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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.

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

January 2014 Standards Navigator Overview

Medical device software

- Work on the committee draft for ballot of the amendment to IEC 62304 has been completed. The CDV will be circulated after French translation is completed (or France okays circulation without translation). Included in the amendment are changes to the determination of software safety class, and requirements for manufacturers to bring legacy software into compliance with 62304. Final approval of the amendment is expected by the end of 2014.

Health IT and mobile health regulation

- A committee draft for guidance on healthcare delivery organization self-assessment to IEC 80001-1 has been circulated for comment. ISO/TR 80001-2-7: Application of risk management for IT-networks incorporating medical devices — Application guidance — Part 2-7: Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1.

  This document provides an exemplar assessment method which includes a set of questions which can be used to assess the performance of risk management of a medical IT network incorporating a medical device. This assessment method can be used in its presented form or can be tailored to meet the needs of a specific HDO. A process reference model (PRM) and an example process assessment model (PAM) that meet the requirements of ISO/IEC 15504-2 are included in the Appendices of this document The PRM and PAM can be used as to provide a standardized basis for tailoring the exemplar assessment method where required.

  The committee draft is available on the SoftwareCPR Standards Navigator web page.

- A draft technical report on a survey of mHealth in Low to Middle Income Countries has been circulated for vote. ISO DTR 19231 Health informatics — Survey of mHealth Projects in Low to Middle Income Countries (LMIC).

  This TR surveys on-going national mHealth projects in LMIC, to which some emerging technologies such as zero configuration and proximity computing are applicable, especially when the ICT infrastructure is not well set up in those countries. The scope is constrained to mHealth use cases and technologies for Information and Communication infrastructures that are useful for LMICs. In addition, the purpose of this standard is to survey not only national mHealth projects in LMICs, but also possible mHealth frameworks that might be used.

  The committee draft is available on the SoftwareCPR Standards Navigator web page.

- A new set of guides and interactive tools to help health care providers more safely use electronic health information technology products, such as electronic health records (EHRs), are now available at www.HealthIT.gov. The Office of the National Coordinator for Health Information Technology (ONC) at HHS released the Safety Assurance Factors for EHR Resilience (SAFER) Guides. These guides are a suite of tools that include checklists and recommended practices designed to help health care providers and the organizations that support them assess and optimize the safety and safe use of EHRs. Each SAFER Guide addresses a critical area associated with the safe use of EHRs through a series of self-assessment checklists, practice worksheets, and recommended practices. Areas addressed include:

  - High Priority Practices
  - Organizational Responsibilities
  - Patient Identification
  - Computerized Physician Order Entry (CPOE) with Decision Support
  - Test Results Review and Follow-up
  - Clinician Communication

- Contingency Planning
- System Interfaces
- System Configuration

Each SAFER Guide has extensive references and is available as a downloadable PDF and as an interactive web-based tool.

- An amendment to ISO/IEC 19793: Information technology — Open distributed processing — Use of UML for ODP system specifications has been circulated for vote. This amendment incorporates notation for representing obligations and policies.

  ISO/IEC 19793 is one of a number of standards that are based on ITU recommendations for modeling Open Distributed Processing systems. The concepts are included in ISO/IEC 10746 parts 1-4. Part 3 of the Reference Model, ITU-T Rec. X.903 | ISO/IEC 10746-3 defines a framework for the specification of ODP

  systems comprising:

  a) five viewpoints, called enterprise, information, computational, engineering and technology, which provide a basis for the specification of ODP systems;

  b) a viewpoint language for each viewpoint, defining concepts and rules for specifying ODP systems from the corresponding viewpoint.

  This International Standard defines:

  – use of the viewpoints prescribed by the RM-ODP to structure UML system specifications;

  – rules for expressing RM-ODP viewpoint languages and specifications with UML and UML extensions (e.g. UML profiles).

  The draft standard incorporating the amendment is available on the SoftwareCPR Standards Navigator web page.

