Report of the 8th meeting of the JCTLM Executive Committee 3-4 December 2009, BIPM, Sèvres, France

List of participants:
Prof J-C. Forest (JCTLM Chairman, IFCC)
Dr R I Wielgosz (JCTLM Secretariat, BIPM)
Dr G. Jones (ILAC)
Prof M. Müller (IFCC)
Prof M. Panteghini (IFCC)
Prof L. Siekmann (JCTLM WG 2 Chair)
Mr A. Squirrell (ILAC)
Prof L. Thienpont (JCTLM WG 2 Chair)
Prof A. Wallard (BIPM)
Dr S. Maniguet (BIPM)
Dr H. Schimmel (JCTLM WG1 Chair)
Dr R. Kaarls (BIPM)
Prof M. Kühne (BIPM)

Apologies received:
Dr W.E. May (JCTLM WG1 Chair)

Report of Day 1 meeting:
Prof J-C. Forest opened the meeting, and welcomed Prof Michael Kühne, Deputy Director of the BIPM, to the meeting.
Dr R. Wielgosz informed the Committee that the EDMA and DG Enterprise would not attend tommorrow's meeting on future activities of the JCTLM.

1. Approval of the agenda [JCTLM-EXEC/09-01]

Prof L. Thienpont asked for an additional agenda point to be added related to a proposal of a new activity for the JCTLM. Prof J-C. Forest agreed that this should be dealt with under the agenda point 1.2 during tomorrow's meeting.

2. Report of 7th JCTLM Executive Committee Meeting

There were no comments related to the report of the 7th Executive Committee meeting, which had been finalized in April 2009 and published on the JCTLM website.

2.1 Review of action points arising from the 7th meeting [JCTLM-EXEC/09-03]

Dr Wielgosz summarized the action items that were still outstanding:
(A/07-01): JCTLM Secretariat to write to Prog BA.
(A/07-02): JCTLM Secretariat to write to all JCTLM Member Organizations regarding privileges and obligations of Members.
These two actions had not been completed and were pending the drafting of a new paragraph on Membership obligations in the Declaration of Cooperation.
(A/07-03): JCTLM Secretariat to draft additional text on Membership obligations for approval by the Executive.
This action will be taken up by the Secretariat after the discussion on obligations for members of the JCTLM scheduled at tomorrow's meeting.

Action (A/07-11): JCTLM Secretariat to send response to Dr Weykamp
This action was not completed. The laboratory network has been an ongoing issue which requires further clarification before drafting the letter.

3. JCTLM Framework and Declaration of Cooperation

3.1 JCTLM President and Secretariat [JCTLM-EXEC/09-02, 09]

Dr Wielgosz informed the Committee that the procedure for the selection of the JCTLM Chairman and Secretariat was followed. The Secretariat contacted the sponsoring organizations, the IFCC, the ILAC and the BIPM for nominations. The nomination of Prof M. Müller from the IFCC was received for JCTLM President, and no nominations for the Secretariat were received.
The JCTLM Executive approved the Chairmanship of Prof M. Müller, and the BIPM's continued role as Secretariat for the JCTLM.

Actions:
Action (A/09-01): JCTLM Secretariat to contact the sponsoring organizations and inform them of the appointment of the new Chairman, and update the JCTLM website.

3.2 Representation on the Executive

Prof Panteghini commented on the need to have a new IFCC representative since Prof M. Müller was taking over as Chairman in January 2010. He informed the Committee that the IFCC Board anticipated the need for a second IFCC representative in the JCTLM Executive Committee, while nominating Prof Müller as JCTLM Chairman, and had decided to nominate Dr G. Beastall (the IFCC President) as a new IFCC representative for the next three years. The Executive Committee welcomed the nomination of Dr Beastall.
Dr Wielgosz referred to the JCTLM Declaration of Cooperation in which the total number of representatives for each sponsoring organization was not explicitly stated, as it was the Sponsoring Organizations' role to nominate its representatives on the Committee.

Prof Panteghini further asked whether the composition of the Executive Committee could be made available on the JCTLM website. Dr Wielgosz replied this could be done.

Actions:
Action (A/09-02): JCTLM Secretariat to publish the composition of the JCTLM Executive Committee onto the JCTLM website.

3.3 JCTLM membership [JCTLM-EXEC/09-11]

Dr Wielgosz informed the Committee that one organization had applied for membership of the JCTLM, the Interdepartmental Centre for Metrological Traceability in Laboratory Medicine – CIRME.
Dr Wielgosz reminded the Committee that at last year's meeting it had been agreed to accept a local organization as a JCTLM Member. Therefore he had no comments regarding this application and which would be acceptable based on previous decisions.
Dr Jones asked what is the status of the CIRME? Prof Panteghini (Director of CIRME) replied that it represented two laboratories and was also part of the University of Milan.

The Chairman commented that according the Declaration of Cooperation this type of organization was not originally foreseen as a member organization of the JCTLM, but recent

decisions of the Executive had allowed a wider range of organizations to be Members of the JCTLM, and that a review of the Declaration of Cooperation was required.

The consensus of the Committee was to postpone the Executive's decision on this issue until after the discussion on the privileges and obligations of the members of JCTLM at the tomorrow's meeting, to be dealt with under agenda item 1.4.

