Report from ISO/WG12 Washington 20150422-24.

Delegates: Wayne Spencer (con) UK, Ralph Basile US, Andrej de Brui NL, Thomas Fengler DE, Henni Helm DE, Wicki Hitchias US, Nupur Jain US, Rodney Parker US, Klaus Roth DE, Astrid Smeeton DE, Dianne Trudeau CA, Jurgen Wegman DE, Stefen Wimme AUT, Gary Wright UK, Terry Mc AU, Massimo Fiamma DE, Birte Oskarsson SE.

Wayne welcomed us and we approved to the agenda and the report from last meeting in September 2014 in London.

FDA have finish the report: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labelling. The idea was that we should have a discussion but the paper was sent out let and not everyone had the chance to read it. Has to wait to the Berlin meeting if there will be any time left.

Discussion of the proposal from DIN. Deciding we will use the text in second part but keep the bullets in the document in clauses 6.4-6.11.

Continuation of the review of comments. This document is mainly to the manufactures but the user also needs to read it so they will understand the parameters to successfully reprocess medical devices. But we found out that we were going down into too much details, so after some discussion we all decided to delete table A:2.

As usual we struggle with validation and verification; it has to fit both ways to process. We had several interesting discussions and some difficult issues to solve but after finish all the comments we were very satisfied with the document.

Even if the content in table A:2 is correct the layout has to be better. Three of us volunteer to take care of it.

Recommendations to ISO TC 198 Chairman Secretariat of the next step for ISO 17664 will be a CDV.

Next meeting will be in Berlin Dec 2015. WG 14 will meet three days.

Wayne thanked us and closed the meeting.

Birte Oskarsson

Chairman of TK 349