Usability

- A revised committee draft for vote of ISO 62366-1 has been circulated. This replaces the draft that was circulated last month. The commenting period remains the same.

  The draft standard on the SoftwareCPR Standards Navigator web page has been updated to the new revision.

Security

- NIST received comments on the Preliminary Cybersecurity Framework for improving critical infrastructure cybersecurity and is updating the framework. They have announced that the final version (Version 1.0) will be released on February 13.

  When it is released, the Final Framework will be posted here: http://www.nist.gov/cyberframework

  The draft framework is available at http://www.nist.gov/itl/upload/preliminary-cybersecurity-framework.pdf

Software Engineering

- A draft for ballot of ISO/IEC/IEEE DIS 15288:201x(E) Systems and software engineering — System life cycle processes has been circulated. This edition of 15288 will replace the 2008 version. This version was the result of a cooperative effort by ISO/IEC JTC1 and IEEE.

  Abstract: This International Standard establishes a common process framework for describing the full life cycle of man-made systems from conception through retirement. It applies to the acquisition or development of systems whether performed internally or externally to an organization. The standard also supports the definition, control, assessment and improvement of these processes. These processes can be applied concurrently, iteratively, and recursively to a system and its elements throughout the life cycle of a system. Users of the standard can apply the processes and terminology to construct a suitable life cycle model, composed of stages that use processes selected from the standard. ISO/IEC/IEEE 15288 and ISO/IEC/ 12207 are fully aligned so that one may select appropriate processes from both standards for use in systems with substantial software content.

  The DIS is available on the SoftwareCPR Standards Navigator web page.

- A draft for ballot of ISO/IEC 33063 Information technology — Process assessment — Process assessment model for software testing has been circulated. A process assessment model comprises a set of indicators of process performance and process capability. The indicators are used as a basis for collecting the objective evidence that enables an assessor to assign ratings. The ISO/IEC 33063 standard, a process assessment model for software testing, contains a set of indicators to be considered when interpreting the intent of the Process reference model. These indicators may also be used when implementing a process improvement program or to help evaluate and select an assessment model, methodology and/or tools. The process reference model defined in ISO/IEC/IEEE 29119-2 - Software and Systems Engineering — Software Testing — Part 2: Test Processes has been used as the basis for the ISO/IEC 33063 exemplar process assessment model for software testing.
- The DIS is available on the SoftwareCPR Standards Navigator web page.

Activity – January 2014

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO/TR 80001-2-7 CD	Medical IT-networks	Hospitals	*ISO/TR 80001-2-7: Application of risk management for IT-networks incorporating medical devices — Application guidance — Part 2-7: Guidance for Healthcare Delivery Organizations (HDOs) on how to self-assess their conformance with IEC 80001-1.* This document provides an exemplar assessment method which includes a set of questions which can be used to assess the performance of risk management of a medical IT network incorporating a medical device. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on March 21, 2014.***
ISO/TR 19231 DTR	mHealth		*ISO DTR 19231 Health informatics — Survey of mHealth Projects in Low to Middle Income Countries (LMIC).* This TR surveys on-going national mHealth projects in LMIC and possible mHealth frameworks that might be used. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on April 6, 2014.***

NEW STANDARDS, REPORTS & REGULATIONS

	Topic	Use / Users	Description
ISO/IEC 19793 DAM	Open Distributed Processing	Manufacturers	*ISO/IEC 19793: Information technology — Open distributed processing — Use of UML for ODP system specifications* This International Standard defines: – use of the viewpoints prescribed by the RM-ODP to structure UML system specifications; – rules for expressing RM-ODP viewpoint languages and specifications with UML and UML extensions (e.g. UML profiles). The amendment incorporates notation for representing obligations and policies. ***The draft standard including the amendment can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC/IEEE 15288 DIS	System Engineering	Manufacturers	*ISO/IEC/IEEE DIS 15288:201x(E) Systems and software engineering — System life cycle processes* This International Standard establishes a common process framework for describing the full life cycle of man-made systems from conception through retirement. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***
ISO/IEC 33063 DIS	Process	Manufacturers	*ISO/IEC 33063 Information technology — Process assessment — Process assessment model for software testing* A process assessment model comprises a set of indicators of process performance and process capability. The indicators are used as a basis for collecting the objective evidence that enables an assessor to assign ratings. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page.***

