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Dnr

Reserapport DAY 1.

Report of the meeting of ISO/TC 198/WG 12, Instructions for reprocessing
31 March -1 April 2014 Standards Australia
Sydney, Australia

The meeting was convened by Vicki Hitchins (US) and had 28 attendees from 8 countries. Ralph Basile (US) served as recording secretary.

Vicki Hitchins, Convenor, Clifford Bernier, ISO Secretariat, Joe Lewelling, ISO Secretariat, Richard Bancroft, UK, Ralph Basile, US, Adrie de Bruijn, NL,Vivienne Christ, AU, Lena Cordie, US, Kevin Corrigan, US, Thomas Fengler, DE, Kate Haberfield, AU (Observer), Helmi Henn, DE, Elaine Jose, AU (Observer), Hiroaki Kanai, JP (Observer), Linda Kingsbury, CA Steven Kirckof, US, Brian Kirk, UK, Gerald McDonell, UK, Seizoh Nakata, JP, Birte Oskarsson, SE, Renee Pringle, AU (Observer), Elinor Radke, AU (Observer), Klaus Roth, DE, Astrid Smeeton, DE, Wayne Spencer, UK, Dianne Trudeau, CA, Jürgen Wegmann, DE, Robyn Williams, AU.

The Working Group reviewed the assignments that had been given out at the June 2013 Arlington meeting on ISO/WD-3 17664-3, Sterilization of medical devices – Information to be provided by the device manufacturer for processing medical devices. All of the assignments were incorporated into the document. A letter that had been submitted by Germany was reviewed and their two major comments were resolved and addressed in the document. Some additional assignments were addressed and pending questions that had been left unresolved from the previous meeting were resolved. The Canadians presented their comments and the resolutions to their comments were incorporated into the document. The Working Group agreed that the document should go forward as a CD for comment.

Germany made a suggestion to make the document in three parts: critical, semi-critical and non-critical. All the rest of us said no, will just lead to confusions. Further on Germany would like to take away the word disinfection in the scope since they think the scope has become more. We have already voted once about this so the suggestion was declined. We had a long discussion about transmission of infection through accessories, would this be included? Finally we said no, will not be possible to estimate all accessories.

Teamwork: Group 1, We need to add risk analyse, to show the analysis step by step. 11 different steps. This was built on ISO 14971:2012

Group 2, Criteria design. Canada had done some work and with small changes we were able to use the table. We also used the text from ISO TS 17665-3

New Annex, C, title: Classifications of medical device.
The Swedish suggestion about transport was taken.
We ended the day with the discussion how much must the manufacture give in information?

DAY 2
We continued were we stopped the day before. We decided to start a working group around the subject: AU, DE, SE, CA, NL and UK will take part.

Swedish complain: this WG had several different convener and different secretary. This make confusing of the document and not everything is put out on the web as it should. The complaint was noted and was agreed that there has been some problem.

A schedule for development of the CD was agreed:
8 April 2014 – Revised doc to AAMI (from Ralph Basile)
April 2014 – (CD-1) to circulated to TC 198 for comment
July 2014 – Deadline for submitting comments 2
August 2014 (or sooner) – Collated comments out to WG12 members and TC 198
22-23 Sept 2014 – Meeting in at BSI in London

The Working Group sends its regrets that Gillian Sills was not able to attend the meeting and wishes her good health.

The Working Group agreed to meet in 22-23 September 2014 at BSI in London to resolve comments on ISO/CD-1.

After the meeting Sweden made a suggestion to AU and CA; would it be helpful if we add a new annex regarding what has the user to think on before purchase instrument? We decided that SE start to work on a document and then comments from AU and CA. If we think it looks good we ask to bring it up in the group.

Birte Oskarsson