Report of the 9th meeting of the JCTLM Executive Committee
2-3 December 2010, BIPM, Sèvres, France

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

Apologies received:
Dr W.E. May (JCTLM WG1 Chair)
Dr G. Beastall (IFCC)
Prof. L. Thienpont (JCTLM WG 2 Chair)
Prof. A. Wallard (BIPM)

Prof. Müller opened the meeting, and welcomed the participants.

1. Approval of the agenda [JCTLM-EXEC/10-01]

Dr G. Jones asked for an additional agenda point to be added related to the future activities of the JCTLM. Prof. M. Müller agreed that this should be dealt with under the agenda point 13.

2. Report of 8th JCTLM Executive Committee Meeting

There were no comments on the report of the 8th Executive Committee meeting, which had been finalized in March 2010, and published on the JCTLM website.

Dr. H. Schimmel remarked that the procedures of the JCTLM WG1 Quality Manual were currently published on the public website with revisions marked in red in the text, and requested that only clean versions of these documents be posted on the public website. Dr Wielgosz explained that the version of the document appearing on the web was consistent with the decision made during last year's meeting. Prof. M. Kühne added that this was also in line with the Quality System put in place at the BIPM. In the discussion that followed, the Committee agreed that versions with revision marks would only remain on the website for one year after which they would be replaced by clean versions of the document.

Actions:
Action (A/10-01): JCTLM Secretariat to update the documents related to JCTLM WG1 and WG2 Quality Manual/Procedures, in order to remove revision marked in red, for the procedures approved during last year's meeting.

2.1 Review of action points arising from the 8th meeting [JCTLM-EXEC/10-02]

Dr Wielgosz summarized the action items that were still outstanding:

Action (A/09-04): Dr G. Jones to contact the NMIA for further experts for the Drugs Review Team.
Dr G. Jones referred to the document JCTLM-EXEC/10-37, and reported that he had contacted NMIA several times and no positive outcome was achieved.
Action (A/09-07): JCTLM Secretariat to provide IFCC with BIPM statement on the JCTLM Secretariat activities. This action was covered by the document JCTLM-EXEC/10-41 (JCTLM Secretariat activities for 2010) which would be presented during the meeting under the agenda point 3.5.
Action (A/09-11): Secretariat to inform the WHO of this Nucleic Acid document.
Action (A/09-13): JCTLM Executive sub-group to review recommendations for the Blood Cell Counting nominations.
This action was completed. However, the final decision for these outstanding nominations was still needed, and would be discussed under the agenda point 4.2.1.
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. The BIPM had contacted the ISO TC 212, but had not received any clear response on the status of the revised ISO 15195 standard. Prof. L. Siekmann added that the DIN had approached also the ISO TC 212 Secretariat and received no response either.
Dr R. Kaarls proposed that this issue be discussed during the tri-partite meeting BIPM/ISO/ILAC which would be held on 9 March 2010 at the BIPM.
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
This action was completed. Prof. M. Müller reported that neither the proposal for a JCTLM Symposium nor the proposal for the workshop on the results of the EMRP project on CLINBIOTRACE had been accepted for the IFCC-WordLab Congress in Berlin in May 2011. Dr Schimmel explained that the workshop organized in the framework of the EMRP project on CLINBIOTRACE was now scheduled to take place at the PTB (Berlin) and would focus on C-reactive proteins and human growth hormones, and profiling Mass Spectrometry for protein measurements.
The Chairman concluded that he would contact the IFCC-WordLab organizing committee and investigate the possibility to schedule the workshop at the IFCC-WordLab Congress.
Action (A/09-25): JCTLM Secretariat to develop a new draft on JCTLM Membership Privileges and Obligations for comment and approval by the Executive.
This action was covered by JCTLM-EXEC/10-39, and would be discussed under agenda point 3.1.
Action (A/09-26): Dr Wielgosz and Dr G. Jones to draft traceability statement, and circulate it to the members of the Committee.
Dr G. Jones said that the draft for the traceability statement had been circulated during the JCTLM WGs meeting in Anaheim. Discussions focused on the use of JCTLM as a trusted brand. This document referenced as JCTLM-EXEC/10-38 will be discussed further under agenda point 6.2.
Action (A/09/28): Dr Jones to draft terms of reference for the working group as well as a work programme and circulate to working group members and the Executive.
This action was not completed. Dr G. Jones expressed his concerns on the establishment of a third working group for issuing publications. The discussion on this issue would be dealt with under agenda point 6.

Actions:
Action (A/10-02): BIPM to address the issue of the revision of the ISO 15195 standard at the BIPM/ILAC/ISO to be held at the BIPM in March 2011.

Action (A/10-03): Dr. H. Schimmel to provide Prof. M. Müller with the final program of the workshop organized in the framework of the EMRP project on CLINBIOTRACE
Action (A/10-04): Prof. M. Müller to contact by email Bernd Guettler from the PTB, and the organizers of the workshop, and see if it is still possible to schedule the workshop at the congress IFCC-WordLab 2011 in Berlin.

