

<p style="text-align: center;">Meeting notes of Joint Initiative Working Group Open Forum: Software as Medical Device Educational Session Oct 10, 2010 Rotterdam</p>

The JWG Harmonization Open Forum met on October 10, 2010 from 4:30-6:30pm

1 Moderator: Kees Molenaar

(see presentation for detailed notes)

- Three EU medical devices directives
- Use of harmonized standards
- Regulate medical devices
- MDD (medical device directive)
- Software for general purposes when used in a healthcare setting is not a medical device
- If it is a software medical device, it must be regulated

2 Jos Kraus: software as a medical device; regulatory framework, NL

(see presentation for detailed notes)

- Example: patient record? Is the paper version a medical device, no. If patient record is electronic, then yes.

3 Martin Ellis: Chair – Intellect (It industry) clinical safety forum, UK

(see presentation for detailed notes)

- Should we manage clinical risks? Incidents are becoming better understood in the NHS
- 1/3 users (US veterans, sample 153) reported problems after the annual software was distributed; issues are non-trivial
- How are these managed? Systematic process that looks at hazards, controls, testing, etc.
- Clinical Risk mgmt system (NHS DSCN 14/2009)
- An international standard is urgently needed for safety mgmt software not considered to be a medical device

4 Neil Gardner: Provider/Industry View, CA

(see presentation for detailed notes)

- Health Canada is regulator (Aug 2009)
- Standards and best practices (product and process)
- Would like to see a tech report on how to leverage standards that exist

5 Jeremy Thorp: Provider view, UK

(see presentation for detailed notes)

6 Björn-Erik Erlandsson: Swedish provider view

(see presentation for detailed notes)

- Guidelines in 2 versions. July 12, 2010 is now open for comment from iso. p6, p7 (considered questionable/misleading). Melvin taking care of comments/notes.

7 Melvin Reynolds: EU CEN/CLC JTF, Software as Medical Device

(see presentation for detailed notes)

- The directives have definitions but some terms are undefined, inconsistent, ambiguous
- No comments submitted to date which is problematic; it affects the global vendors for anyone bringing into EU

8 Todd Cooper: IEC 80001-1 work

(see presentation for detailed notes)

- Approved in FDIS in Nov. 2010

Final Discussion/Questions:

- Ireland (Chrissie K): medical devices directive is not helpful in solving the dilemma.
Response: (Todd) Framework will help; manufacturer must disclose risk when system is put into use
- It's unclear in the ppts whether clinical vocabs are included?
Response: Melvin R; not according to UK regulator.
- Austria (Stefan S) – it is difficult for us to collect comments and know where they are coming from; too much confusion around CEN, ISO, etc., if you want comments from smaller countries, provide a decision tree diagram to help us understand. Also please make process simpler and streamline.
Response: Melvin R noted that standards makers cannot determine interpretation of regulation.
- Tight modular design and general def of software will pose problems.
- Ross F: have been aware of this for 2 years (shortage of comments) . What role should the TC be taking and how can we solve it quickly and effectively.
Response: we have tried to expand a wide enough joint debate (TC62 and TC215 and TC251). Kees M; this should be driven by member states needs.
- From patient safety perspective, you need to go ahead and ignore vendor community if they are not contributing.
- From Canadian perspective, taking a risk based approach is what we need to do. Not only manufacturers'...there is a key human factor; we need standards and education.
- Mark S: regulating ontology will be too complex. What can be regulated simply and provide guidelines instead?

- Peter G: decision support tool is most important; what thought has been given to assess risks in knowledge based systems embedded in these?
Todd; many are embedded and many manufacturers have had to be regulated. (Don) in Canada, where the physicians have done it, it is not the software that will regulate it.
- We continuously look at the tech as the source of the problem (where the real errors are human and paper); many errors are reported for software /but it is the caregivers who make more errors; so we need to look at where we will get more bang for the buck. So while we are spending the time; education should be highlighted for providers.
- England (Maureen B): we have applied a formal safety method for safety mgmt of health it. We are applying one standard for suppliers, and one for the orgs. It is an important step; we can take a standards based approach. We have been formally collecting it incidents; we have 660 incidents from health it collected over past few years. Applying safety principles for health it is very appropriate.

Don: thanks for the presentations.

- Incidents are important and we need to pay attention. Challenge is the definition; it is not the same across the world. Some software that is a medical device and some that is not (how big those circles are is the real question). But the key is some software is not a medical device– and we should pay attention to that in tc 215 to figure out that. Global market does not like to deal with the all the layers in different countries and we cannot solve that now (sympathies are with them).
- Picture is not clear to say what is the scope for software that is not a medical device.
- Data and system security is as important as patient safety.
- Work to be done for tc 215
- Slot available tomorrow 4pm – we will be dealing with this issue.