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

IEC/TR 80002-3 DTR	Medical device software	Manufacturers	*IEC/TR 80002-3: Medical device software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304)* A draft technical report containing a process reference model (PRM) for IEC 62304. The process descriptions in the PRM incorporate a statement of the purpose of the process which describes at a high level the overall objectives of performing the process, together with the set of outcomes which demonstrate the successful achievement of the process purpose. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 14, 2014.***
IEC/TR 80001-2-5 CD	Alarm systems	Manufacturers, Hospitals	*IEC/TR 80001-2-5: Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems.* Guidance on application of risk management to distributed alarm systems including causes and risk control methods that should be considered when developing, configuring, and maintaining a distributed alarm system. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 14, 2014.***
ISO 62366-1 DIS	Usability	Manufacturers	*IEC 62366-1: Medical devices – Part 1: Application of usability engineering to medical devices* A usability engineering process to provide acceptable risk related to usability of a medical device. This standard defines the requirements of the usability engineering process that a manufacturer will be required to meet. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on March 21, 2014.***

IEC/TR 60601-4-3 CD	Medical electrical equipment	Manufacturers	*IEC/TR 60601-4-3: Medical electrical equipment – Part 4-3: Guidance and interpretation – Considerations of unclear or unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements* This draft TR contains a number of issues that have been reviewed by a working group of IEC 62A and their recommendation or interpretation of how the issue can be addressed. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on March 21, 2014.***
ISO/IEC TR 30103 DTR	Quality	Manufacturers	*ISO/IEC TR 30103 Software and Systems Engineering — Lifecycle Processes — Framework for Product Quality Achievement* Guidance on the application of *ISO/IEC/IEEE 15288:2008 life cycle processes* with specific reference to addressing quality in projects that deliver systems and software products and services. ***The draft technical report can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on April 8, 2014.***
ISO/IEC 16350 DIS	Software products	Manufacturers	*ISO/IEC 16350 Systems and Software Engineering - Application Management* This standard addresses the actions, responsibilities, activities and tasks required to support use and operation of an application that is in production use. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 29, 2014.***
ISO/IEC/IEEE 26531 DIS	Software products	Manufacturers	*ISO/IEC/IEEE 26531 Systems and software engineering — Content management for product life-cycle, user, and service management documentation* This standard provides requirements for the management of the content used in product life cycle, software, and service management system documentation. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 21, 2014.***

ISO/IEC/IEEE 23026 DIS	Websites	Manufacturers	*ISO/IEC/IEEE 23026 Systems and software engineering — Engineering and management of websites for systems, software, and services information* This standard defines system engineering and management requirements for the life cycle of websites, including strategy, design, engineering, testing and validation, and management and sustainment for Intranet and Extranet environments. ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on May 25, 2014.***
IEC 82304-1 CD2	Software products	Manufacturers	*IEC 82304-1: Health Software - Part 1: General requirements for product safety.* This standard is intended to provide requirements for health software products. These are product requirements, and 82304-1 refers to 62304 for software process requirements. This standard is expected to cover the EU essential requirement for software validation when the product is only software (this essential requirement is covered by IEC 60601-1-1 for software that is a part of medical electrical equipment.) ***The draft standard can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 28, 2014.***
IEC 80001-2-x NP	Security	Manufacturers	*IEC 80001-2-x, Application of risk management for IT networks incorporating medical devices - Part 2-X: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2* This proposed technical report maps applicable requirements in six security standards to the security capabilities identified in IEC 80001-2-2. This provides guidance to medical device manufacturers as to which security standards and requirements are possibly useful in achieving the security capabilities. A supplemental document is provided to assist reviewers in assessing the appropriateness of the identified security requirements. ***The draft standard and supplemental document can be found on the SoftwareCPR Standards Navigator web page. The ballot closes on February 28, 2014.***

