

**Report of the 3<sup>rd</sup> meeting of the JCTLM Executive Committee  
25 July 2005, Rosen Centre, Orlando USA**

**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 L. Penberthy (ILAC)  
Dr H. Schimmel (JCTLM WG1 Chair)  
Prof L. Siekmann (JCTLM WG 2 Chair)  
Mr A. Squirrell (ILAC)  
Prof L. Thienpont (JCTLM WG 2 Chair)

Observers:

Dr W. Koch (NIST)

Apologies received:

Prof A. Wallard (BIPM)  
Dr R. Kaarls (BIPM)

**Report of meeting:**

**1. Approval of the agenda [JCTLM-EXEC-05-01]**

The agenda was accepted with no changes.

**2. Report of 2<sup>nd</sup> JCTLM Executive Committee Meeting**

There were no comments related to the report of the 2<sup>nd</sup> Executive Committee meeting, which had been finalized in March 2005 and published on the JCTLM website.

**2.1 Review of action points arising from the 2<sup>nd</sup> meeting**

Dr Wielgosz brought the Committee's attention to the action points listed in the report of the 2<sup>nd</sup> meeting of the Committee. He noted that the actions points A1, A3, A6 and A10 had not been completed or needed to be discussed. The Committee discussed each of the points in turn:

- in relation to A1, Dr May confirmed that review forms were being collected for Cycle II nominations and would be forwarded to the JCTLM Secretariat;
- in relation to A3, Prof Siekmann reported that the IFCC-CTLM had discussed and approved the document outlining the procedures to be used for the IFCC EQAS scheme for Reference Measurement Laboratories. He agreed to circulate the document to the JCTLM Executive, and take on board any comments received.

- in relation to A6, Dr Wielgosz reported that the criteria for membership of Working Group 1 were being addressed in the quality manual of the working group;
- in relation to A10, Dr May and Wielgosz replied that a 'standard' JCTLM presentation would be addressed and discussed during the upcoming JCTLM WG1 meeting (September 2005).

#### **ACTIONS:**

(A/03-01) Prof Siekmann to distribute procedure document for the IFCC-EQAS to JCTLM Executive Committee members for comment;

(A/03-02) Drs May and Wielgosz to prepare a 'standard' JCTLM presentation

### **2.2 Review of action points arising from the JCTLM Executive and WG Review Team Leaders' meeting**

Dr Wielgosz brought the Committee's attention to the action points arising from the JCTLM Executive and WG Review Team Leaders' meeting, which still needed to be addressed, notably points 5, 8, 11, 12, 13, 14, 15 and 21. The Committee discussed the various points in turn, and noted:

- (point 5) that the schedule for the re-review of materials and methods published in the JCTLM database (DB) would be discussed in the JCTLM WG1's meeting in September 2005;
- (point 8) Dr Schimmel's offer to make available a document which contained a comparison of ISO 15194 and ISO Guide 34. The document was being developed by the IRMM's quality manager, and would be submitted to both ISO TC212 and the JCTLM. (Mr Squirrell stated that the ILAC were also preparing a number of documents comparing written standards, and that this might eventually lead to a revision of ISO Guide 43. He would keep the Committee informed on any plans for the revision of this guide).
- (point 11) that in the case of procedurally defined measurands, if an internationally agreed reference measurement procedure existed only this would be published in the JCTLM DB. When no internationally agreed upon reference measurement procedures existed, one or more national reference measurement procedures could be published within the JCTLM DB, until international agreement was reached.
- (point 12) that a clear statement would be made on the JCTLM website that the JCTLM is making no recommendation on the applicability of the listed reference measurement procedures in the fields of forensics or sports drug testing.
- (point 13) that Prof Forest would provide the Executive Committee and WG1 with a statement on the IFCC policy for endorsing reference methods relying on substrates which are patented;
- (point 14) in the case where two or more List II materials are nominated for publication, for nominally the same analyte, but whose values are traceable to different Conventional International Standards, the database entry should indicate to which standard the value of the material is traceable, and a note must be added stating the difference between the materials.
- (point 15) that the statement of intended use of the material should be contained in its certificate, but would not be provided as information within the database.
- (point 21) that a new website had been established for the IFCC EQAS ring trial results, and a link will be established to the BIPM and IFCC webpages.

#### **ACTIONS:**

(A/03-03) JCTLM WG1 to recommend schedule for the re-review of materials and methods published in the JCTLM DB

(A/03-04) Dr Schimmel to provide the JCTLM Executive with the report comparing ISO 15194 and ISO Guide 34

(A/03-05) JCTLM Secretariat to add statements to website

(A/03-06) Prof Forest to provide the Executive Committee and WG1 with a statement on the IFCC policy for endorsing reference methods relying on substrates which are patented

(A/03-07) JCTLM Secretariat to add links to IFCC-EQAS website

### **3. JCTLM Framework and Declaration of Cooperation**

#### **3.1 JCTLM membership**

The Committee discussed how ‘national’ should be interpreted for a non-governmental organization as this was one of the criteria stipulated for JCTLM membership. The Chair reminded that Committee that the purpose of participation of organizations within the JCTLM was to provide the Committee with the expert knowledge and advice needed to carry out its work. The consensus of the Executive Committee was that an organization with expert knowledge of relevance to the JCTLM, that operated schemes at the national level, on effectively a non-profit basis, would be eligible for membership of the JCTLM.