3. JCTLM Framework and Declaration of Cooperation

3.1 Modified text for Membership Obligations and Privileges [JCTLM-EXEC/10-39]

Dr Wielgosz presented the document JCTLM-EXEC/10-39 which modified the text of the Declaration of cooperation between the CIPM, IFCC and ILAC. He explained that the changes were in line with the current process of the JCTLM, as well as the comments made by the BIPM regarding the revision of European Directive on *In Vitro* Medical Devices. The Appendix III was revised to provide references to the dated international standards used by the Working Groups for the evaluation for compliance of the nominations. In addition, a statement for the obligations of Member Status was drafted within the Appendix IV.
The Committee commented the document, and agreed on a revised JCTLM Declaration of Cooperation which would be circulated for comments amongst the sponsoring organizations for their approval.

Actions:
Action (A/10-05) : JCTLM Secretariat to circulate the revised text for the Declaration of Cooperation amongst the three sponsoring organizations for their approval
Action (A/10-06) : JCTLM Secretariat to inform the JCTLM member organizations of their obligations, and that they would need to report regularly (every 2 years) on their activity in support of the JCTLM.

3.2 Representation on the Executive [JCTLM-EXEC/10-21]

Prof. Mauro Panteghini had written to the committee to inform them of his resignation from the Executive Committee as IFCC representative, and of his willingness to remain the Leader of the JCTLM Review Team for Enzymes.
The Committee thanked Prof. Mauro Panteghini for his work in support of the JCTLM, and agreed that he should remain the Leader of the JCTLM Review Team for Enzymes.

Dr Wielgosz presented the document JCTLM-EXEC/10-21, which was an email from Dr Ian Young (Chairman of the IFCC Scientific Division), informing the committee that IFCC had decided to nominate Prof. Siekmann as new IFCC representative on the JCTLM Executive Committee.
The Committee welcomed the nomination of Prof. Siekmann.

3.3 JCTLM membership [JCTLM-EXEC/10-22]

Dr Wielgosz presented the document JCTLM-EXEC/10-22, which summarizes the member organizations of the JCTLM, as printed in the Appendix 1 of the Declaration of cooperation on April 2010. There were twenty five JCTLM member organizations.
There had been no applications received for membership to the JCTLM during the year.

3.4 JCTLM Working Groups

3.4.1 Review of JCTLM Review Teams and RT Members [JCTLM-EXEC/10-03, 04]

Dr Wielgosz presented the documents JCTLM/10-03, and 04, which summarized the review team membership by working group and analyte type on 19 April 2010, and included a new application for membership of review team. The JCTLM Executive Committee approved the membership application from Dr Paul Wallace from the Quality Control Molecular Diagnostic (QCMD) for the Nucleic Acid WG1 Review Team.

Dr Wielgosz asked if nominations for reference measurement methods in the field of immunosuppressive drugs could be expected for next review cycle of the JCTLM, as expert in this field has been approached. Prof. Müller replied that he will contact Dr Seeger, member of the Drugs review team, to see if reference measurement methods would be ready for submission during the next review cycle

3.4.2 Review Team Scope of activities [JCTLM-EXEC/10-23]

Dr Wielgosz presented the document JCTLM/10-23 which described the scope of activity provided by each review team, except for Enzymes and Electrolytes and Blood gases.
Dr Jones informed the committee that further to last JCTLM Working Groups meeting in Anaheim, a revised version of the terms of reference for review team had been drafted by Dr Jackson. This document was circulated amongst the members of the Committee during the meeting. It included a preamble, references to ISO standards that are applied during the review process, clear distinction between WG1 and WG2, and definition of the analytes/measurands based on that provided by the review team leaders. The committee commented on the document, and requested the JCTLM Secretariat to circulate the revised document among the Review Team Leaders for comment.

Action
Action (A/10-07): JCTLM Secretariat to circulate the revised document for the Review Teams' terms of reference for review team leaders' comments.

3.5 Funding of the JCTLM Secretariat [JCTLM-EXEC/10-24, 41]

Dr Wielgosz presented the document JCTLM/10-24 and 41, which included the budget required for 2011 to 2015 for JCTLM Secretariat activities, and described the activities undertaken by the JCTLM Secretariat in 2010. The operating costs of the JCTLM Secretariat included the tasks related to the organization of the JCTLM Executive meeting and related documentation, the processing of JCTLM submissions and reviewed nominations, the development and the maintenance of JCTLM Database, the development of quality documentation for the JCTLM Executive and Secretariat, and the activity for liaison with external organizations related to JCTLM. The financial support required for the JCTLM Secretariat activities for the next five year period was produced based on that of 2010 with an increase of 2% per year.

Prof. Müller requested that an estimate of time spent for each task described in the document JCTLM/10-41 be added which he could present to the IFCC Executive Board.