REFERENCES

	Topic	Use / Users	Description
IMDRF SaMD Definitions	Software	Manufacturers	Software as a Medical Device (SaMD): Key Definitions Report on international harmonization of definitions for software as a medical device. Adopted by IMDRF in November. ***The report can be found on the SoftwareCPR Standards Navigator web page.***
Euro Commission	Medical Devices	Manufacturers	Commission recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices. ***The document can be found on the SoftwareCPR Standards Navigator web page.***
FDA draft premarket cybersecurity guidance	Security	Manufacturers	Recommendations for security controls to assure medical device cybersecurity and documentation to submit in a premarket review to demonstrate effective cybersecurity management. Recommends identifying cybersecurity risks and providing a traceability matrix that links cybersecurity controls to cybersecurity risks that were identified. Also recommends documentation to demonstrate that the device will be provided to purchasers free of malware and a plan for providing updates and patches to provide up-to-date protection. This is a draft for comment. Comments should be submitted before September 13.
FDA Safety communication on cybersecurity	Security	Manufacturers and hospitals	FDA has become aware of cybersecurity vulnerabilities and incidents that could directly impact medical devices or hospital network operations. This safety communication recommends that medical device manufacturers take steps to limit opportunities for unauthorized access to medical devices and hospitals take steps to evaluate network security and protect the hospital systems. The FDA also recommends prompt reporting of events that have impacted the performance of a medical device or hospital network.

ICS-CERT Alert regarding medical devices with hard-coded passwords	Security	Manufacturers, hospitals	ICS-CERT is issuing this alert to provide early notice of a report of a hard-coded password vulnerability affecting roughly 300 medical devices across approximately 40 vendors. According to their report, the vulnerability could be exploited to potentially change critical settings and/or modify device firmware. The alert also identifies baseline mitigations for reducing risks to these and other cybersecurity attacks.
ONC Patient Safety Action & Surveillance Plan	Health IT safety	Health IT manufacturers, hospitals	The final version of the ONC plan that has the objectives to use health IT to make care safer and to continuously improve the safety of health IT.
ONC contract with the Joint Commission to investigate health IT-related safety events	Health IT safety	Hospitals, health IT manufacturers	The purpose of this contract is to ensure that there is an early detection system on health IT-related safety issues, including those associated with EHRs.
ONC guidance on annual surveillance plans by authorized certification bodies	Surveillance of certified EHRs	Authorized EHR certification bodies	Authorized Certification Bodies are expected to conduct surveillance on EHRs that they have certified. This guidance provides the priorities for topics to assess in the surveillance plan. Safety-related capabilities and security capabilities are two of the four areas for priority identified in this guidance.
NIST draft outline of a cybersecurity framework for critical	Security	Hospitals, manufacturers	NIST was directed to prepare a cybersecurity framework for critical infrastructure in Presidential Executive Order 13636. Healthcare was identified as one of the areas with critical infrastructure. This draft for comment is only an outline of the framework. NIST intends the framework to take a risk management approach at a high level, focusing on key functions of cybersecurity management which are broken down into categories and subcategories. References such as existing standards, guidelines and practices will be provided for each