3.4 JCTLM Working Groups
3.4.1 Review of JCTLM Review Teams and RT Members [JCTLM-EXEC/09-7, 10, 13, 23]
Dr Wielgosz presented the documents JCTLM/09-07, and 10 which summarized the review team membership by working group and analyte type on 23 October 2009, and included new applications for membership of review teams. The JCTLM Executive Committee approved the following membership applications:
-Dr Barbara Jones from the USP for the Drugs Review Team (WG1 and WG2);
-Dr Shigeru Ueda from ASAKEI KASEI Pharma for the Enzymes Review Team (WG1).

The Committee made a number of comments:
- Dr G. Jones expressed his concerns over the limited number of members in the Review Team for Drugs, and wondered whether this is enough for the review team to be active. Dr Schimmel replied that 3 to 4 members would be the minimum required for a review team to be active. Dr G. Jones stated that he will contact NMIA for further experts for the Drugs Review Team.
- Prof. Müller added that the JCTLM review Team for Drugs should have links to the field of immunosuppressive drugs where there was a need for reference methods. He stated that he will contact Dr Seeger to see if he is willing to participate in the Review team for Drugs. Dr. Seeger (Medical University of Innsbruck, Austria) had been contacted and agreed. His application papers will be sent in due time.

Dr Wielgosz introduced the document JCTLM-EXEC/09-13 which summarized the scope of activity for each review team which had currently been provided by review team leaders for ten of the fourteen review teams. He added that the development of scope of activity statements was agreed during the last JCTLM WGs' meeting in July. This document would be completed with the addition of the four remaining review teams' scope of activity statements and circulated for approval to the members of the Executive and posted on the JCTLM website.

Prof Schumann had written to the Committee informing them of his resignation from the Electrolytes Review team (JCTLM-EXEC/09-23). The Committee thanked him for his work in support of the JCTLM. Dr H. Schimmel stated that the IRMM could provide a new candidate to take over the role of Review Team Leader for the Electrolytes and Blood Gases. He proposed Dr Brigitte Toussaint for this post and the Committee agreed on this proposal. Prof Schumann's letter stressed the importance of the role of the National Accreditation Bodies for the work of the review teams. Further discussion on this issue was delayed as it would be dealt with under agenda point 5.

Actions
Action (A/09-03): The JCTLM Secretariat to contact new review team members and inform them of their approved applications.

Action (A/09-04): Dr G. Jones to contact the NMIA for further experts for the Drugs Review Team.
Action (A/09-05): Prof. Müller to contact Dr Seeger to see if he is willing to participate in the Review Team for Drugs.
Action (A/09-06): JCTLM Secretariat to circulate the document on the review teams' scope of activity by the 31st of January 2009 for review and approval by the Executive.

3.5 Funding of the JCTLM Secretariat
Dr Wielgosz reported that the work of the JCTLM Secretariat for 2009 had been supported by financial contributions from the IFCC and the BIPM. The operating costs of the JCTLM Secretariat included the maintenance of JCTLM Database, the development for the redesign and update the JCTLM database due to changes in nomination forms necessitated by the revision of ISO 15194, and the coordination of the nominations from submission to posting. The financial support required for the JCTLM Secretariat activities for 2010 would be similar to that for 2009, and the JCTLM Secretariat would produce a budget request for the five year period following this for the next Executive Committee Meeting.

Prof Panteghini requested that the BIPM prepare a short statement of JCTLM Secretariat activities which he could present to the IFCC Executive Board.

Actions:
Action(A/09-07): JCTLM Secretariat to provide IFCC with BIPM statement on the JCTLM Secretariat activities.

3.6 JCTLM Database
Dr Maniguet gave an update on the JCTLM Database which currently lists 208 Certified Reference Materials (CRMs), 146 Reference Measurement Procedures (RMPs) and 128 Reference Measurement Services (RMSs) with the publication of the nominations approved during last year's meeting. It was also reported that the development for the redesign and update the JCTLM database due to changes in nomination forms necessitated by the revision of ISO 15194 had been done by an external contractor. The new version of the system had been delivered, was currently under test with a public version of the new database foreseen in January 2010. The database received approximately 800 to 1000 hits per month.
Prof Panteghini requested a copy of the BIPM presentation on the JCTLM Database for reporting to the IFCC Executive Board.

Actions
Action(A/09-08): JCTLM Secretariat to provide IFCC with JCTLM Database presentation.

4. JCTLM WG1 – Reference Materials and Reference Measurement Procedures

4.1 Report of the JCTLM WG1 and 2 meeting, July 2009, Chicago US [JCTLM-EXEC/09-04]
Dr Schimmel summarised the status of each action item arising from the WG meeting held in July. He brought a number of issues to the attention of the Committee. He had no further information on the issue date of the revised versions of mandated standards with regards to the European Directive's essential requirement on traceability. Dr Wielgosz reported that C. Giroud did communicate which versions of the standards were mandated, but could not confirm the date at which the ISO 15193:2009 and 15194:2009 would become referenced in the Official Journal of the EC. Therefore, the Secretariat had contacted the Secretariat of ISO

TC 212 and CEN TC140 for further clarification on this issue, but no clear date for the citation of the EN ISO 15193:2009 and 15194:2009 in the Official Journal of the European Community had been obtained.

Dr Schimmel said that the deadline of the 30th September 2009 for the Review Team Leaders to send RT recommendations and Review Reports to WGs Chairs and Secretariat has to be discussed. During the last review cycle the Review Team Leaders had communicated the review documents with considerable delays. Prof Panteghini commented that this had rendered the review of the recommendations difficult for the members of the Committee before the annual meeting. Dr Schimmel noted that the documents would have to be available to the Committee at least one month before its meeting. It was noted that in the case of Proteins approval of recommendations was not possible as the reports were received only 2 days before the meeting. Dr Schimmel requested that the deadline for review reports to be sent to the JCTLM Secretariat be the 31st of October for the next review cycles.