Actions:
Action(A/10-08): JCTLM Secretariat to provide IFCC with the budget request and activity report for JCTLM Secretariat activities.

3.6 JCTLM Database

Dr Maniguet gave an update on the JCTLM Database which currently lists 220 Certified Reference Materials (CRMs), 146 Reference Measurement Procedures (RMPs) and 86 Reference Measurement Services (RMSs) with the publication of the 16 new entries for reference materials and 7 for services approved during last year's meeting. She added that 49 reference measurement services were delisted in May 2010 based on the reference measurement service providers not meeting the deadline set by the JCTLM for applying for accreditation. Also she 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 completed in March 2010.

Dr Kaarls communicated to the committee two observations which he had received from Mrs H. Parkes of the LGC.
The first request was to make the database more user friendly, which was a comment raised during a workshop organized in the UK. Dr Wielgosz replied that any requests would be investigated. However, he would contact Mrs Parkes for further information on the improvements to the database that were being requested. The second was a request related to the need to organize a workshop on JCTLM activities for regulators and assessors. It was noted that if there was a need for educating or training assessors, and National Accreditation Bodies on metrological traceability and measurement uncertainty, this could be dealt with by WG3. Dr Jones commented that the first task would be to have feedback from a panel of users of the database in order to respond as closely as possible to their needs.

3.7 Responses to 98/79/EC IVD Directive Public Consultation [JCTLM-EXEC/10-25, 26]

Prof. Müller reported that the BIPM had taken the opportunity of the public consultation launched by the European Community on the revision of the 98/79/EC IVD Directive to send a letter co-signed by the Director/ Presidents of the BIPM, IFCC and ILAC (JCTLM-EXEC/10-25) which requested that the JCTLM be referenced.

Dr Schimmel informed the Committee that the European Commission had received hundreds of comments, and feedback from the EC could be expected only after these had all been reviewed.

Discussion followed on the necessity for the JCTLM to liaise further with the EC to ensure awareness of the contribution of the JCTLM. The Chairman concluded that the three sponsoring organizations of the JCTLM would define a strategy to identify the appropriate entity/organisation to be approached to ensure that EU would take into account the contribution of the JCTLM activity.

Actions
Action (A/10-09) : Dr Wielgosz to contact Mrs Parkes for further information on suggested modifications to the JCTLM Database.
Action (A/10-10) : JCTLM Secretariat to develop a feedback page on the JCTLM website for comments.
Action (A/10-11) : Prof. Müller will contact the Austrian Ministry of Health to identify an appropriate contact.
Action (A/10-12) : Prof. Siekmann will contact the PTB to investigate how Germany deals with IVD Directive's requirements.

Action (A/10-13): Dr Wielgosz to address the need for a strategy for lobbying for JCTLM at the Metchem Meeting in 2011.

4. JCTLM WG1

4.1 Report of the JCTLM WG1, 2 and 3 meeting, July 2010, Anaheim US [JCTLM-EXEC/10-05]

Dr Schimmel reported that there had been only a limited attendance by Review Team Leaders during the JCTLM WGs meeting in July. He believed that this was partly due to the fact that the review of nominations had just started having been distributed to Review Teams in June. Discussion followed on the possibility to schedule future WGs' meetings later during the year, or to change the closing date for call for submissions to enable the review teams to report on the review of the nominations during the meeting. The committee was not in favour of rescheduling the review process, and concluded that the AACC Annual meeting was a convenient venue to arrange the next WGs' meeting.

Prof. Müller reviewed the status of each action item arising from the WGs meeting held in July. The following outstanding actions items were discussed:

(Action 5) Look into the possibility of BIPM/JCTLM posting the new ISO guides on the JCTLM protected site for the review team members.

Mr Squirrell said that the posting of the ISO Standards on the JCTLM website, even on a protected sub-section of the website, was not possible for legal reasons linked to copyrights. The committee requested ILAC to contact ISO to see if it would be possible for JCTLM to buy an electronic version of each of the standards, and then post them on a password-protected ("read-only") site on the JCTLM website.

(Action 7) Request that the JCTLM Executive engage with the JCTLM partners to provide a definition for "higher-order", within the context of laboratory medicine.

Dr Wielgosz said that the term "higher-order" which was introduced by the European Directive on *In Vitro* Diagnostic Devices, was explained in the standard ISO 17511, in particular, through the calibration hierarchy diagrams which would allow manufacturer to identify higher-order items.

(Action 9) The Quality Manual Team will draft Frequently Asked Questions (FAQs) for the Working Groups and JCTLM Website.

There were no documents received.