infrastructure			subcategory. A draft of the framework will be released in October.
TEAM-NB position paper on use of ISO 14971:2012	Risk management	Manufacturers	Describes the steps TEAM-NB members plan to verify where relevant if requirements of EN ISO 14971:2012 have been met. This should help manufacturers update their risk management procedures and files to maintain compliance with the Essential Requirements of the directives, when building on the presumption of conformity. ***The position paper can be found on the SoftwareCPR Standards Navigator web page.***
TEAM-NB "Vision on Revision"	Regulation	Regulators, Manufacturers, Notified bodies	This document forms the input of TEAM-NB into the debate on The Revision of European Legislation on Medical Devices. Contributions came from BSI Germany, BSI UK, DEKRA Netherlands, TUV Austria, and TUV Sud. ***The report can be found on the SoftwareCPR Standards Navigator web page.***
Report	Interoperability	Medical device manufacturers, Hospitals, Regulators	AAMI/FDA Interoperability Summit report An AAMI/FDA sponsored summit meeting on medical device interoperability was held in late 2012. This report documents the discussion and identifies themes from the summit. This report can be found at http://www.aami.org/interoperability/Interoperability_Summit_publication.pdf
Report	Wireless	Hospitals, Medical device manufacturers	AAMI Wireless Workshop report A workshop with approximately 80 invited medical wireless experts was held in late 2012. This report documents the discussion and outcomes of this workshop. A follow-up meeting is planned for March 2013. This report can be found at http://www.aami.org/wireless/2012_Wireless_Workshop_publication.pdf

Presentation	Research	Medical device manufacturers	Medical Device Innovation Consortium (MDIC) Presentation from FDA and MDIC FDA and Life Science Alley have been collaborating on establishing a public-private partnership for research into regulatory science. A non-profit organization called the Medical Device Innovation Consortium has been created. This presentation by the FDA and the temporary director of the non-profit describes the need and the plans for this organization. ***This presentation can be found on the Standards Navigator web page.***
Announcement	Interoperability	Medical device manufacturers, Hospitals, Regulators	AAMI/UL collaboration on interoperability standards AAMI and UL have announced that they will collaborate on a series of standards for medical device interoperability. The press release announces the collaboration and its benefits. This announcement can be found at http://www.aami.org/news/2012/091712_press_AAMI_UL_Interoperability.pdf
Report	Security	Medical device manufacturers, Regulators	GAO report on FDA review of certain medical devices 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. In addition, the guidance is now expected to provide information on when a security issue is reportable to the FDA and when a security event will result in a recall. 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. This report can be found at http://www.gao.gov/products/GAO-12-816

Report	Mobile medical devices	Medical devices manufacturers, Hospitals, Regulators	FCC report on Mobile Medical Devices 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 ***This report can be found on the Standards Navigator web page***
Report	Health IT	Hospitals, EHR vendors, MD manufacturers	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.***

Regulation	Regulation	Medical device manufacturers, IVD manufacturers	EU draft proposed new Medical Device Regulation and In-Vitro Device Regulation These draft regulations can be found at http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf - medical devices http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_541_en.pdf - In-vitro devices

STANDARDS CURRENTLY UNDER DEVELOPMENT OR REVISION

	Topic	Use / Users	Description
IEC 62304 Amendment 1	Software Life Cycle	Medical Device manufacturers, Regulators	Amendment to the Medical Device Software Life Cycle standard. This standard is harmonized in the EU. The amendment addresses software safety classification and how to be compliant with legacy software. Current status: Comments received on the first CD are being resolved. Next step: Second CD or CDV will be circulated. Expected completion: January 2014
IEC 82304-1	Health Software	Medical device manufacturers, Regulators	New standard on Health Software: General Requirements. This standard is intended to be for standalone software products and to cover the product level requirements such as product validation, labeling, documents to be provided to the user, etc. Current status: Second CD has been circulated. Ballot closing February 28, 2014. Next step: Comments on second CD will be resolved and a CDV circulated. Expected completion: 2015

IEC 62366-1	Medical devices	Medical device manufacturers, Regulators	The standard on human factors engineering is being revised and divided into two documents. The first is a standard that includes requirements for the process. The second will be a technical report providing information about good practices for implementing the human factors process. This document is the first part. Current status: Comments have been resolved on the first CD and a second CD circulated. Next step: Comments received on the second CD. Expected completion: 2015
ISO 13485	Medical devices	Medical device manufacturers, Regulators	The Quality Management System standard is being revised to bring it into alignment with ISO 9001:2008. Current status: Comments have been received on the first CD and are being resolved. Next step: Second CD or DIS. Expected completion: 2015