Dr Schimmel reported that he had contacted the Review Team Leader for Electrolytes regarding the outstanding nominations from previous cycles, but the review status of these nominations was not finalised and would be dealt with the newly appointed Review Team Leader.

Prof Müller asked whether the Microbial Serology Review Team should be the Microbiology Review Team as the microbiologists' daily work combines serology and PCR measurements. Dr Schimmel replied that the Microbial Serology Review Team had not yet been active in reviewing nominations and that the CMV DNA reference material nomination was dealt with by the Nucleic Acid Review Team with the rationale that PCR technology was used. The Committee requested that the Nucleic Acid review team provide a description of the scope of its activity.

The following outstanding actions items were summarized:
Actions 9 and 12 - LGC (H. Parkes) to propose applicants for WG1 and WG2 RT for Drugs and WG2 RT for Proteins
Dr Schimmel will send a reminder to H. Parkes
Action 13 - JCTLM Secretariat to circulate the 'Nominations mailing list' to the RT Leaders for additional contributions. This action was not completed.
Action 15 – EDMA to organize a survey among industry on requirements for higher order reference materials, and share this information with the JCTLM Secretariat for dissemination on the JCTLM website.
Dr Wielgosz reported that C. Giroud had informed the Secretariat that this issue would be discussed during the EDMA meeting in December 2009.
Prof Müller commented that this survey could be done in cooperation with the IFCC.
Discussion followed on how to proceed with a survey at an international level. It was proposed to wait for the response of C. Giroud on the EDMA decision but to inform him of IFCC's willingness to collaborate.
Action 16 – JCTLM Executive to consider the issue of requesting information on CRM availability for dissemination to interested parties.
It was noted that in any case according to the WG1 Quality Manual a CRM is expected to be available for a minimum period of 18 months after posting. Dr Schimmel said that requesting the availability of CRMs beyond the period already currently required by JCTLM raised the issue of the disclosure detailed long term planning information, which would, from the point of view of the producers, not be feasible.

Dr Schimmel asked whether it could be possible to review nomination in a fast track process to reduce the time the CRM producer has to wait for a CRM replacing an exhausted one to be listed in the JCTLM Database, and release the material. Dr Wielgosz replied that this would be difficult considering the time schedule for the review process that had been set up to ensure the quality of the review by the JCTLM.

Actions:
Action (A/09-09) : Secretariat to send Dr Schimmel a summary of the outstanding issues for Electrolyte nominations from previous cycles.
Action (A/09/10) : WG1 Chair to send a reminder to Helen Parkes for the missing scope of activity statement for the Nucleic Acid Review Team in order to clarify their activity with regards to Microbial Serology.

4.2 Review Criteria for Nucleic Acid Reference Materials – Nominal properties
Dr Wielgosz reported that the document "*Criteria to assess the quality of nominated nucleic acid reference materials with stated nominal properties*" from the Nucleic Acid Review Team approved in April 2009 had been posted as a separate document on the JCTLM webpage.
The Committee noted that WHO should be informed of the document.

Actions
Action (A/09/11) : Secretariat to inform the WHO of this Nucleic Acid document.

4.2.1 Approval of category "List III"
Dr Wielgosz reported that the creation of a category List III for nominal properties was recommended by the Nucleic acid review team following the review completed for the Cycle 3 reference materials.
The Committee approved the new category "List III covering nominal properties".

4.3 Approval of Cycle VI RM and RMP nominations and Outstanding issues from previous Cycles [JCTLM-EXEC/09-16, 20]
Dr Maniguet summarized the recommendations made by the review teams for Cycle VI Reference Material nominations and outstanding nominations from previous cycles. For Cycle VI there had been 18 nominated Reference Materials, and all of these had been reviewed, and of these sixteen were being recommended for approval and publication in the JCTLM database.
The committee approved 3 reference materials one in each of the categories of Drugs, Enzymes and Non-peptide hormones, but requested an extension of the deadline to review the recommendations for approval for the thirteen reference materials for Proteins, as these were distributed only two days before the meeting. The Chairman requested that all comments related to the protein recommendations should be sent to the Secretariat before 15 January 2010, after which uncontested recommendations would be approved.

Recommendation from previous cycles were also dealt with, notably: 3 nominations for Nucleic Acids which had been reviewed, and recommended for approval and publication in the JCTLM database. The committee approved these nominations for listing. There were also sixteen reference material nominations and 2 reference measurement procedures for Electrolytes which were still outstanding, and organizing a fast track review of these would be the task of the new Review Team Leader.

Nominations outstanding from previous cycles in the Blood Cell Counting are dealt with under agenda point 4.3.1.

Actions:

Action (A/09-12): JCTLM Executive to send comments related to the WG1 recommendations for proteins to the Secretariat before 15 January 2010, after which uncontested recommendations would be approved.

4.3.1 Recommendations for Blood Cell Counting

Five reference measurement methods/procedures had been reviewed by the Review Team, and of these 3 were being recommended for approval and publication in the JCTLM database, and for 2 nominations the recommendation for approval was dependant on the implementation of corrective action items listed in the review reports.
Dr Wielgosz proposed that these recommendations be reviewed by a sub-group of the Executive Committee, and Prof Forest, Prof Muller and Dr Wielgosz agreed to form this sub-committee.
The Committee thanked Lili Wang for her leadership in this review process and the contribution of Review Team members.