JCTLM member status was approved for four institutes:

- National Association of Testing Authorities, Australia
- National Research Centre for Certified Reference Materials, China
- RCPA Quality Assurance Programs Pty Ltd, Australia
- Institute for Standardisation and Documentation in the Medical Laboratory (INSTAND) e.V., Germany

Dr Wielgosz brought the Committees attention to document JCTLM-EXEC/05-03, which summarized the structure and operation of the JCTLM. The document had been drawn up in response to requests for clarification on matters such as attendance at meetings. The Executive Committee requested that the document be modified to allow observers invited by the JCTLM Chair, to attend the JCTLM Executive or JCTLM meeting; and that observers could attend the JCTLM Working Group meetings if invited to do so by the Working Group Chairs. In addition, the Executive Committee suggested that whereas the JCTLM meeting would be held annually at the BIPM, there would be considerable benefits in organizing JCTLM Stakeholder meetings in other parts of the world linked to meetings of relevance to laboratory medicine.

The Committee also suggested that the Chairmanship and Membership of the Working Groups should be reviewed on a two year time frame. The procedure documents will be modified to include this process.

#### **3.2 Legal issues**

No legal issues were raised.

#### **3.3 Policy on the funding of meetings**

The Committee agreed that, in line with the JCTLM’s policy of meeting costs where they arose, the cost of organizing a meeting would be met by the organization that hosted the meeting.

#### **4. JCTLM WG1 – Reference Materials and Reference Measurement Procedures**

##### **4.1 Issues arising / review of Cycle I published RMs and RMPs**

Dr Schimmel noted that ISO 15193 had been written for the evaluation of Reference Measurement Procedures rather than for Reference Measurement Methods, but it was the latter which were being submitted to the JCTLM WG1 for review. Dr May replied that the WG1 review teams were aware of this, and that the matter would be discussed fully at the next WG1 meeting.

##### **4.2 Cycle II RMs and RMPs recommended for publication**

The Cycle II review process will be completed in September, so that the Executive Committee may authorize the recommended publications in its November 2005 meeting.

##### **4.3 Progress / plans for Cycle III call for RMs and RMPs**

The open call for Cycle III nominations had not yet been made. Dr May commented that an annual process had been envisaged, but that it might now be sufficient to make a call for new nominations once every two years. This issue would be discussed in the September JCTLM WG1 meeting.

##### **4.4 Review of WG1 and Review Team Membership**

The WG1 membership was not reviewed, but will be addressed in the next WG1 meeting (September 2005).

Dr May asked whether the JCTLM would consider developing an award scheme for an individual or individuals that had made outstanding contributions to the work of the Committee. Prof Thijssen suggested that possible processes for establishing such a scheme should be discussed at the next Executive Committee meeting.

##### **4.5 Progress with the JCTLM WG1 quality manual**

A revised version of the JCTLM WG1 quality manual had been distributed for comment to the Executive. A number of Committee members had comments on the document. These would be forwarded to the WG1 team leader who had compiled the manual.

Dr May stated that the manual now provided a comprehensive description of the process being used to review materials and methods. The document would be discussed by JCTLM WG1 in September, and a final version would be presented to the Executive for approval in November.

Prof Muller acknowledged the importance of the document, but expressed his concern that the document was becoming rather lengthy. He stressed that the document should be comprehensive but not become too unwieldy, and that major revisions of the document should not be expected for a number of years once it had been approved and published.

##### **4.5.1 Review of preamble to the JCTLM published lists of RMs and RMPs**

The currently approved preamble will remain unchanged.

##### **4.6 Progress with the JCTLM database**

Dr Wielgosz informed the Committee that technical specifications for a web searchable JCTLM database had been completed in May 2005, and that a number of internet

development companies had provided bids for this work. Construction of the database is expected to start in December 2005 and be completed by April 2006.

## **5. JCTLM WG 2 – Reference Measurement Laboratories**

### **5.1 Progress with the JCTLM WG2 quality manual**

Prof Siekmann presented the WG2 quality manual. A number of Committee members requested additional time to comment on the document. Prof Thijssen stated that he would like to see the document at a stage where it could be approved by the Executive Committee during its next meeting (November 2005). He therefore asked that any additional comments related to the document be sent to Prof Siekmann during the next six weeks (by 29 August).

#### **ACTIONS:**

(A/03-08) Executive Committee members to provide comments on WG2 Quality Manual to Prof Siekmann by 29 August

### **5.2 ILAC ARC comments on ISO 15195 accreditation**

Prof Thijssen brought the Committee's attention to the ILAC document which concluded that Reference Measurement Laboratories should seek accreditation to a combination of ISO 17025 and ISO 15195. Prof Siekmann pointed out that this outcome was caused by the omission of ISO 17025 in the normative reference section of ISO 15195, and that this was an issue that needed to be addressed by ISO. Furthermore, the revision of ISO 15195 might be expected to start as soon as 2006.

