SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

Standards Navigator

Standards Navigator Monthly Report

12-July-2016

SoftwareCPR Standards Navigator provides information and tools related to standards that play a significant role in health software and software intensive medical devices. In addition to information on existing standards, SoftwareCPR Standards Navigator keeps you up to date on new standards activity and gives you expert insight into future changes to existing standards.

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

Standards and regulatory activity overview

A lot of standards and regulatory activity is expected in 2016. Here are some of the areas to watch. Changes to status since the last report are in red text.

- IEC 82304-1 *Health Software: General requirements for safety* will be completed during the first half of 2016. It is intended that this standard be harmonized in the EU, but it is not clear when this may happen.

  Status: The FDIS has been submitted to IEC and will be circulated when the French translation is complete. The FDIS should be circulated by the end of July for final approval. This is a two month up or down vote so the approval should occur by October and publication late in 2016 or early 2017.

- A first committee draft of the second edition of IEC 62304 will be circulated for review in the first half of 2016. The second edition will expand the scope of the standard to health software.

  Status: The first CD has been circulated for comments.

- New standards for health software covering all parts of the life cycle will be proposed in 2016.

  Status: A proposal for a new standard, Health software and health IT systems safety, effectiveness and security – Foundational principles, concepts, and terms has been circulated to ISO and IEC for approval to begin developing the standard.

- AAMI will move its work on HIT quality management systems and HIT risk management forward. The goal is to complete these by the end of 2016.

  Status: Drafting of these standards has begun. An HIT committee has been established in AAMI. The next meeting of the committee to review a draft of the standards will be in June. The AAMI standards board approved new work on EHR Usability. This will be added to the work of the AAMI HIT committee.

- A revision of IEC 80001-1 will begin in 2016.

  Status: The proposal for extending the scope of the 80001 series and for revising 80001-1 has been submitted to ISO and IEC for approval to begin the revision. Work on the revision is expected to start in October.

- The revision to ISO 13485 will be published in the first half of 2016.

  Status: The 2016 edition of ISO 13485 has been published by ISO.

- ISO 14971 is currently under review. It is likely that a revision (amendment or new edition) will be started in 2016.

  Status: The review of 14971 has been completed with mixed results. A meeting of the working group was held in June to discuss whether a revision is necessary. The working group did not come to consensus on revising 14971. Another meeting of the working group will be held in October and a final decision will be made at the ISO TC 210 meeting in November.

- A second amendment to IEC 60601-1 will be started in the second half of 2016. This amendment is scheduled to be completed in 2019. A fourth edition of 60601-1 will be started following the completion of the amendment and will be scheduled for completion in 2024. Discussions about the structure of the fourth edition will likely begin in 2017 and decisions made before work is started on the fourth edition.

  Status: A meeting of the advisory group for the second amendment was held in February. This meeting identified the most important changes that are needed to be made in the amendment. The proposed changes will be discussed and an approved list finalized at a meeting of SC 62A in October.

- Draft texts of the EU Medical Device Regulation and the IVD regulation have been released. These still need legal editing and translation before being published in the Official Journal. Publication is expected around the end of the year.
- The first deliverables from UL/AAMI 2800 on medical device interoperability should be completed in 2016.

  Status: The committee met in June and hopes to have a draft of the first parts available for review soon.
- AAMI TIR 57 on medical device cybersecurity risk management will be published in 2016.

  Status: The TIR has been recognized by the FDA before it has even been made available for purchase by AAMI. The TIR is expected to be made available to the public this summer.
- The AAMI Device Security working group intends to begin work on guidance for postmarket cybersecurity activities and plans at its next meeting in December.
- Many documents, both standards and regulations, on security and privacy will be in process during 2016.

  NIST has announced that it will be revising SP 800-53, the most complete compilation of security controls.

  UL has begun publishing a series of standards on security, UL 2900.

  A group in Germany active in medical device standards has expressed an intention to propose an international standard for medical device security risk management.

  The new General Data Privacy Regulation has been approved in the EU.

  The second edition of *ISO 27799 Health informatics -- Information security management in health using ISO/IEC 27002* has been submitted for publication. The published standard should be available before the end of 2016.

  A new standard has been released by the Diabetes Technology Society - Standard for Wireless Diabetes Device Security (DTSec).

June 2016 Standards Navigator New Documents

Medical device software

- A draft for comment of the second edition of *IEC 62304 HEALTH SOFTWARE – SOFTWARE LIFE CYCLE PROCESSES* has been circulated.. The second edition of IEC 62304 extends the scope to health software. In addition, new general requirements have been added for:
    - determining and complying with all appropriate laws and regulations,
    - security risk management, and
    - usability engineering.

  Several box notes are included asking national committees and member bodies for comment on areas that the project team has not yet fully addressed or has not come to consensus about.

  A red-lined version of the draft (changes from the consolidated edition 1 plus amendment 1) is available on the SoftwareCPR Standards Navigator web page.

Medical Devices

- The draft consolidated texts of the new EU medical device regulation and EU IVD regulation have been published. The texts will be edited for legal issues and translation issues before they are published in the Official Journal and go into effect. Publishing is expected around the end of this year and a three year transition period is expected. Several items in the drafts will have a specific impact on software, though some are rather vague and the actual impact won't be known until a consensus interpretation is formed. Some items in the MDR with specific software impact include:
    - "It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is qualified as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being application is not a medical device. The qualification of software, either as device or accessory, is independent of its location or type of interconnection between the software and a device." (Clause 18a)
    - Software shall be considered an active device (Article 2 definition 4)
    - One of the risks that must be removed or reduced is "the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts" (Annex I Clause 11.2)
    - In the specific requirement for software the phrase including information security has been added to the list of state of the art principles that must be taken into account when developing and manufacturing the software. (Annex I Clause 14.2)
    - Software intended to be used with mobile platforms needs to consider specific features of the mobile platforms and external factors related to their use. (Annex I Clause 14.3)
    - "The manufacturer shall describe minimum requirements on hardware, IT network characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended." (Annex I Clause 14.3a)
    - Requirements for UDI placement for software and for when a new UDI-DI or UDI-PI is required if the software is modified. (Annex V Part C Clause 6.5)

- Classification rules for software as a medical device (Annex VII section III clause 5.2a.).