(Action 12) With the JCTLM Executive's assistance, suggest manufacturers provide test kits/methods to enable laboratories to come up with traceable results. **Lothar Siekmann will provide details and notes on this subject matter. Working Group members should make proposals to be presented to the JCTLM Executive for these suggested changes.**

It was noted that there were no proposals received from any working group members. Prof. Siekmann stressed that this action was in line with comments that the IFCC made regarding the revision of the EU IVD, where it was requested that the statement on metrological traceability referred to the patient's results rather than that of the calibrator. Mr Squirrell informed the Committee that the standard ISO 17511 was pending systematic review. The committee suggested that the BIPM, ILAC, and IFCC as liaison A organizations should provide their comments for improvements in the calibration hierarchy diagrams. The definition of the measurand should also be updated according to VIM3.

(Action 13) Remove arbitrary qualitative descriptions of multiple reference measurement procedures for same analyte in database, e.g. "NIST Definitive Method Total Cholesterol in Serum" to "NIST Method for Total Cholesterol in Serum"

Working Group Chairs will present this change to the JCTLM Executive.
These references should be modified as needed with the JCTLM Secretariat.
The committee approved the proposed modification

Actions
Action (A/10-14): ILAC to contact ISO to see if it would be possible for JCTLM to purchase electronic versions of each of the standards for use by JCTLM Review Team members
Action (A/10-15): BIPM, ILAC, and IFCC to comment on ISO 17511 which is pending for systematic revision
Action (A/10-16): The JCTLM Secretariat to remove arbitrary names as needed for reference measurement methods listed in the database.

4.2 Approval of Cycle VII RM and RMP nominations and outstanding issues from previous Cycles

Dr Maniguet presented the nominations for reference materials and measurement methods with the final review teams' recommendations which had been submitted to WG1. There were outstanding nominations from previous review cycles, including sixteen reference materials and two measurement methods for Electrolytes, as well as five reference measurement method nominations for Blood Cell Counting. In addition, there were forty-two nominations for reference materials for five groups of analytes, and thirty nominations for reference measurement methods for six groups of analytes which had been submitted for review cycle 7.

It was noted that 23 of the thirty reference measurement method submissions had been reviewed, and that only one had been recommended for approval and publication in the JCTLM database. The non-compliance preventing the other submissions to be listed in the JCTLM database was due to the lack of a citation/reference to a peer reviewed publication describing the method and validation data. The Committee agreed with WG1's recommendation which requested that a reference method had to be published in a non-changeable format, such as a peer reviewed article. This requirement would be clarified in the WG1 Instructions document for completing WG1 nominations.

The review teams' recommendations for approval and publication in the JCTLM Database are summarized in the following sub-sections for each group of analytes.

4.2.1 Recommendations for Blood Cell Counting [JCTLM-EXEC/10-06, 07, 08]

Dr Wielgosz reported that two members of the sub-group of the Executive Committee formed during last year's meeting submitted their comments to the Blood Cell Counting Review Team with respect to the review team's recommendations for 5 PTB reference measurement methods. He added that Prof. Müller commented on the technical aspects of these recommendations, while he had commented on the procedural aspects. From the Blood Cell Counting review team responses presented during the WGs meeting, he stated that the comments made by the sub-group of the Executive Committee were not dealt with. For instance, it was not clear whether the English version of standard describing the method was yet available. Prof. Müller said that there should be a report on the difference between the existing ICHS method and the PTB method submitted for review to JCTLM, which would allow the Committee to determine if an additional reference measurement method listed by JCTLM would be of added value in the establishment of reference measurement systems in hematology.

Prof. Siekmann suggested that he would contact the PTB regarding the outstanding issues commented by Dr Wielgosz and Prof. Müller regarding their Blood Cell Counting Methods.

Actions
Action (A/10-17): Prof. Siekmann to contact the PTB regarding the outstanding Blood Cell Counting nominations to see if the major non-compliance have already been corrected.

4.2.2 Electrolytes (Cycle IV) [JCTLM-EXEC/10-09, 20]

There were sixteen nominations for reference materials, and two nominations for reference measurement methods for Electrolytes, which were outstanding from previous cycles. All of these had been reviewed, and six reference materials from the NIST as well as the ion chromatography reference measurement method for ortho-phosphate were being recommended for approval and publication in the JCTLM database.
The committee stated that the review team's comments on the calibrant SRM 200b used for the ortho-phosphate IC reference measurement method in document JCTLM-EXEC/10-20, were not relevant for the review of the reference method.
The PTB ion chromatography reference measurement method for lithium was not recommended for approval and publication in the JCTLM Database, as no agreement amongst the members of the Electrolytes review team had been reached. The Executive will review the nomination and come to a decision by the end of January 2011.

4.2.3 Electrolytes (Cycle VII) [JCTLM-EXEC/10-10]

There were ten nominations for reference materials, and eight nominations for reference measurement methods for Electrolytes. All of these had been reviewed, and seven reference materials from the NIST were being recommended for approval and publication in the JCTLM database.

It was noted that the three nominations for reference materials which were not recommended for approval, critical non-compliances were found due to language issues in the documentation submitted for review. The Committee stated that the parts of the documentation (i.e. certificate or certification report) which were required/relevant for the review of a CRM submission and which were referenced in the JCTLM nomination form must be provided in English.

