

**Report of the 4th meeting of the JCTLM Executive Committee
14 November 2005, BIPM, Sèvres, France**

List of participants:

Prof J. Thijssen (JCTLM Chairman, IFCC)
Dr R I Wielgosz (JCTLM Secretariat, BIPM)
Prof J-C. Forest (IFCC)
Dr W.E. May (JCTLM WG1 Chair)
Prof M.Muller (IFCC)
Dr H. Schimmel (JCTLM WG1 Chair)
Prof L. Siekmann (JCTLM WG 2 Chair)
Mr A. Squirrell (ILAC)
Prof L. Thienpont (JCTLM WG 2 Chair)
Prof A. Wallard (BIPM)
Dr R. Kaarls (BIPM)

Apologies received:

Dr L. Penberthy (ILAC)

Report of meeting:

1. Approval of the agenda [JCTLM-EXEC-05-19]

Dr May asked for an additional agenda point to discussion of the recognition of contributions from individuals to the work of the JCTLM, to be added to any other business. Dr Wielgosz requested that the topic of JCTLM Executive Committee and Secretariat procedures be addressed after point five of the agenda. The agenda was approved with the requested modifications.

2. Report of 3rd JCTLM Executive Committee Meeting

There were no comments related to the report of the 3rd Executive Committee meeting, which had been finalized in August 2005 and published on the JCTLM website.

2.1 Review of action points arising from the 3rd meeting

Prof Thijssen asked the members of the Committee to report on the action points listed in the report of the 3rd meeting of the Committee. The Committee discussed each of the points:

- Actions A/03-01, 06 and 08 had been completed;
- in relation to A/03-02, Drs May and Wielgosz reported that a ‘standard’ JCTLM presentation was in preparation, and that further input would be requested from the JCTLM;
- in relation to A/03-03, Dr May replied that further consideration should be given to the process of re-review of published reference materials and methods. Dr Kaarls commented that a re-review of all published entries in the JCTLM database should be performed at least once every five years. Prof Muller stated that the JCTLM should ensure that this process was an active one, and one way of ensuring this would be to

distribute a questionnaire to reference material producers asking whether their materials should continue to be listed. Prof Siekmann added that in the case of Working Group 2, a re-review of Reference Laboratory Measurement Services was foreseen every three years;

- in relation to A/03-05, Dr Schimmel and Mr Squirrell confirmed that they would forward documents related to the comparison of ISO 15194 and ISO Guide 34 to the JCTLM Secretariat before 1 January 2006. Dr Schimmel commented that ISO 15194 did not address in sufficient detail the technical requirements that should be fulfilled by international consensus materials (e.g. WHO reference materials), but ISO Guide 34 permitted traceability to the values of these materials. This was an issue that should be brought to the attention of Working Group 2 of ISO TC 212.
- In relation to A/03-07, Dr Wielgosz commented that links from the JCTLM website would be updated in January 2006.
- In relation to A/03-09, Prof Siekmann reported that a group had been in contact by email, and that a list of criteria that should be fulfilled by EQAS providers for JCTLM purposes had been drafted.

ACTIONS:

(A/04-01) Drs May and Wielgosz to complete the JCTLM presentation

(A/04-02) Dr Schimmel and Mr Squirrell to forward documents comparing ISO 15194 and ISO Guide 34 to the JCTLM Secretariat by 1 January 2006

3. JCTLM Framework and Declaration of Cooperation

3.1 JCTLM membership

Dr Wielgosz informed the Committee that twenty organizations were now members of the JCTLM, and that no further applications had been received since the last meeting of the Executive in July 2005. NMIJ, the Japanese National Metrology Institute, had contacted the JCTLM Secretariat regarding JCTLM membership, and the Secretariat was waiting for further information.

3.2 Representation, Chair and Secretariat

Prof Thijssen reminded the Committee that, as announced last year, he would be stepping down as the Chair of JCTLM and that the IFCC had been asked to propose a new Chair for the JCTLM. Prof Muller replied that the IFCC was proposing Prof J-C. Forest for this post. This proposal was accepted by the Executive Committee. Prof Muller reminded the Committee that the Executive was to be composed of nominated representatives of the three international sponsoring organizations, and that the IFCC confirmed the additional nominations of Dr Panteghini, representing the IFCC scientific division, and himself, representing the IFCC Executive Board to the JCTLM Executive. The Executive agreed that a maximum of three nominated representatives per organization would be optimal for the efficient running of its meetings and to ensure continuity.

