CEN / CENELEC Joint Task Force, Software as Medical Devices: Current Status

JIC Open Forum - Software as Medical Devices

Educational session, Melvin Reynolds

at ISO/TC215 and CEN/TC 251 JWGs meeting

Rotterdam, 10 October 2010

New Essential Requirement

- Annexes I to X to Directive 93/42/EEC shall be amended as follows:

1. Annex I [ESSENTIAL REQUIREMENTS] shall be amended as follows: …

   The following Section [12.1a] shall be inserted:

   "For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification."

CEN/CLC JTF SAMD Purpose

- Provide adequate standards to enable consistent application of 93/42/EEC, as amended by 2007/47/EC, to standalone software.
- Seek to achieve consistency with the emerging international requirements as articulated in, e.g., the Global Harmonization Task Force.
- Co-ordinate input to international standards to ensure European Regulatory Requirements are met; and, if necessary, to supplement such international standards with specific CEN/CENELEC material.

JTF SAMD – to date

- Provide candidate definitions for MDEG Guidance.
- Review emerging draft MDEG Guidance:
  - Consequences for standards development?
- Understand standards used by IT industry active in the health sector for their internal software engineering and quality standards:
  - Consequences for standards development?
- Provide input to revision of existing 'conventional' medical device oriented standards to suit 'standalone software' needs.
  - Consequences for standards development?

Candidate Definitions

- The Directives have definitions – but some terms are:
  - Undefined;
  - Inconsistently defined;
  - Badly (ambiguously) defined.
- Aim of guidance is therefore to assist understanding without conflicting with (defined)intent of Directives.
- SAMD have produced a first set of definitions for review by MDEG:
  - Currently finalising clarification of issues where the EC perceive conflict with Directives.

MDEG Guidance

- The current draft MDEG Guidance was made available to industry, regulators and CEN 251 NSBs for review and comment.
- In theory comments should have been submitted by 30th September…
  - … I saw none by that date but because the Software subgroup to B&CG meet in two weeks time – and B&CG meet at the end of November it is important that comments are submitted in the next week.
- So far the draft Guidance has been at one near-extreme and the another.
  - Consequences for standards development unclear.

Understand standards

- Because many IT organisations active in the health sector have not deemed their products to be within the scope of the MDD they are likely to be using a different, and non-harmonized, set of software engineering and quality standards.
- At present we have little idea what standards (if any) are actually used for their software engineering and quality standards.
  - What standards are in use? Survey underway in EU
  - Consequences for standards development?
  - Consequences for EC harmonization?

JTF SAMD – the future?

- The likely outcome of the development of Guidance is that some IT organisations active in the health sector will find their products are covered by the MDD.
- The health IT sector needs to remain viable while it transitions to a regulated environment.

- Next weekend, in Seattle, IEC TC62 ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE will formally be asked to decide on a proposal (62_217_INF_ME+IT) to undertake work on software in SC62A…

> *"However, TC 62 will never have all the knowledge … collaborate … actively engaging with newer partners such as ISO/TC 215, DICOM, HL7, IHE and industry consortia."*

IEC TC62 proposal

- *62_217_INF_ME+IT proposes:*

1. *TC 62 must embrace a broader view of safety that goes beyond the current scope of ISO/IEC Guide 51 and ISO 14971 to include security and privacy concerns.*
2. *TC 62 must come to grips with a work program that embraces organic growth.*
   … importance of software … is leading TC 62 into areas where speed to market is king …
   To embrace an organically grown component of its work program, TC 62 should:

IEC TC62 proposal

a) *… develop and maintain an IT strategic policy statement dealing with IT-based and IT driven medical and health technologies … must recognize that … these technologies go well beyond the medical electrical equipment/system manufacturer, often reaching deeply into healthcare delivery organizations, IT technology providers, IT-network integrators and software providers.*

b) *… However, TC 62 will never have all the knowledge necessary to meet every stakeholder need. This work will require that TC 62 continues to collaborate with old allies such as ISO/TC 121 and ISO/TC 210 while actively engaging with newer partners such as ISO/TC 215, DICOM, HL7, IHE and industry consortia.*

IEC TC62 proposal

3. *TC 62 should develop new deliverables …*
4. *TC 62 needs to critically review its existing subcommittee structure …*

- *The TC CAG should report the results of its review and its recommendations to the P-members of TC 62 within 12 months of the Seattle meeting.*
- *The goal is to implement those recommendations agreed by the P-members before the plenary session of TC 62 following Seattle.*

JTF SAMD – the future?

- CEN/CLC JTF SAMD needs (in an international context) to provide input to revision of existing 'conventional' medical device oriented standards to suit 'standalone software' needs as specified in the new Essential Requirement.
  - e.g. IEC 62304:2006 *Medical device software. Software life-cycle processes*, has just opened for revision.
- Software Engineering standards may need to be formally recognised as a means of demonstrating compliance with Essential Requirements:
  - Harmonized?
  - Normatively referenced in something new?

JTF SAMD – contact?

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