Action (A/09-13): JCTLM Executive sub-group to review recommendations for the Blood Cell Counting nominations.

4.4 Delisting of RMs and RMPs

Two reference materials were delisted from the JCTLM database this year. These were BCR 470 for proteins in serum and SRM 955c for lead in blood which were no longer available. It was noted that a new proteins in serum material had been nominated for review Cycle VI and a new lead material had been listed this year in the database.
Dr Schimmel asked if the removal needed to be approved. Dr Wielgosz replied that the material producer has to provide a comment on the reason why the material is delisted for addition on the PDF file of delisted reference materials.

4.5 Progress / plans for Cycle VII call for RMs and RMPs

Dr Wielgosz confirmed that the new call for nominations for Reference Materials, Methods and Measurement Services would be launched in January 2010, with a deadline for submissions in May 2010.

4.6 Revisions of ISO 15194 and 15193

ISO 15194:2009 and 15193:2009 had been published in May 2009. It was noted that the nomination form for reference materials had been modified for compliance with the requirements of the revised standards and included direct links to the paragraphs of the standard. The review process has been modified such that the organization submitting a nomination has to indicate in the form any existing non-compliances with the standard and has also to provide the supporting documentation cited in the application form. This new review process will be implemented for the 2010 review cycle, and the criteria that would render a nomination incomplete have been defined to facilitate the work of reviewers.

The re-review of listed reference materials against the revised ISO standard was discussed by the Committee which agreed on the proposal made by the WGs during its meeting in July, namely that the JCTLM secretariat will inform RM producers having JCTLM listed (C)RMs of the revised ISO 15194 standard, and of the deadline of May 2012 by which time they

would need to be compliant with the new standard, which would require a resubmission of the nomination using the ISO 15194:2009 template. It was agreed that any listed (C)RMs that were not complaint with ISO 15194:2009 requirements by May 2012 would be greyed-out in the JCTLM-DB website to indicate to manufacturers the status of the reviewed nominations.

Actions:

Action (A/09-14): JCTLM secretariat to inform RM producers having JCTLM listed (C)RMs of the publication of the revised ISO 15194 standard, and of the deadline of May 2012 by which time they would need to be compliant with the new standard, which would require a resubmission of the nomination based on ISO 15194:2009.

4.7 WG1 quality/ procedure manual [JCTLM-EXEC/09-14, 22]

Dr Wielgosz introduced the document JCTLM-EXEC/09-14 which dealt with the revised WG1 procedures and nominations forms. C. Jackson had revised these quality documents for consistency with the standards ISO 15194:2009 and ISO 15193:2009, VIM 3 and addition of the List III category for nominal properties. These were approved by the Executive Committee, with a request that revisions be marked in red.
C. Jackson had drafted the document JCTLM-EXEC/09-14 which described the documents used for the review, their scope and indicated if the documents were for the potential user of the material or for reviewers' use only. The document was approved by the Executive.

Actions

Action (A/09-15): JCTLM Secretariat to post the revised WG1 Quality documents on the JCTLM website.

4.8 JCTLM /CCQM/NIST Workshop, July 2009, Chicago

Dr Schimmel reported on the "JCTLM/CCQM/NIST Workshop on Measurement Standards Needs for Next Generation Healthcare delivery" which preceded the AACC meetings held in July. He commented that the meeting had concentrated on health metrology activities at NIST, within the European programme (EMRP) and at the KRISS rather than directly on the JCTLM. Dr Wielgosz commented that activities where directly related to the health area and that such events allowed JCTLM activities to be publicized.

4.9 Metrology and its Application to the Clinical Laboratory session during the AACC meeting, July 2009

Dr Wielgosz reported on the Metrology and its Application to the Clinical Laboratory session that had been organized as part of the AACC meeting in Chicago. The session had been a success with approximately 300 participants.
The Committee thanked David Armbruster for having organized this session.

5. JCTLM WG 2 – Reference Measurement Laboratories

5.1 Update on status of accreditation of Reference Measurement Service Providers [JCTLM-EXEC/09-06]

Prof Siekmann presented the document JCTLM-EXEC/09-06 which summarized the status of accreditation of the reference laboratories having reference measurements services listed in the JCTLM Database on 16 November 2009. He noted that there were sixteen laboratories listed, and of these 6 had not yet applied for accreditation for any of their listed services. He drew the Committee's attention on the fact that about half of the services currently listed in the database would be removed in January 2010 according to the set deadlines. Dr Kaarls asked if the laboratories were still willing to be accredited?

Dr Wielgosz replied that the Secretariat had contacted the laboratories for an update on their accreditation status, and had not received any feedback from the laboratories on whether they were still in the process of preparing for accreditation.

Prof Thienpont explained that she had asked for a checklist from the AB in her own country but it appeared that BELAC was not ready in November 2009 to carry out accreditations against 15195 although this AB had declared in May 2009 to ILAC that they were prepared to offer this service and we are able to accept applications at that time. The Executive asked the ILAC representative to provide an updated list of the ABs offering accreditation to ISO 15195.

Considerable discussion followed on how the accreditation requirement and deadline would be dealt with. The Chairman concluded that the accreditation requirement and deadline should remain unchanged and that a JCTLM listed reference laboratory would need to be accredited against both ISO 15195 and ISO/IEC 17025 as calibration laboratory by 01 January 2011, and would have to demonstrate that it had applied for accreditation before 01 January 2010.
The Executive asked the Secretariat to contact laboratories and request copies of their application letters for accreditation and the response from the AB. Failure to provide these letters would result in the delisting of the reference measurement service.