4.2.4 HbA1c Reference Materials [JCTLM-EXEC/10-27]

Dr Wielgosz reported that the JCTLM had received a request for information on the HbA1c reference materials listed in the JCTLM Database for the purpose of the calibration of the IFCC reference measurement methods listed in the database. Two materials were currently listed, namely the IRMM-BCR405 material (with supporting documentation stating that it was not a certified reference material), and the Japanese reference material for HbA1c JDS Lot 2. Dr Schimmel provided further information on the BCR matreial: *"in principle the IRMM material and the Japanese material are certified for two different measurands. BCR-405 provides a method defined (ion chromatography) certified value which compares with the listed ion chromatography based RMP also listed by JCTLM, whereas the Japanese material has been value assigned with the IFCC reference method. For both method principles the two listed materials are the higher order reference materials. JCTLM has added comments on the two RMPs for HbA1c listed. Since the IFCC reference method is identified as the RMP of the higher order one would, on a first glance, conclude that the Japanese material is therefore also of higher order than BCR-405. Since IRMM does not think that it is a good idea to have 2 coexisting RMPs and higher order RMs listed by JCTLM we had the intention to withdraw*

BCR-405 once we have finalised the production of a CRM characterised with the IFCC reference method in order to further promote the IFCC reference system."
He went on to explain that he still had questions on a number of aspects of the JDS Lot2 material, and believed that this material needed to be reviewed further.
The Committee decided to request further review by WG1, and recommendations on whether both Reference Methods and Materials for HbA1c should remain listed or be removed from the database.

Actions
Action (A/10-18): WG1 and Review team on Proteins to review currently listed reference methods and materials for HbA1c and recommendations on whether both Reference Methods and Materials for HbA1c should remain listed or be removed from the database.

4.2.5 Drugs (Cycle VII) [JCTLM-EXEC/10-11]

There were four nominations for reference materials for Drugs. All of these had been reviewed, and of these the CRM from the LGC Limited was being recommended for approval and publication in the JCTLM database.

The committee remarked that the review report forms for the three remaining CRMs would need to be revised as the non-compliances are not explicitly stated in the reports.

4.2.6 Non-electrolyte metals (Cycle VII) [JCTLM-EXEC/10-12]

There were ten nominations for reference materials, and seven nominations for reference measurement methods for Non-electrolyte metals. All of these had been reviewed, and six reference materials from the NIST were being recommended for approval and publication in the JCTLM database.

4.2.7 Non-peptide hormones (Cycle VII) [JCTLM-EXEC/10-13]

There were two nominations for reference materials, and six nominations for reference measurement methods for Non-peptide hormones. All of these had been reviewed, and of these only one reference material from the NMIJ, and one method were being recommended for approval and publication in the JCTLM database.

4.2.8 Metabolites and substrates (Cycle VII) [JCTLM-EXEC/10-14

There were sixteen nominations for reference materials, and seven nominations for reference measurement methods for Metabolites and substrates. All of the submissions for reference materials had been reviewed, and none of these were recommended for approval and publication in the JCTLM database, due to the lack of certificate or certification report.

The review team had not yet sent feedback on the review of the reference measurement methods submitted for Metabolites and Substrates.

4.2.9 Enzymes (Cycle VII) [JCTLM-EXEC/10-15]

There was one nomination for reference measurement method for ALP, which was not recommended for approval and listing in the database, since the proposed RMP for ALP was not yet published and IFCC approved.

4.2.10 Proteins (Cycle VII) [JCTLM-EXEC/10-16, 40] (Review reports not yet available)

The review team had not yet sent feedback on the review of the reference measurement method submitted for Proteins.

The Committee remarked that there was a high percentage of rejected nominations in the cycle. It was also the first cycle to use the revised nomination forms based on the new ISO standards for Reference Materials and Methods. The Committee recommended that the WGs should review the lessons learnt from this cycle at their next meeting. In addition, the Committee agreed to send further comments on the WG1 recommendations to the JCTLM Secretariat by 31 January before final approval.

Actions

Action (A/10-19): JCTLM Secretariat to update the Instructions document for completing WG1 nominations to state that any documentation should be provided in English in order to be considered by the review team, and that a peer reviewed publication with description of the method and validation data should be attached with the nomination form.

Action (A/10-20): Executive Committee to send their comments on the RT recommendations by the 31 January 2011

4.3 Delisting of RMs and RMPs

There had been no reference materials delisted since the 8th Executive Committee meeting.

4.4 Progress / plans for Cycle VIII call for RMs and RMPs

Dr Wielgosz confirmed that the new call for nominations for Reference Materials, and Methods would be launched in January 2011, with a deadline for submissions in May 2011.

4.5 WG1 quality/ procedure manual

There had been no requests for modifications/updates to the WG1 Quality Manual since the 8th Executive Committee meeting.

