and can be found on the SoftwareCPR Standards Navigator web page.***
AAMI/FDA Summit on Interoperability and workshop on wireless challenges in hospitals	AAMI and FDA co-sponsored a Summit meeting on Medical Device Interoperability on October 1 &2 in the Washington area. It was attended by approximately 270 people. At the end of the two-day summit, the attendees reached consensus on a list of potential actions. Among them are creating consistent device implementation standards, empowering healthcare organizations with standardized contracting language; developing a device interoperability design control process, including a decision tree; and helping hospitals make a business case to promote interoperability's benefits to C-Suite executives. Presentations made at the Interoperability Summit can be found at http://www.aami.org/interoperability/presentations Immediately following the summit was the invitation-only workshop on wireless challenges in hospitals, which was attended by almost 100 experts. It was jointly convened by AAMI, the American College of Clinical Engineering, ECRI Institute, and the American Society for Healthcare Engineering. Takeaways from the workshop include, for example, the need to better manage radio spectrum in hospitals, develop stronger "how to" tools that support the importance of the network risk management standard IEC 80001, and help the C-Suite understand the enormous patient safety risks if these issues aren't addressed as a high priority.

HEALTH IT STANDARDS AND GUIDANCE

NWIP	AAMI Technical Report - Guidance on the application of quality management principles to health software This TIR will provide recommendations for using quality management principles for health software to improve patient safety. It will also interpret requirements of FDA regulations and international standards when these are required for regulated software. This NWIP was discussed at the AAMI Software Committee meeting on June 1-2. Work will begin following approval by the AAMI Standards Board. The NWIP has been approved by the AAMI Standards Board. Work will begin this fall. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***
NWIP	AAMI Technical Report - Guidance on Health software safety and assurance This technical report will provide recommendations for how to achieve safety in health software and how to demonstrate assurance that health software is safe by organizing the evidence in an assurance case. This NWIP was discussed at the AAMI Software Committee meeting on June 1-2. Work will begin following approval by the AAMI Standards Board. The NWIP has been approved by the AAMI Standards Board. Work will begin this fall. Alan Kusinitz of SoftwareCPR will be co-leader of this technical report with Rick Chapman of FDA. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***
NWIP	AAMI Standard - Classification of defects contributing to unacceptable risk in health software In order to gather useful data on the causes of safety related software failures, there needs to be a common way of identifying and reporting the software defects that lead to the failures. Classifying and reporting defect types will provide input for developers to create evidence to demonstrate that these types of defects have been addressed in their software. This NWIP was discussed at the AAMI Software Committee meeting on June 1-2. Work will begin following approval by the AAMI Standards Board. The NWIP has been approved by the AAMI Standards Board. Work will begin this fall. ***The NWIP can be found on the SoftwareCPR Standards Navigator web page.***

GENERAL SOFTWARE STANDARDS

ISO/IEC 29119 Part 2 DIS	ISO/IEC 29119-2 Software and Systems Engineering — Software Testing — Part 2: Test Processes The purpose of this international standard is to define a generic process model for software testing that can be used by any organization when performing any form of software testing. Testing is a key approach to risk-mitigation in software development. This standard follows a risk-based approach to testing. Risk-based testing is a best-practice approach to strategizing and managing testing, as it allows testing to be prioritized and focused on the most important features and quality attributes. ***The DIS draft can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 29119 Part 5 NWIP	ISO/IEC 29119-5 Software and Systems Engineering — Software Testing — Part 5: Keyword-Driven Testing This new work item is proposed to develop a new standard on keyword-driven testing. The basic idea of keyword-driven testing is to create test specifications neither written down in natural language nor in a technical script-based language but based on a fixed vocabulary (a set of keywords). An outline for the standard is provided. This NWIP ballot closes on December 22, 2012. ***The NWIP draft can be found on the SoftwareCPR Standards Navigator web page.*** ***The NWIP draft outline can be found on the SoftwareCPR Standards Navigator web page.***