Actions:
Action (A/09/16): ILAC to send the Secretariat an updated list of ABs that are able to provide an accreditation service against 15195 and 17025.
Action (A/09/17): JCTLM Secretariat to contact laboratories and request a copy of their official submission letter to the AB and the response from the ABs.

5.2 Approval of Cycle IV Laboratory RMS nominations [JCTLM-EXEC/09-15]
Dr Maniguet summarized the recommendations made by the review teams for Cycle IV nominations for RMSs. For Cycle IV there had been 7 nominated Reference Measurement Services submitted by 1 laboratory, and all of these had been reviewed, and recommended for approval and publication in the JCTLM database. It was noted that the submission for cortisol measurements had been recommended for approval for blood serum but not for the urine matrix as it was not in the scope of the JCTLM listed reference measurement method.
The Committee approved all nominations recommended for listing.

5.2.1 Accreditation deadline and actions
The accreditation deadline remains the same and discussion on this issue was dealt with under 5.1.

5.2.2 Re-review of database entries –post accreditation deadline (2011)
Dr Wielgosz addressed the issue of future reviews of accreditation status after 2011. The Committee agreed that every 2 years the laboratory should present a copy of its accreditation certificate together with a report of its participation in EQAS ring trials.

5.3 Progress / plans for Cycle V call for Laboratory RMS
Dr Wielgosz confirmed that the new call for nominations for Reference Measurement Services would be launched in January 2010 in parallel to the call for Reference Materials and Methods.

5.4 JCTLM WG2 procedure/quality manual

This agenda point was not discussed during the meeting.

5.5 Update on IFCC EQAS results [JCTLM-EXEC/09-24]
Prof Siekmann presented a proposal on the determination of the required limits of equivalence for the performance of laboratories in the IFCC EQAS scheme based on the concept of total error. Until now there had been no equivalence statement published with the results of the RELA scheme. The Chairman stated that the JCTLM should not enter into the technical details of the definition of the limits of equivalence of a laboratory participating in the RELA scheme. This will have to be discussed in the IFCC-CTLM.
Dr Wielgosz commented that the BIPM would like to comment on the IFCC's formal proposal, and requested that a full copy of the proposal be sent to him.

It was also recalled that the JCTLM does not assess the performance of a laboratory participating in the IFCC EQAS scheme, but does verify if the laboratory participates regularly in ring trials for the group of measurands for the service that is being nominated.

Prof Siekmann presented some RELA results on Enzymes and Non-peptide hormones for which there was one participant. He further proposed that the JCTLM criteria for reference measurement service providers should be extend so that a reference laboratory would need to participate in the EQAS at least once every 3 years for each of the listed measurands for which they offered a service.

The Committee agreed on this new policy which will be implemented in January 2013, as the ring trial system starts in January 2010

Actions
Action (A/09/18): WG2 Chair to modify the appropriate WG2 procedure document to include this new criteria for laboratory participation in ring trials.

5.6 Revision of ISO 15195
Prof Siekmann informed the Committee that he had had no information on how or when the revised version of ISO 15195 would be published.
The Committee requested that the BIPM liaise with ISO TC 212 to request information on the status of the standard.

Actions
Action (A/09/19): JCTLM Secretariat/BIPM to liaise with ISO TC 212 to request information on the status of the revised ISO 15195 standard.

5.7 Reference Laboratory Networks and the JCTLM [JCTLM-EXEC/09-05]
Dr Jones presented the document JCTLM-EXEC/09-05 which was prepared as a discussion document for the JCTLM Executive on networks of reference laboratories.
Dr Wielgosz commented that a number of networks had been developed by the IFCC and as a sponsoring organization of the JCTLM it would be helpful if the IFCC would develop a policy on how these networks should interact with the work of the JCTLM.

The Committee discussed the document and requested that Dr Jones modify the first paragraph and title of the document to ensure that the criterion for accreditation of laboratories was clearly stated, before circulating it for comments.

The Committee requested in a second step that Dr Jones discuss with individuals of the networks and inform them that this concept was discussed during the Executive meeting.

Actions:
Action (A/09-20): Dr Jones to liaise with individuals in the networks to discuss his proposal, and appraise the Executive on this issue.

6. Documents submitted by JCTLM Members and Stakeholders for consideration by the Executive Committee
There were documents submitted during the year.

7. Liaison with the EC
7.1 Correspondence from DG Enterprise
Dr Wielgosz informed the Committee that he had exchanged emails with Mrs C. Bourguignon, and that there had been no further progress with the note drafted by Dr Brennan (JCTLM-EXEC/07-05). He explained that the change in staff at DG Enterprise meant that further efforts would need to be made to re-establish a close working relationship.

7.2 Liaison with the Global Harmonization Task Force (GHTF) [JCTLM-EXEC/09-08, 17, 18, 19]
Dr Wielgosz presented the document JCTLM-EXEC/09-08, 17, 18, and 19 which were the correspondence letters with the Global Harmonization Task Force, and the GHTF STED document for demonstrating conformity to the essential principles of safety and performance of *in vitro* diagnostic medical devices. The STED document had been communicated to the BIPM/JCTLM late in November and the JCTLM was invited to comment on this document and notably on the paragraph 10.1.3 on traceability by the 2nd of January 2010. He remarked that this STED document is of great importance and the JCTLM should provide comments.