3.3 Funding of the JCTLM Secretariat

Dr Wielgosz reported that the work of the secretariat for 2004-2005 had been supported from financial contributions from the IFCC and the BIPM. The budget for the work to be undertaken by the Secretariat for 2006 had been prepared. A substantial increase in expenditure was expected, resulting from the Secretariat's increased role in the coordination

of the JCTLM nomination and review process and the publication of a JCTLM Working Group 2 database for Reference Measurement Laboratories.

Prof Muller replied that considering the increases in expenditure, he would request all three sponsoring organizations to consider the level of financial support they could provide for the activities of the JCTLM Secretariat. Prof Forest added that if the requested financial contributions continued to increase, the Committee might have to look for alternative sources of income. Dr Kaarls added that in any case it would be necessary to prepare a budget which covered the next five years, so that the Executive might make the necessary decisions related to the financing of JCTLM activities. It was also proposed that a task force should investigate the possibilities of fund raising from the membership and other resources. The new Executive should come-up with a proposal in 2006.

ACTIONS:

(A/04-03) JCTLM Secretariat to produce five year plan on projected expenditure.

4. JCTLM WG1 – Reference Materials and Reference Measurement Procedures

4.1 Approval of Cycle II RM and RMP nominations

Dr May gave a presentation on the activities of JCTLM WG1 and a summary of the outcomes of their recent meeting that had been held at the IRMM in September 2005. Cycle II nominations had been reviewed at this meeting. Dr May was currently compiling all recommendations of the working group, and a list of materials and methods recommended for publication would be submitted to the JCTLM Secretariat for approval by the Executive and publication before 1 January 2006.

Dr May noted that the working group had also discussed the procedures they were using for the review of materials and methods. A number of suggestions had been made by the working group, notably:

- a request should be made to reference material producers to include appropriate JCTLM listed materials in their certification process, so that the extent of equivalence of materials with nominally the same measurand could be determined;
- for further consideration to be given to the format used for the listing of Reference Measurement Methods. This discussion had been precipitated by the submission of a number of closely related methods for the same measurand. The working group was concerned that this trend would continue, and this would make it necessary to group together methods that were based on the same measurement principle. This issue would become particularly evident with the development of the JCTLM database, and the JCTLM secretariat was charged with developing a proposal for the format in which information on reference methods should be published.
- a gap analysis of reference materials and methods should be performed for each analyte area.

4.2 Progress / plans for Cycle III call for RMs and RMPs

Dr May stated that the call for Cycle III nominations would be made in February 2006.

4.3 Approval of the JCTLM WG1 quality manual

Dr May commented that the updated JCTLM WG1 quality manual had been circulated to the Executive for approval. Dr Wielgosz replied that he had a small number of comments:

- point 6.4.10.3 of procedure JCTLM WG1-P-02 should be deleted, as no upload facility for nominations was available on the JCTLM website;
- point 6.5 and 6.6.1 of procedure JCTLM WG1-P-02, should be modified to extend the time period for the review of nominations for completeness by the JCTLM Secretariat to 1 month;
- the example template for CRM nominations, WG1-P02-F02, should be modified to contain a short list of entries covering a selected number of different measurands, and not the partially corrected Cycle I entries currently listed;
- point 8.2 in procedure JCTLM WG1-P-05, should refer to ‘elements’ and not ‘attributes’ to be consistent with the terminology used in the ISO standards.
- Procedure JCTLM WG1-P-06 and the associated form should be revised to clearly define the role of the Secretariat in the process and the archiving of application/nomination forms;
- the header of procedure JCTLM WG1-P-08 was numbered incorrectly.

Prof Thijssen summarised that the updated quality manual, taking into account the points listed above, was approved, and any additional comments from the Executive should be sent to Dr Jackson, team leader of the quality manual drafting group, during the next few weeks. The quality manual would be published on 1 January 2006, and be valid for a period of three years, at which point its status would be reviewed.

4.4 Review of WG1 and Review Team Membership

Dr May presented a list of members for each of the review teams active in WG1. He requested that the blood gases team be merged into the electrolytes team. This was approved. The review team leaders had asked the members of their teams whether they were prepared, and able, to continue to be active in the review teams. The list of members was being revised accordingly.

Prof Thijssen requested that two standard letters be produced by the Secretariat on behalf of the Executive: one to confirm the appointment of an individual to a review team; the second to thank individuals who were retiring from a review team for their work and contribution to the JCTLM.