4.6 Availability of ISO standards

This was dealt with under agenda point 2.1.

5. JCTLM WG 2 – Reference Measurement Laboratories

5.1 Update on status of accreditation of Reference Measurement Service Providers [JCTLM-EXEC/10-17, 28, 29]

Prof. Siekmann referred to the document JCTLM-EXEC/10-17 which had been prepared by the JCTLM Secretariat, and included the list of the laboratories having their services listed in the JCTLM Database with their accreditation status, as well as the list of those that had been removed from the database as an application for accreditation requirement (ISO 15195 and ISO/IEC 17025) had not been met by 1 January 2010.

He added that some laboratories that had had their services removed in May 2010 were still willing to re-submit their services for review in future review cycles.

Mr Squirrell confirmed that the National Accreditation Bodies were offering an accreditation service for compliance with ISO 15195 in the countries where reference laboratories have had their services delisted.

5.2 Approval of Cycle V Laboratory RMS nominations [JCTLM-EXEC/10-18,19]

Dr Maniguet reported that there was one reference measurement service for Enzymes, and three for Electrolytes submitted and reviewed during WG2 Cycle 5. Non of these were recommended for approval and listing in the database, given that the services were based on reference measurement methods not listed in the JCTLM Database.
The committee approved these recommendations.

5.2.1 Accreditation deadline and actions

Dr Wielgosz reported that one laboratory had submitted copies of its accreditation application letters (JCTLM-EXEC/18, 19), and that the process for accreditation for compliance with ISO 15195 and ISO/IEC 17025 as a calibration laboratory would begin in March 2011.
The committee agreed that the laboratories with listed services which were in the process of being accredited would remain in the database, and would have to demonstrate that their application for accreditation had been accepted by the ABs and that they were ready with their Quality Manual. The Executive asked the Secretariat to contact laboratories and request copies of the acceptation letter for accreditation from their ABs. Failure to provide these letters would result in the delisting of the reference measurement service.
The accreditation status of these laboratories would be re-reviewed in January 2011.

Actions:
Action (A/10-21): JCTLM Secretariat to contact laboratories and request a copy of the acceptation letter for accreditation from the ABs.

5.2.2 Update on IFCC EQAS results

Prof. Siekmann reported that the acceptance limits for EQAS based on a quarter of the total error limit permissible for routine purposes was discussed by the IFCC-CTLM. The next CTLM meeting was scheduled in May 2011.
He also requested that NMIs participate in RELA Scheme. Dr Wielgosz said that links to NMIs could be achieved through the samples being used. Therefore, Prof. Siekmann was invited to contact PTB to see if they would be interested in proposing and coordinating a CCQM study based on the RELA materials.

Actions:
Action (A/10-22): Prof. Siekmann to contact the PTB to see if they would be interested in coordinating a CCQM study with a RELA sample.

5.2.3 Re-review of database entries –post accreditation deadline (2011) and with modified comparison participation requirements

The committee asked that the Secretariat to contact the laboratories to inform them that they would need to provide a copy of the accreditation certificate and an update of their participation in RELA exercise by the 01 January 2013.

Actions:
Action (A/10-23): Secretariat to contact the laboratories to inform them of the deadline of 01 January 2013 by which they would need to send a copy of their accreditation certificate and an update of their participation in RELA exercice.

5.2.4 Progress / plans for Cycle VI call for Laboratory RMSs

Dr Wielgosz confirmed that the new call for nominations for Reference Measurement Services would be launched in January 2011 in parallel to the call for Reference Materials and Methods.

5.3 WG2 quality/ procedure manual

There had been no requests for updates of the WG2 procedure manual during the year.

5.4 Revision of ISO 15195

This issue was dealt with under 2.1.

6. JCTLM WG3 - Publications [JCTLM-EXEC/10-31]

6.1 Terms of reference and proposed work programme for WG3

Dr Jones said that there were no terms of reference for WG3 and a work programme for WG3 was yet to be approved by the Executive. Furthermore he said that he was not in favour of the establishment of a third WG on publications.
Considerable discussion followed on which structure would be the most appropriate to focus on publications promoting/describing JCTLM activities. The Committee agreed that an ad hoc WG3 be formed, and that two position papers be drafted, and coordinated by Dr Jones.
The first position paper would be drafted with the participation of Prof. Müller, Dr. Kaarls, and Dr Schimmel, and would be dealing with the history and function of the JCTLM.
The second position paper would be drafted with the participation of Prof. Siekmann, Dr. Kaarls, and Dr Wielgosz, and would focus on how to implement metrological traceability / and possible revisions to ISO 17511.

Action
Action (A/10-24): Dr Jones to coordinate ad hoc WG3 for the drafting of two position papers

6.2 Draft Traceability statement

The committee agreed to comment on the draft of the Traceability Statement from Dr Jones (JCTLM/10-31) by 31 January 2011.