  "Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, is in class IIa, except if such decisions have an impact that may directly or indirectly cause:
  - the death or an irreversible deterioration of the state of health, in which case it is in class III;
  - a serious deterioration of the state of health or a surgical intervention, in which case it is in class IIb.

  Software intended to monitor physiological processes is in class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, in which case it is in class IIb.
  All other software is in class I."

The draft IVDR has similar software items except for the software classification rules.

The draft MDR and IVDR texts are available on the SoftwareCPR Standards Navigator web page.

- A committee draft for vote has been circulated for *IEC TR 60601-4-1: Medical electrical equipment – Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy*. This Technical Report is intended to help a manufacturer through the key decisions and steps required to perform a detailed risk management and usability engineering process for medical electrical equipment employing a degree of autonomy (DOA). Current medical electrical equipment standards do not fully address higher DOA modes of operation, and this Technical Report is intended to provide guidance for on how DOA could be introduced into medical electrical equipment and medical electrical systems.

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

Health IT and mobile health applications

- No new documents this month.

Medical device and Health Security

- A draft Technical Report for vote has been circulated for *IEC TR 80001-2-9: Application of risk management for IT networks incorporating medical devices – Part 2-9: Application guidance – Guidance for use of security assurance cases to demonstrate confidence in IEC TR 80001-2-2 security capabilities.* This Technical Report outlines a process for supporting confidence in the use of IEC 80001 by developing security assurance cases to complement a security risk management process. It integrates the information and guidance contained in IEC TR 80001-2-2 and IEC TR 80001-2-8 together to provide guidance to healthcare delivery organizations and medical device manufacturers for identifying, developing, interpreting, updating and maintaining security assurance cases.

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

Software Engineering and Information Technology

- A final draft for ballot (FDIS) of *ISO/IEC/IEEE 15939 Software and Systems Engineering – Measurement process* has been circulated. This International Standard defines a measurement process applicable to system and software engineering and management disciplines. The process is described through a model that defines the activities of the measurement process that are required to adequately specify what measurement information is required, how the measures and analysis results are to be applied, and how to determine if the analysis results are valid. The measurement process is flexible, tailorable, and adaptable to the needs of different users.

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

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

These draft documents were issued in a previous month and are still being reviewed. They can be found on the SoftwareCPR Standards Navigator until their review period completes.

	Topic	Use / Users	Description
IEC 80002-2 DTR	Quality management	Manufacturers	This technical report provides guidance for validation of process software used in medical device quality systems using a risk-based approach. This includes software used in the quality management system, software used in production and service provision, and software used for the monitoring and measurement of requirements, as required by subclauses 4.1.6, 7.5.6 and 7.6 of ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes.
IEC 60601-4-4 CD	Medical devices	Standards writers	This guidance is addressed to writers of medical device standards when alarm system requirements are included in the standard. It includes suggested model language for common alarm system requirements. This guidance is considered necessary because of inconsistency in the references to alarm system-related requirements in various medical device standards. The goal is to provide a consistent model language that can be used in any medical device standard that includes alarm system requirements.
health_sw_and_IT_foundations_NP	Health IT	Manufacturers, integrators, Implementers, users	A new project for a standard on Health software and health IT systems safety, effectiveness and security – Foundational principles, concepts, and terms has been proposed. The intent of this new proposal is to provide a common explanation of the principles, concepts and terms for health software and health IT systems across the entire lifecycle, from concept to disposal. The need for this standard became apparent when it was recognized that different communities in healthcare had different understandings of same or similar terms. This document will provide a unifying foundation for other standards that collectively address all lifecycle stages, the context of use, and focus areas necessary to ensure the safety, effectiveness, and both data and system security (including privacy) of health software and health IT systems. This work is intended to complement existing established standards.

STANDARDS & GUIDANCE DRAFTS STILL IN REVIEW

These draft documents were issued in a previous month and are still being reviewed. They can be found on the SoftwareCPR Standards Navigator until their review period completes.

	Topic	Use / Users	Description
ISO/IEC 20246 DIS	Software Engineering	Manufacturers	The purpose of ISO/IEC 20246 Work Product Reviews is to provide an International Standard that defines work product reviews, such as inspections, reviews and walkthroughs that can be used at any stage of the software and systems life cycle. It contains a generic process, activities, tasks, review techniques and documentation templates that are applied during the review of a work product.
ISO 33053 NP	Quality management	Manufacturers	This technical specification defines a process reference model (PRM) for the domain of quality management. The scope of the quality management domain is determined by the requirements in ISO 9001:2015. The model specifies a process architecture for this domain, and comprises a set of processes, with each described in terms of process purpose and outcomes. This is a new proposal for vote.
ISO 33073 NP	Quality management	Manufacturers	This Technical Specification defines a process capability assessment model (PAM) for quality management based on the PRM defined in ISO/IEC TS 33053. It defines an exemplar PAM that supports the performance of an assessment by providing indicators for guidance on the interpretation of the process purposes and outcomes as defined in ISO/IEC TS 33053 and provides guidance, by example, on the definition, selection and use of assessment indicators of process performance and process capability.