### **5.3 Robust documented peer review of Networks of Laboratories**

Dr May commented that a workshop on 'Strategies for Credentialing Clinical Reference Procedure Laboratories in North America' sponsored by the AACC and the NIST was being held later in the week. The workshop would examine how laboratories functioning in well established networks could most readily demonstrate compliance with ISO 17025/15195 requirements.

### **5.4 Progress with quality manual/procedures for (IFCC) EQAS for JCTLM WG2**

Prof Siekmann reported that the IFCC-CTLM had discussed and approved the document outlining the procedures to be used for the IFCC EQAS scheme for Reference Measurement Laboratories. He agreed to circulate the document to the JCTLM Executive, and take on board any comments received.

### **5.5 Proposal for CDC coordinated JCTLM WG2 ring trials for lipids and lipoproteins**

Prof Thijssen drew the Committee's attention to the letter which had been sent by CDC to the JCTLM. The CDC had offered to extend its lipid and lipoprotein external blind survey scheme to any laboratory listed by JCTLM WG2 using a cholesterol reference method. These surveys would be offered free of charge on an annual or biannual basis, and would later be extended to triglyceride (TG), HDL-cholesterol (HDL-C) and LDL-cholesterol (LDL-C).

Dr Wielgosz pointed out that the JCTLM declaration of cooperation document foresaw laboratories participating in relevant international comparisons, for example in the CIPM key comparisons or IFCC EQAS, but that no document yet existed giving general guidelines for the criteria to be met for interlaboratory comparisons to be acceptable for JCTLM purposes. He asked whether the IFCC EQAS procedures document could be extended to become such a document?

Dr Penberthy commented that he had expected that one interlaboratory scheme would become designated as the 'JCTLM scheme', since the number of laboratories participating in such schemes was expected to be small, and this would more readily allow the comparability of laboratory results to be established.

Dr May replied that this would probably not be possible as two schemes already existed (Key comparisons and IFCC EQAS). What was important was to ensure that all relevant schemes were linked and organised under similar general principles.

Prof Muller suggested that an appropriate way to proceed was to establish a working party, including CDC and IFCC representatives, within JCTLM WG 2, to draw up a set of guidelines for interlaboratory comparisons for JCTLM listed reference measurement service providers. There was general agreement for this proposal.

#### **ACTIONS:**

(A/03-9) JCTLM WG2 to establish a working party to develop guidelines on interlaboratory comparisons relevant to the JCTLM

#### **5.6 Review of WG 2 membership**

The membership of WG2 was not reviewed.

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

Prof Thijssen reminded the Committee that in addition to the letter from the CDC, the Executive had received letters from Dr Libeer, from the Belgian Competent Authority for IVDs, and EDMA addressing the implementation of metrological traceability for IVDs. He reminded the Executive that the JCTLM had no regulatory role in this process, and only provided technical recommendations for those wishing to implement metrological traceability for IVDs.

A letter had also been received from Equalis, suggesting that a future JCTLM workshop could tackle the area of coagulation analysis. The next workshop would be planned in 2006.

#### **7. Liaison with the EC**

The Committee agreed that the JCTLM Secretariat should write to the relevant competent authorities within the EU, informing them of the activities of the JCTLM.

#### **8. Liaison with the WHO**

There were no issues arising.

#### **9. Liaison with ISO TC 212**

The BIPM had recently obtained liaison status with ISO TC 212.

#### **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 following meetings were confirmed:

- JCTLM WG 2: 27 July, Rosen Centre Orlando
- JCTLM WG1 meeting: 19-20 September, IRMM
- JCTLM Members and Executive Committee meeting, 14-15 November, BIPM

## **12. Any other business**

There was no other business. Prof Thijssen thanked the members for their participation and closed the meeting.

R.I. Wielgosz (BIPM)  
11 August 2005

## **Annex 1: Summary List of Actions**

- (A/03-01) Prof Siekmann to distribute procedure document for the IFCC-EQAS to JCTLM Executive Committee members for comment;
- (A/03-02) Drs May and Wielgosz to prepare a 'standard' JCTLM presentation
- (A/03-03) JCTLM WG1 to recommend schedule for the re-review of materials and methods published in the JCTLM DB
- (A/03-04) Dr Schimmel to provide the JCTLM Executive with the report comparing ISO 15194 and ISO Guide 34
- (A/03-05) JCTLM Secretariat to add statements to website
- (A/03-06) Prof Forest to provide the Executive Committee and WG1 with a statement on the IFCC policy for endorsing reference methods relying on substrates which are patented
- (A/03-07) JCTLM Secretariat to add links to IFCC-EQAS website
- (A/03-08) Executive Committee members to provide comments on WG2 Quality Manual to Prof Siekmann by 29 August 2005
- (A/03-09) JCTLM WG2 to establish a working party to develop guidelines on interlaboratory comparisons relevant to the JCTLM