Dr May stated that new members of review teams would be requested to complete nomination/application forms before their appointment to the review teams. Prof Siekmann reminded the Committee that members of the JCTLM WG1 review teams had also reviewed lists of Reference Measurement Laboratory services for WG2, and requested that the review teams become JCTLM review teams, reflecting their role in the work of both working groups. Dr May replied that this issue had been discussed at the JCTLM WG1 meeting in September, and it had been noted that not all members of review teams could commit to being active both in WG 1 and WG 2 processes.

Prof Thijssen summarised that it would be appropriate to have a single set of review teams, but that all review team members would be asked to complete the nomination application forms. These forms were to be modified to allow review team members to indicate whether they would be active in either WG1 or WG2 review processes, or both.

4.5 Progress with the JCTLM database

Dr Wielgosz informed the Committee that construction of the database was expected to start in January 2006 and be completed by April 2006, provided the issue of the format for the publication of reference measurement methods could be resolved.

ACTIONS:

- (A/04-04) Dr May to submit Cycle II JCTLM WG1 recommendations to the JCTLM Secretariat for approval by the Executive and publication by 1 January 2006.
- (A/04-05) Executive members to forward remaining comments regarding the JCTLM WG1 quality manual to Dr Jackson by 2 December 2005.
- (A/04-06) JCTLM Secretariat to produce two standard letters for JCTLM review team members
- (A/04-07) Application/ nomination form for JCTLM review team membership to be revised, allowing members to indicate which activities they will participate in
- (A/04-08) Completed application / nomination forms to be registered with the JCTLM Secretariat prior to the start of the JCTLM WG1 Cycle III call.

5. JCTLM WG 2 – Reference Measurement Laboratories

5.1 Approval of the JCTLM WG2 quality manual

Prof Siekmann presented the WG2 quality manual for approval. A number of comments were made by Committee members:

- the flow chart of measurement hierarchy in WG-2 P-00 should be modified since JCTLM does not have responsibility for Reference Measurement Laboratories, but rather lists measurement services that comply with set criteria;
- the responsibility for routine testing laboratories lies with different bodies in different countries, and therefore National Regulatory Bodies should only be given as an example of a body having responsibility for these laboratories;
- in WG2-P00 it was agreed that in the last paragraph which refers to ‘successful on-site assessment by accreditation bodies’ should be modified to read ‘successful, and in general on-site, assessment’;
- the requirement in WG2-P03-A for NMIs to participate in ‘at least annual inter-laboratory comparisons’ should remain, thus establishing a level playing field for laboratories wishing to provide reference measurement services.
- the procedure JCTLM WG-2 P-05 should be revised to include an appeals process for laboratories who wished to contest the removal of their reference measurement service from the JCTLM list.

Prof Thijssen summarized that the quality manual was approved, with the implementation of the points listed above, and any further comments which were to be sent to Prof Siekmann in the next few weeks. The quality manual would be published on 1 January 2006, and be valid for a period of three years, at which point its status would be reviewed.

Prof Siekmann asked what time frame could be envisioned for Cycle I of the WG2 process. Dr May stated that for WG1 the next cycle would start at the beginning of February with an open call for nominations, and be completed at the end of November, when recommendations for publication, would be presented to the Executive. Prof Thijssen agreed that this was a workable timetable, and it should also be adopted by WG2.

5.2 Accreditation of Laboratories participating in networks

A workshop on ‘Strategies for Credentialing Clinical Reference Procedure Laboratories in North America’ sponsored by the AACC and the NIST had been held earlier in the year. The workshop examined how laboratories functioning in well established networks could most readily demonstrate compliance with ISO 17025/15195 requirements. No proposals had yet been submitted to the JCTLM Executive by the organizers of the workshop.

5.3 Progress with quality manual/ procedures for IFCC EQAS for JCTLM WG2

Prof Siekmann reported that the procedures for the operation of IFCC EQAS had been submitted to the JCTLM Executive.

5.4 Progress of Working Party on Criteria for EQAS for Reference Laboratories

Prof Siekmann reported that he had distributed a set of six points which described the requirements for proficiency testing schemes to be acceptable for JCTLM purposes. He had received comments on these points from Dr Kimberly of CDC, and had modified the points accordingly.

Mr Squirrell commented that point two should be modified to read ‘ILAC member’ rather than ‘ILAC full member (signatory)’. Dr Wielgosz suggested that points one and six should be modified to read ‘the proficiency testing provider shall’ rather than ‘the proficiency testing provider should’.

5.5 Review of WG2 membership

Prof Siekmann presented the list of Working Group 2 members. Dr Wielgosz pointed out that the WG1 review team leaders and members that would be active in the WG2 process were not listed. Prof Siekmann agreed to modify the list appropriately.