Action
Action (A/10-25): EC members to send their comments on the draft for traceability statement by 31 January 2011.

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

There were no documents submitted during the year.

8. Liaison with the EC [JCTLM-EXEC/10-30]

8.1 Correspondence from DG Enterprise

This issue was dealt with under 3.7.

8.2 Liaison with the Global Harmonization Task Force (GHTF) [JCTLM-EXEC/10-32,33,34]

Dr Wielgosz informed the committee that GHTF had not yet sent any feedback to JCTLM further to the comments made by JCTLM on the STED document.

Actions
Action (A/10-26): JCTLM Secretariat to contact GHTF to request information the status of GHTF STED document and a response to comments made by the BIPM and the IFCC.

9. Liaison with the WHO

9.1 Issues arising from the WHO-ECBS meeting (IFCC)

Prof. Müller informed the committee that Dr Ian Young was the new contact liaison for WHO-ECBS, and would ask him to provide a copy of the last meeting report for circulation to the members of the Committee.

Dr Wielgosz commented that the WHO-ECBS was moving towards metrological traceability considering that projects focusing on the value assignment of the amount of small protein reference materials such as insulin in SI units had been tabled at their last meeting.
Dr Schimmel commented that the JCTLM would have a key role to play in such cases to ensure that value assignments in SI-units would guarantee that the measurement results were traceable to the SI system.
The Chairman concluded that the JCTLM should re-establish an active liaison with the WHO, and arrange a meeting with them.

Actions
Action (A/10-27): Prof. Müller to circulate the last year's WHO-ECBS meeting report

10. Liaison with ISO TC 212[JCTLM-EXEC/10-36]

Dr Schimmel informed the committee that ISO 15189 was under revision and appeared to not follow the VIM 3 definition of the measurand.
Prof. Siekmann explained that he had sent his comments to the ISO TC 212 WG2 convener regarding the revision of the standard ISO 17511 (JCTLM-EXEC/10-36), and that to date he had no response. The Committee agreed that the JCTLM via the IFCC, BIPM, and IFCC would contact ISO TC 212 to point out the need for revision of the ISO 17511 and ISO 15195 standards in the framework of the WG2 ISO TC 212.

Actions
Action (A/10-28): IFCC, BIPM, and ILAC to contact ISO TC 212 Secretariat to address the need for revision of the standards ISO 17511 and ISO 15195

11. Report from related activities/meetings

11.1 AACC meeting on Harmonization [JCTLM-EXEC/10-35]

Prof. Siekmann reported on the AACC meeting on harmonization that was held at NIST in October 2010. He expressed his concerns on the fact the harmonization would have to deal with heterogeneous analytes. Considering the lack of method specificity, and the fact that different isoforms could be measured, one has to be careful to deliver the correct medical diagnosis.
He concluded that a structure has been proposed, and that further actions should be taken within the AACC.

11.2 Master Comparisons Proposal

Master Comparisons schemes for manufacturers had been proposed at last year's meeting, with the aim of creating a database documenting the current standardization status on commutable sera.
Prof. Müller reported that Prof. Thienpont's proposal had been discussed with the IFCC Scientific Division, and they commented that reference method values needed to be used for such comparisons as far as these were available, and that the name of the manufacturer should be disclosed. To date the issue of disclosure of the manufacturer's name remained a critical point in the discussion which was still ongoing.

11.3 Facilitation of a 'gap analysis' in traceability

Prof. Müller proposed to distribute the outcomes of the IFCC survey identifying priorities for analyte standarization.

12. Publicity for the JCTLM

There was no further discussion of this topic.

13. Future meetings of the JCTLM

13.1 Meetings for 2011 and 2012

It was proposed that the JCTLM Working Groups meeting be held preceding the AACC meeting in July 2011 in Atlanta. The date of Saturday 23 July was retained with a WG1 and WG2 morning session, and *Ad Hoc* WG3 in the afternoon. The JCTLM Secretariat would contact Dr May to see if a meeting venue could be arranged.

The 10th and 11th meetings of the JCTLM Executive would be held at the BIPM on 8 and 9 December 2011, and on 6 and 7 December 2012, respectively.

Actions
Action (A/10-29): JCTLM Secretariat to contact Dr May to see if a meeting venue can be arranged for JCTLM WGs on 23 July 2011 in conjunction with the AACC meeting.

13.2 JCTLM Symposium and Stakeholder meetings (2011)

Dr Wielgosz proposed that a sub-committee be formed to establish the agenda of the next JCTLM Symposium and Stakeholder meeting.
Prof. Müller replied that in line with earlier discussion he would write first to WordLab 2011 to propose a Workshop with a session on JCTLM which would be based on the CLINBIOTRACE programme Workshop. The venue for the next Stakeholder Meeting would be either PTB or WordLab in Berlin depending on their responses.

