ISO/TC 210 N206
ISO/TC 210/WG 1 N61
September 2002

BRIEF MINUTES OF THE MEETING OF ISO/TC 210/WG 1, APPLICATION OF QUALITY SYSTEMS TO MEDICAL DEVICES
9-12 September 2002
Berlin

The meeting was chaired by Ed Kimmelman (USA) and was attended by 41 delegates and observers from 16 countries (see attendance list, Attachment 1).

1. Opening of meeting and roll call of delegates

Mr. Kimmelman opened the meeting at 9:00 a.m. and delegates introduced themselves. Ms. Woehrle served as recording secretary.

2. Adoption of the agenda (doc. 210/WG 1 N58)

The agenda was adopted as written.

3. Brief overview of the 1-3 May 2002 meeting of ISO/TC 210/WG 1 in Ottawa, Canada (doc. 210/WG 1 N59) and overview of the 4 May 2002 meeting of the ISO/TC210/WG1 ad hoc writing group on ISO/TR14969

Mr. Kimmelman reported that the meeting(s) were spent revising the first working draft of ISO/TR 14969:200X. He noted that a second working draft would be circulated to members of ISO/TC 210 and WG 1 for comment after the meeting.

4. Review of results of voting and resolution of comments received ISO/DIS 13485 (doc. 210 N200 REV)

Mr. Kimmelman reported that there were sufficient votes on ISO/DIS 13485 to advance the document to the FDIS stage. He added that after review of the compilation of comments (doc. 210 N200 REV) members would agree on the best path forward.

Mr. Plenio noted that the German vote was still negative and that the abstention referenced in doc. 210 N204 pertained only to the German comments on documentation.

Mr. Kimmelman gave a slide presentation (see attachment 2) that categorized the comments into three categories: 1) comments directed at the objectives of ISO/DIS 13485; 2) comments intended to improve the content of ISO/DIS 13485; and 3) editorial comments.

Members appointed an ad hoc editing task group (George Clevett, Ian Campbell, and Ken Slickers) that would address the editorial comments.

Mr. Kimmelman pointed out that the primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems and the overriding objective of harmonized medical device regulatory requirements is to ensure the provision of safe and effective medical devices.

Mr. Kimmelman opened the discussions by addressing the comment regarding the inclusion of all requirements contained in ISO 9001:2000, including those that relate to "customer satisfaction" and "continual improvement". There was concern that ISO 13485:200X would require two certifications from registrars/notified bodies which would increase the cost to companies. Mr. Dorman-Smith reported that he consulted with two notified bodies who indicated that in such a situation they would issue two certificates and the second one would be at no extra cost. A vote was taken and members rejected this comment with a vote of 9 to 3.

Mr. Kimmelman noted that he would consult with the ISO/CS regarding the format of ISO 13485:200X in relation to the distinction of texts of ISO 9001:2000 and ISO 13485:200X (i.e. italicize or change the font of the text of ISO 9001). Members agreed that they did not want to utilize colored text. The convener also noted that he would inquire with ISO/TC 176 to see if they still require that the complete text of ISO 9001:2000 be included in ISO 13485:200X (Annex B).

Members spent three days reviewing and resolving the comments on ISO/DIS 13485 with the objective of publishing the resulting document as ISO/FDIS 13485.

5. Review of the Second Working Draft Revision of ISO 14969:1999

The second It was reported that the second working draft of ISO/TR 14969:200X would be issued to TC 210 and WG 1 for comment after meeting. It was agreed that the comments would be discussed at the next meeting of WG 1 and the intent was to issue a committee draft for vote after that meeting. The following timeline has been developed for ISO/TR 14969:

- WD2 issued after the 9-13 September 2002 meeting for comment (comments by 1 January 2003)
- Comments on WD2 resolved at a late February or early March 2003 meeting tentatively to be held in Phoenix
- CD issued after that meeting (ballot: X March – X June 2003)
- Resolve comments on CD at X September 2003 meeting (location TBD)
- IS published December 2003

6. Update on the work of the transition writing group and discussion of WD1 Transition Planning Guidance for ISO 13485: 200X (doc. 210/WG 1 N60)

Members reviewed the revised Transition Planning Guidance for ISO 13485: 200X (see attachment 3) circulated at the meeting. Changes were made and it was agreed that the working draft, as revised at the meeting, would be circulated to members of TC 210 and TC 210/WG 1 as

for comment (comments will be resolved at the X March 2003 meeting of WG 1 tentatively to be held in Phoenix, Arizona, USA) before being sent back to members of TC 210 for approval as an internal guidance document. It will then be discussed with representatives of the International Accreditation Forum (IAF) and the ISO Committee for Conformity Assessment (ISO/CASCO) before being circulated more widely.

7. Status of the CEN/CENELEC adoption of ISO 13485

Mr. Dorman-Smith reported that ISO/DIS 13485 was supposed to have been issued by CEN as a prEN, however this did not happen so a preliminary questionnaire (PQ) was issued. The PQ asked CEN member countries whether they would accept ISO/DIS 13485. It is anticipated that the final text of ISO 13485:200X will undergo the unique acceptance procedure (UAP) to determine whether it will be adopted by CEN.

8. Recommendations to be reported to ISO/TC 210

WG 1 confirmed that the following recommendations should be put forward to TC 210 for adoption at the plenary session on 13 September 2002:

1) request the secretariat to submit DIS 13485, as revised by WG 1 during this meeting (including editorial changes to be made "offline" by the ad hoc editing task group), for vote as a Final Draft International Standard.
2) request that the "ISO 13485:200X Transition Planning Guidance", as revised by WG 1 during this meeting, be circulated to TC 210 for acceptance as an ISO/TC 210 internal guidance document which will be made available to the intended users (medical device manufacturers, accreditation bodies, certification bodies, regulatory authorities, and international and national standards bodies) of ISO 13485:200X.

9. Any other business

There was no additional business discussed.

10. Plans for next meeting

The next meeting was tentatively scheduled for sometime in March 2003 at Medtronic in Phoenix, Arizona, USA. A communication will be circulated to members inquiring about the best possible dates.

Adjournment

The convener thanked the members for their participation and the German delegates for arranging the facilities and graciously hosting the meeting. The meeting adjourned at 12:00 p.m. on 12 September 2002.