5.6 JCTLM Executive and Secretariat Procedures

Dr Wielgosz noted that the JCTLM quality manuals referred to a number of activities which would be performed by the Executive or the Secretariat. Procedures describing these activities would be developed by the Secretariat.

ACTIONS:

- (A/04-09) Prof Siekmann to update JCTLM WG2 Members’ list
- (A/04-10) Executive members to forward remaining comments regarding the JCTLM WG2 quality manual to Prof Siekmann by 2 December 2005.
- (A/04-11) JCTLM Secretariat to develop Executive and Secretariat procedures

6. Documents submitted by JCTLM Members and Stakeholders for consideration by the Executive Committee

No documents were submitted to the Executive Committee.

7. Liaison with the EC

The JCTLM Secretariat had written to the relevant competent authorities within the EU, informing them of the activities of the JCTLM, and representatives of two competent authorities would be attending the JCTLM meeting. Representatives of DG Enterprise were unfortunately unable to attend the JCTLM meeting. Dr Schimmel informed the Unit Head at DG Enterprise responsible for the IVD directive had changed, and that the JCTLM should contact DG Enterprise again. Prof Forest replied that he together with Prof Wallard would contact DG Enterprise.

ACTIONS:

(A/04-12) Prof Forest and Prof Wallard to contact DG Enterprise

8. Liaison with the WHO

There were no issues arising.

9. Liaison with ISO TC 212**9.1 Revisions of ISO 15193 and ISO 15194**

Dr Wielgosz brought the Committee's attention to the recent circular letter sent out to members of WG2/4 of ISO TC212 regarding the revisions of ISO 15193 and 15194. The JCTLM had the possibility to comment or propose revisions to the text, and he proposed to circulate the texts for comment to the JCTLM WGs who had been using them for review purposes. A list of comments could then be submitted to the ISO working group, before its meeting on 25 January 2006.

ACTIONS:

(A/04-13) Dr Wielgosz to distribute ISO documents to JCTLM WGs, and compile comments received.

10. Publicity for the JCTLM

Prof Thijssen reminded the Executive that it was important to continue to publicize the work of the Committee.

11. Future meetings of the JCTLM

The next meeting of the JCTLM Executive would be held at the BIPM in November/December 2006.

12. Any other business

Dr May asked the Committee to consider establishing a award scheme for individuals who had made a substantial contribution to standardization in laboratory medicine. Prof Müller replied that the IFCC could consider establishing such a scheme, and would return with a proposal to the next Executive meeting.

Prof Thijssen thanked the members for their participation. He wished Prof Forest success in his new role as the Chair of JCTLM and closed the meeting. The members expressed their gratitude for Prof Thijssen's leadership from 2002 to 2005.

ACTIONS:

(A/04-14) Dr. May and Prof Müller to prepare a proposal for an IFCC award scheme for contributions to standardization and traceability in Laboratory Medicine

R.I. Wielgosz (BIPM)
22 November 2005
revised 12 January 2006

Annex 1: Summary List of Actions

- (A/04-01) Drs May and Wielgosz to complete the JCTLM presentation
- (A/04-02) Dr Schimmel and Mr Squirrell to forward documents comparing ISO 15194 and ISO Guide 34 to the JCTLM Secretariat by 1 January 2006
- (A/04-03) JCTLM Secretariat to produce five year plan on projected expenditure.
- (A/04-04) Dr May to submit Cycle II JCTLM WG1 recommendations to the JCTLM Secretariat for approval by the Executive and publication by 1 January 2006 .
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- (A/04-07) Application/ nomination form for JCTLM review team membership to be revised, allowing members to indicate which activities they will participate in
- (A/04-08) Completed application / nomination forms to be registered with the JCTLM Secretariat prior to the start of the JCTLM WG1 Cycle III call.
- (A/04-09) Prof Siekmann to update JCTLM WG2 Members list
- (A/04-10) Executive members to forward remaining comments regarding the JCTLM WG2 quality manual to Prof Siekmann by 2 December 2005.
- (A/04-11) JCTLM Secretariat to develop Executive and Secretariat procedures
- (A/04-12) Prof Forest and Prof Wallard to contact DG Enterprise
- (A/04-13) Dr Wielgosz to distribute ISO documents to JCTLM WGs, and compile comments received.
- (A/04-14) Dr May and Prof Muller to prepare a proposal for an IFCC award scheme for contributions to standardization and traceability in Laboratory Medicine