Actions:
Action (A/09-21): BIPM, ILAC and IFCC to comment on the GHTF STED document.

8. Liaison with the WHO
8.1 Issues arising from the WHO-ECBS meeting [JCTLM-EXEC/09-12]
Prof Forest introduced the document JCTLM-EXEC/09-12 which was his report on the ECBS meeting which he had attended. He remarked that it was very encouraging to see that the discussion at the WHO had included Metrological traceability. He added that some organizations are pushing towards traceability.

9. Liaison with ISO TC 212
Dr Schimmel reported that this technical committee had met this year, its plenary meeting held in Ghent in June and the meeting held in London in October, that he could not attend. However he informed the Committee that the major issue was the changes in ISO 15189, which was being dealt with by WG1, whereas WG2 dealing with Reference Systems had not met during the year.
A. Squirrel stated that he would send the minutes of the meetings.

10. Publicity for the JCTLM
The Committee noted that the JCTLM website was the main tool used to publicize JCTLM activities.

Dr Schimmel informed the Committee that the JCTLM had been mentioned in an EMRP project related to health.
Prof Panteghini informed the Committee that the IFCC Meeting would be held in Berlin in May 2011 and this would be a possible place to advertise JCTLM. In the discussion that followed it was proposed that a JCTLM Symposium be organized as part of the Congress. The JCTLM proposal would need to be sent to Prof Panteghini for discussion and approval during the IFCC General Conference in Corfu in April 2010.
Dr Schimmel noted that establishing traceability for heterogeneous analytes was a topic of future interest and that a workshop on the results of the EMRP project on CLINBIOTRACE would be organized at around this time and that this could possibly be combined with the JCTLM symposium.

Prof Siekmann stated that there should be greater cooperation and awareness of the JCTLM activities, and that the RELA activities should be linked to NMI measurement capabilities to ensure global comparability. Prof Siekmann will send a request to the PTB to develop comparison proposals for the CCQM WGs that will link to JCTLM related EQAS activities.

Action
Action (A/09/22): JCTLM Secretariat to send a Symposium proposal to Prof. Panteghini a week before the IFCC General Conference in Corfu in April 2010

11. Future meetings of the JCTLM
11.1 Meetings for 2010 and 2011
It was proposed that the JCTLM Working Groups meeting be held preceding the AACC meeting in July 2010. The dates of the 23 and 24 July 2009 were retained, and the JCTLM Secretariat would contact Dr May to see if a meeting venue could be arranged.
The next meeting of the JCTLM WG-1, WG-2 and WG-3 will be held during the AACC Conference in Anaheim CA, on Saturday, July 24, 2010, from 8:30 am - 6:00 pm, in the Anaheim Marriott Hotel, Platinum Ballroom, Salons 3+4.

The 9th meeting of the JCTLM Executive would be held at the BIPM on 2 and 3 December 2010.

Action
Action (A/09/23): JCTLM Secretariat to contact Dr May to see if a meeting venue can be arranged for JCTLM WGs on 23/24 July 2010 in conjunction with the AACC meeting.

11.2 JCTLM Symposium and Stakeholder's meeting
It was proposed that a possible meeting site for the JCTLM Symposium and Stakeholder's meeting would be at the 12th Asian-Pacific Congress of Clinical Biochemistry (APCCB) to be held in Seoul on 3-7 October 2010. In the discussion that followed it was agreed that a symposium would need to be held during and in the same facilities as the Congress, to ensure participants from the Congress attended the JCTLM Symposium. Dr Kaarls and Prof Wallard agreed to contact the KRISS directly the following week to see if they could help in the organization of the meeting.

Action
Action (A/09/24): Dr Kaarls and Prof Wallard to contact KRISS to determine whether a JCTLM symposium can be organised as part of the APCCB Congress.

12. Close of Day 1

Report of Day 2 meeting on future activities of the JCTLM

1. JCTLM Structure and Declaration of Cooperation – proposed changes

1.1 Executive

The Executive discussed the number of representatives from each organization in the Committee. The number of representatives per organization was not limited in the declaration of cooperation, and a continuation of this policy was supported by the BIPM although the IFCC expressed a preference of limiting the number of members to a maximum number. The Chairman concluded that there would be no change in policy, but that the appointment of representative would be confirmed on a three year cycle in accordance with the decision of the Committee at its last meeting.

1.2 Working Groups

The Chairman asked the Chairs of the Working Groups if changes were needed.
Dr Schimmel and Prof Siekmann replied that they were happy with the way the WGs operate with respect to the review process. They formulated no requests for changes.
Dr Wielgosz remarked that over the years the workload for organizing review process had shifted from the WG Chairs to the JCTLM Secretariat, and meant that a considerable resource was dedicated to this activity by the BIPM as the JCTLM secretariat.

Prof Thienpont circulated a document which dealt with a proposal for JCTLM- Master Comparisons, which she further presented to the Committee. She stated that the objectives of this initiative were to organize EQA/PT schemes for manufacturers, with the aim of creating a database documenting the current standardization status on commutable sera. She proposed that this activity be organized by the JCTLM with the creation of Working Group 3.

Prof Panteghini commented that the interest of industry in this initiative was of importance and the question on whether they were prepared to support this initiative needed to be investigated.

The Chairman stressed that this was a new orientation of the JCTLM, and asked if the JCTLM was the right entity to deal with this issue and to a judge this proposal.

