CDISC CEN/TC251 GS1
HL7 IHTSDO ISO/TC215

Joint Initiative on SDO Global
Health Informatics Standardization

Joint Initiative Open Forum Session on Software as Medical Devices

Educational session at CEN/TC251 and ISO/TC215 JWG meeting in Rotterdam

MDD Background

- Three Medical Devices Directives.
- Use the "New Approach"
  - Use of harmonized standards as a means of demonstrating compliance with Essential Requirements
- Regulate medical devices in the EU at present.
- The fundamental elements of each ensure that any medical device placed on the market can be recognised by the user, through its CE-mark, as having undergone a suitable process of assessment by appropriate authorities and is safe and effective for use with any given patient and user.

MDD Fundamentals

- Broadly speaking, each EU Medical Devices Directive (MDD) lays out the following:
  - Legal 'whereas' clauses;
  - Definition of a medical device or accessory and classification rules;
  - Articles of Law, surrounding the placing on the market of the device by the manufacturer;
  - Acknowledges the use of (harmonized) standards as a means of demonstrating compliance with Essential Requirements;
  - Essential (Safety) Requirements that each product must fulfil before CE-mark;
  - Compliance assessment Routes, defining future regulatory processes.

MDD 'Whereas:'

…

(6) 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 a medical device. Software for general purposes when used in a healthcare setting is not a medical device.

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."

Consequence

- Some software falls naturally and logically into the definition of Medical Devices Directive 93/42/EEC (MDD) as amended by 2007/47/EC and will be regulated under this directive.
- The responsibility for providing the compliance evidence rests with the manufacturer who places the product on the market under its own name.
  - An interesting scenario emerges when the clinical application of software is considered, such as the situation where one or more parties come together and create a 'System'.

EC Actions

- The European Commission's Directorate General for Enterprise has a Medical Device Expert Group (MDEG) – within which is a Borderline and Classification Group(B&CG).
  - Late EC recognition, despite consistent warnings, that the undefined 'standalone software' expression is the source of confusion.
- Under the Swedish Presidency of the EU a subgroup of B&CG was established to draft MDEG Guidance on the application of the new wording.
- MDEG 'expertise' is mostly in 'conventional' devices…