



Date: 2002-03-15

**ISO/TC 194/WG 15 Strategic approach to biological testing
of medical devices**

**BRIEF MINUTES AND PROGRESS ACHIEVED AT THE MEETING IN BERLIN;
GERMANY; 14 MARCH 2002**

The meeting was attended by 21 delegates from 9 countries.

The meeting was chaired by Mr. Barry Page.

1. Opening

The meeting was opened by the Chairman, Mr. Barry Page, who welcomed all attendants. He introduced the new secretary for WG 15, Mrs. Ellen Wissink (NEN, The Netherlands), who has taken over the secretariat from Mrs. Jeannette van Loon, now a member of the Dutch delegation. Since this has also consequences for CEN/TC 206, which Mrs. Van Loon was unable to attend, the new chairman of CEN/TC 206, Mr. Wim de Jong, was allowed to express his gratitude for her excellent work done in CEN/TC 206 on behalf of the committee. After that Mrs. Van Loon was also thanked for her work as secretary of ISO/TC 194/WG 15 by Barry Page, on behalf of the WG.

2. Approval of the agenda

The agenda, as in N 35 was approved.

3. Brief minutes of last meeting in Hayama-Machi 26 May 2000

There were no comments to the minutes (N 32).

4. Report of Core Group meeting on Monday, 10 March 2002

Mr. Barry Page reported from the Core Group meeting which took place on Monday; the report was tabled at the meeting.

A) Guidance on the use of 10993-series

The NWI prepared by Mr. Jeremy Tinkler (Technical Specification to provide guidance on the use of the 10993-series) was approved by ISO/TC 194 in September 2001 and assigned to WG 1. In the WG 1 meeting on Wednesday it was decided that the members of the WG 15/TF would draft the TS. They should take into account the outline of the presentation by Mr. Tinkler on Risk Management, the result of the work to be circulated in WG 1. The TF, which comprised of several experts, drafted an outline, which was tabled at the WG 15 meeting for information. A more comprehensive document will be drafted next month.

B) TF 2 Format for guidance

Mr. Mel Stratmeyer reported on the basis of N 30. The NWI (Guidelines for the preparation of standards on biological evaluation) was approved by TC 194. He agreed to act as project leader; some of the experts present on Monday already volunteered to give input. After the WG 15 meeting a meeting is scheduled for the TF to start the work. It was suggested and agreed that all ISO/TC 194 convenors would be informed as the user group of this TS.

Mr. Barry Page thanked both Mr. Tinkler and Mr. Stratmeyer for moving the work forward.

C) TF 3 Topological and physiochemical characteristics of materials

Report on TF 3 was given by the TF-leader, Mr. Donald Gibbons.

- The work on Part 18 (Chemical characterization of materials) is awaiting DIS-phase;
- The work on part 19 (Topological and physiochemical characteristics of materials) will start;
- There were some investigations done on the effects of surface morphology and particulate material, which led to recommendations to several WG's.

Mr. Gibbons offered his help to endorse the relevant recommendations during the WG 14-meeting this week, which was gladly accepted.

A written report will be circulated to WG 15 members after the meeting.

D) Contacts with Global Harmonization Task Force (GHTF)

Mr. Barry Page reported that there had been contacts with GHTF on the lack of uniformity in the interpretation of the ISO 10993-series by different regulatory authorities. This was the result of a survey on the use of the series in several countries. It was proposed and agreed to first draft the TS (guidance on the use) before having a new contact with GHTF. It was suggested to conduct a new survey after the guidance document would be finished in order investigate whether the situation is improved.

Mr. Akitada Nakamura asked whether action should be taken towards GHTF on the issue of Medical device GCP in relation to the work of WG 4 (clinical investigation standard). It is decided, that it is up to WG 4 to bring this on the ISO/TC 194 Plenary.

E) Tissue engineering

Mr. Barry Page reported that a recommendation was given by the Core Group to install a new TF on the subject. The hand-outs of the presentation by Mr. Robert Geertsma (The Netherlands) were tabled at the meeting. Mr. Geertsma would be TF leader with the following task:

- to collect information (on regulatory and standardization developments);
- to report back to WG 15, and
- to recommend any actions to be taken by ISO 194 on the subject.

This was agreed by WG 15.

The following suggestions were made for activities to be taken onto account:

- International conference on the subject;
- ISO/TC 150 activities;
- CEN/TC 316 (animal tissue);
- CHeF FTG on Tissue engineering;
- UK Code of Practice;
- ASTM-standardization activities;
- Regulations, f.i. in USA, Japan

F) Biological evaluation of Polymeric Devices

Mr. Barry Page reported on the presentation given by Mr. Akitada Nakamura during the Core Group meeting, of which the hand-out and scientific back ground document were tabled during the meeting.

Mr. Akitada Nakamura pointed out, that some of the parameters were already included in Part 18.

Mr. John Lang, convenor of WG 14 , proposed to discuss the item in his WG. This probably could lead to changes in Part 18, although a significant delay would not be acceptable, since the document is scheduled for publication as DIS.

G) Question on implantable drug devices

Mr. Barry Page reported that a question was raised by ISO/TC 150/SC 6 on implantable drug devices. Due to interactions between drug and device material, the drug may change and even lead to toxic reactions. It was asked whether ISO/TC 194 could play a role in setting requirements for drug device biocompatibility.

The Core Group recognized the problem, but was of the opinion that this belongs to the responsibility of the pharmaceutical companies. Mr. Jeremy Tinkler was asked to report this back to ISO/TC 150/SC 6.

5. Other subjects

On a plenary session on Tuesday Mr. Ron Brown gave a presentation on compromised animal models, which are under development, but need more investigation. It was decided to keep WG 15 and WG 11 informed about the progress on the subject.

Mr. Wim de Jong asked whether a TF on pyrogenicity would come under WG 7 or WG 15. Based on the presentation by Mr. Hartung on Monday on the subject a discussion took place in WG 7. There it was decided that a TF should be installed to gather information and provide a state of the art report.

It was decided that the subject should be brought up by WG 7 during the ISO/TC 194 Plenary, but that WG 15 would gladly provide the coordination for such a TF, if needed (under the condition that experts are available for this TF).

6. Closure

Mr. Barry Page thanked all participants for attending and closed the meeting.