Prof M. Kühne commented that the project would deliver a service and as the JCTLM was not a legal entity this raised the problem of liability. The solution could be that the University of Ghent would be the legal entity with responsibility for the project and deliverables.

The Chairman concluded the discussion, and stated that the project could not be conducted by the JCTLM as it was not in its mission statement, but that this was a valuable proposal that should be proposed as an IFCC project.

The Committee also agreed that the decision on the creation of a WG dealing with the outcomes of such projects would be delayed to the next annual meeting as further discussions were required.

1.3 Meetings

Prof Müller proposed that the JCTLM should be represented on a regular basis at regional meetings of the major IVD Diagnostics community. The World Congress of WASPaLM in 2011 would provide a venue to publicise JCTLM activities.
Prof Panteghini proposed that IFCC booths at Congresses could be used to publicize JCTLM activities with posters or other materials.

1.4 Funding

The Chairman opened the discussion on the role and privileges of the members of the JCTLM.
It was noted that presently the member organizations had limited activity within the JCTLM structure, and that the Executive had approved Membership status to a more varied range of organizations than originally envisaged in the Declaration of Cooperation statement. The application of CIRME was accepted.
The Committee agreed that there was a need for reviewing and re-drafting the paragraph on privileges of Member Status of the Declaration of Cooperation.

The Chairman closed the discussion and concluded that the definition and the privileges of the membership would be adapted based on the concept of promoting metrological traceability in laboratory medicine. In addition the circulation of information between JCTLM and its members should be strengthened.

Action

Action (A/09/25): JCTLM Secretariat to develop a new draft on JCTLM Membership Privileges and Obligation for comment and approval by the Executive.

2. Issues raised

2.1 Use of the term 'JCTLM' in manufacturers' information

Dr Jones informed the Committee that the document CLSI X5 R11 on implementation of traceability would be revised, and proposed that JCTLM participate in the CLSI document. He further added that there was a need to clarify and ensure that the term "JCTLM" would provide confidence when issues of metrological hierarchy and traceability were raised.
Dr Wielgosz proposed that information on how best to describe a calibration hierarchy to JCTLM database entries should be developed and available on the JCTLM website with the view to facilitating the understanding of this concept and harmonizing its application.
The Chairman requested that Dr Wielgosz and Dr G. Jones draft this statement, and circulate it to the members of the Committee.

Actions:

Action (A/09/26): Dr G. Jones and Dr Wielgosz to draft traceability statement, and circulate it to the members of the Committee.

2.2 Facilitation of a 'gap analysis' in traceability

Dr Jones explained that he had looked through the analytes routinely tested in Australia, and noted that only 37 of 400 of these had corresponding entries within the JCTLM database. Therefore it would be useful to perform a gap analysis to determine with which analytes there were issues or problems and for which of these there was a need for reference standards.

3. Current views of JCTLM activities and impact

3.1 Presentations from invited speakers

No invited speakers were present.

3.2 IFCC views

Prof Panteghini explained he expected the JCTLM outputs to be ever more used in future years. He mentioned additional IFCC projects that were under development and that were related to maximum permissible errors for traceable results. The outcome from these working groups should be available soon.

Dr Schimmel remarked on the latter point that this type of work is of great importance as it would allow to highlight how/where the method of measurement would/could be improved.

Prof Panteghini concluded by saying the new IFCC Board was happy with the activities of the JCTLM to date and very supportive for future activities.

3.3 BIPM views

Prof Wallard explained that the JCTLM was seen as an extremely important coordination activity. He added that this was a good example of a successful connection between reference laboratories, the metrology community and the user community. The database had been a successful item.

Dr Wielgosz added that the WG1 and WG2 nominations had currently reached a steady state situation, and that it was important to see that proposals for new activities were being made. He noted that further work was still needed to publicise the JCTLM.

3.4 ILAC views

A. Squirrell reported that ILAC had observed an increase in the appreciation and understanding of issues promoted by the JCTLM worldwide, and that dissemination to the field level remained a key issue. Accreditation for medical laboratories would remain a key issue, and in the case of Reference Laboratories this would require assessors to be recruited at the international level.

3.5 WG Chair views

Prof Siekmann remarked that he expected the number of laboratories nominating reference measurement services to increase slowly.

A. Squirrell asked if the JCTLM covered all Reference Laboratories that existed Worldwide, and mentioned that for instance in Australia there were none.

Prof Siekmann replied that he did not know about the situation in all countries, and whether reference systems had been implemented. He explained that Netherlands was interested and had started to develop methods. In the United States, the CDC, had developed and implemented reference methods.
Prof Panteghini remarked that the infrastructure for traceability was developing in China, where a national committee for traceability in laboratory medicine had been formed.

Dr Schimmel expressed a personal opinion and said that it was important that the JCTLM be seen as neutral entity in order to have the right impact. As Chair of the WG1 he said that it would be important to thank the members of the JCTLM Review Team for their contribution in the work of the JCTLM. In the discussion that followed, the Chairman requested that the Secretariat draft a letter to thank RT members and recognize their work, which would be signed by the BIPM, ILAC, and IFCC.

Actions:
Action (A/09/27): JCTLM Secretariat to draft the letter for thanking the RT members.

3.6 Impact in various regions of the World

It was agreed that JCTLM should have further connection with the ISO TC 212, and that a JCTLM representative should make a presentation on JCTLM activities.

4. Proposals for new activities for the JCTLM

A number of proposals for new activities were discussed during the meeting.