Actions
Action (A/10-30) : Prof Muller to confirm date and venue for a proposed 2011 JCTLM Stakeholder's meeting.

13.3 Future JCTLM activity

In the discussion that followed on future activity for the JCTLM, it was agreed that efforts are needed to re-engage close working relationship with WHO as well as other professional communities (e.g. Coagulation and Haematology) active in Laboratory Medicine.

14. Close

The Chairman closed the meeting on 3 December at 13:30.

S.Maniguet/ R. Wielgosz (BIPM) 19/1/11

Annex 1: Summary List of Actions

Actions from the 9th Executive Meeting

Action (A/10-01): JCTLM Secretariat to update the documents related to JCTLM WG1 and WG2 Quality Manual/Procedures, in order to remove revision marked in red, for the procedures approved during last year's meeting.
Action (A/10-02): BIPM to address the issue of the revision of the ISO 15195 standard at the BIPM/ILAC/ISO to be held at the BIPM in March 2011
Action (A/10-03): Dr. H. Schimmel to provide Prof. M. Müller with the final program of the workshop organized in the framework of the EMRP project on CLINBIOTRACE
Action (A/10-04): Prof. M. Müller to contact by email Bernd Guettler from the PTB, and the organizers of the workshop, and see if it is still possible to schedule the workshop at the congress IFCC-WordLab 2011 in Berlin.
Action (A/10-05): JCTLM Secretariat to circulate the revised text for the Declaration of Cooperation amongst the three sponsoring organizations for their approval
Action (A/10-06): JCTLM Secretariat to inform the JCTLM member organizations of their obligations, and that they would need to report regularly on their activity in support of the JCTLM.
Action (A/10-07): JCTLM Secretariat to circulate the revised document for the Review Teams' terms of reference for review team leaders' comments.
Action(A/10-08): JCTLM Secretariat to provide IFCC with the budget request and activity report for JCTLM Secretariat activities.
Action (A/10-09) : Dr Wielgosz to contact Mrs Parkes for further information on suggested modifications to the JCTLM Database.
Action (A/10-10) : JCTLM Secretariat to develop a feedback page on the JCTLM website for comments.
Action (A/10-11) : Prof. Müller will contact the Austrian Ministry of Health to identify an appropriate contact.
Action (A/10-12): Prof. Siekmann will contact the PTB to investigate how Germany deals with IVD Directive's requirements.
Action (A/10-13): Dr Wielgosz to address the need for a strategy for lobbying for JCTLM at the Metchem Meeting in 2011.
Action (A/10-14): ILAC to contact ISO to see if it would be possible for JCTLM to purchase electronic versions of each of the standards for use by JCTLM Review Team members
Action (A/10-15): BIPM, ILAC, and IFCC to comment on ISO 17511 which is pending for systematic revision
Action (A/10-16): The JCTLM Secretariat to remove arbitrary names as needed for reference measurement methods listed in the database.
Action (A/10-17): Prof. Siekmann to contact the PTB regarding the outstanding Blood Cell Counting nominations to see if the major non-compliances have already been corrected.
Action (A/10-18): WG1 and Review team on Proteins to review currently listed reference methods and materials for HbA1c and recommendations on whether both Reference Methods and Materials for HbA1c should remain listed or be removed from the database. .
Action (A/10-19): JCTLM Secretariat to update the Instructions document for completing WG1 nominations to state that any documentation should be provided in English in order to be considered by the review team, and that a peer reviewed publication with description of the method and validation data should be attached with nomination form.
Action (A/10-20): Executive Committee to send their comments on the RT recommendations by the 31 January 2011

Action (A/10-21): JCTLM Secretariat to contact laboratories and request a copy of the acceptation letter for accreditation from the ABs.
Action (A/10-22): Prof. Siekmann to contact the PTB to see if they would be interested in coordinating a CCQM study with a RELA sample.
Action (A/10-23): Secretariat to contact the laboratories to inform them of the deadline of 01 January 2013 by which they would need to send a copy of their accreditation certificate and an update of their participation in RELA exercise.
Action (A/10-24): Dr Jones to coordinate ad hoc WG3 for the drafting of two position papers
Action (A/10-25): EC members to send their comment on the draft for traceability statement by 31 January 2011
Action (A/10-26): JCTLM Secretariat to contact GHTF to request information the status of GHTF STED document and a response to comments made by the BIPM and the IFCC.
Action (A/10-27): Prof. Müller to circulate the last year's WHO-ECBS report meeting
Action (A/10-28): IFCC, BIPM, and IFCC to contact ISO TC 212 Secretariat to address the need for revision of the standards ISO 17511 and ISO 15195
Action (A/10-29): JCTLM Secretariat to contact Dr May to see if a meeting venue can be arranged for JCTLM WGs on 23 July 2011 in conjunction with the AACC meeting
Action (A/10-30): Prof Muller to confirm date and venue for a proposed 2011 JCTLM Stakeholder's meeting.