Dr Schimmel informed the Committee that the CLINBIOTRACE Project (consortium of LGC, NPL, PTB and IRMM) is planning a workshop/symposium with stakeholders in the health area in the first half of 2011, and that the PTB was the project partner in charge of the workshop. He further proposed that a JCTLM Symposium on heterogeneous analytes could be organized in conjunction with this workshop.
The Committee agreed that the JCTLM Secretariat would contact Dr Schimmel and PTB to see if a common/linked symposium could be organized in 2011 possibly as part of the 2011 IFCC WorldLab Congress.

5. Strategies for working with Regulators.

The Committee noted that the recent exchange of letters with the GHTF was a positive step in working more closely with regulators.

6. Any other business

Dr Jones asked whether further documentation could be prepared on JCTLM activities.

The Chairman proposed the creation of a new Working Group on Publications for which Dr Jones would be the Chair, which he accepted. Dr Jones was asked to draft terms of reference for the working group as well as a work programme, which would be circulated to the Executive. The Chairman suggested that the following should also be members of the WG: Prof Panteghini, Drs Jackson , Maniguet and Wielgosz.

Prof M. Kühne informed the Committee that there had been a Workshop on physiological Quantities held at the BIPM, and that he would circulate the report of the Workshop the members of the Executive Committee.

Actions:
Action (A/09/28): Dr Jones to draft terms of reference for the working group as well as a workprogramme and circulate to working group members and the Executive.
Action (A/09/29): Prof Kuhne to circulate report of the BIPM Workshop on Physiological Quantities.

S. Maniguet 07/01/10
Revised 15/03/10

Annex 1: Summary List of Actions

Actions from the 8th Executive Meeting

Action (A/09-01): JCTLM Secretariat to contact the sponsoring organizations and inform them of the appointment of the new Chairman, and update the JCTLM website.
Action (A/09-02): JCTLM Secretariat to publish the composition of the JCTLM Executive Committee onto the JCTLM website.
Action (A/09-03): The JCTLM Secretariat to contact new review team members and inform them of their approved applications.
Action (A/09-04): Dr G. Jones to contact the NMIA for further experts for the Drugs Review Team.
Action (A/09-05): Prof. Müller to contact Dr Seeger to see if he is willing to participate in the Review Team for Drugs.
Action (A/09-06): JCTLM Secretariat to circulate the document on the review teams' scope of activity by the 31st of January 2009 for review and approval by the Executive.
Action(A/09-07): JCTLM Secretariat to provide IFCC with BIPM statement on the JCTLM Secretariat activities.
Action (A/09-08): JCTLM Secretariat to provide IFCC with JCTLM Database presentation.
Action (A/09-09) : Secretariat to send Dr Schimmel a summary of the outstanding issues for Electrolyte nominations from previous cycles.
Action (A/09/10) : WG1 Chair to send a reminder to Helen Parkes for the missing scope of activity statement for the Nucleic Acid Review Team in order to clarify their activity with regards to Microbial Serology.
Action (A/09/11) : Secretariat to inform the WHO of this Nucleic Acid document.
Action (A/09-12): JCTLM Executive to send comments related to the WG1 recommendations for proteins to the Secretariat before 15 January 2010, after which uncontested recommendations would be approved.
Action (A/09-13): JCTLM Executive sub-group to review recommendations for the Blood Cell Counting nominations.
Action (A/09-14): JCTLM secretariat to inform the RM producers having JCTLM listed (C)RMs of the publication of the revised ISO 15194 standard, and of the deadline of May 2012 by which they would need to be compliant with the new standard, which would require a resubmission of the nomination using the ISO 15194:2009.
Action (A/09-15): JCTLM Secretariat to post the revised WG1 Quality documents on the JCTLM website.
Action (A/09/16): ILAC to send the Secretariat an updated list of ABs that are able to provide an accreditation service against 15195 and 17025 as calibration laboratory
Action (A/09/17): JCTLM Secretariat to contact laboratories and request for their official submission letter to the AB and the response from the ABs.
Action (A/09/18): WG2 Chair to modify the appropriate WG2 procedure document to include this new criteria for laboratory participation in ring trials.
Action (A/09/19): JCTLM Secretariat/BIPM to liaise with ISO TC 212 to request information on the status of the revised ISO 15195 standard
Action (A/09-20): Dr Jones to liaise with individuals in the networks to discuss his proposal, and appraise the Executive on this issue.
Action (A/09-21): BIPM, ILAC and IFCC to comment on the GHTF STED document.
Action (A/09/22): JCTLM Secretariat to send a Symposium proposal to Prof. Panteghini a week before the IFCC General Conference in Corfu in April 2010

Action (A/09/23): JCTLM Secretariat to contact Dr May to see if a meeting venue can be arranged for JCTLM WGs on 23/24 July 2010 in conjunction with the AACC meeting.
Action (A/09/24): Dr Kaarls and Prof Wallard to contact KRISS to determine whether a JCTLM symposium can be organised as part of the APCCB Congress.
Action (A/09/25): JCTLM Secretariat to develop a new draft on JCTLM Membership Privileges and Obligation for comment and approval by the Executive.
Action (A/09/26): Dr Wielgosz and Dr G. Jones to draft traceability statement, and circulate it to the members of the Committee.
Action (A/09/27): JCTLM Secretariat to draft the letter for thanking the RT members.
Action (A/09/28): Dr Jones to draft terms of reference for the working group as well as a workprogramme and circulate to working groups members and the Executive.
Action (A/09/29): Prof Kuhne to circulate report of the BIPM Workshop on Physiological Quantities.