Report of the 10th meeting of the JCTLM Executive Committee 8-9 December 2011, 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)
Prof. M. Kühne (BIPM)
Dr G. Beastall (IFCC)
Prof. L. Thienpont (JCTLM WG 2 Chair)
Dr K. Phinney (NIST)

Apologies received:
Dr H. Schimmel (JCTLM WG1 Chair)
Dr R. Kaarls (BIPM)
Dr W.E. May (JCTLM WG1 Chair)

Prof. Müller opened the meeting, and welcomed Dr Phinney from NIST who was representing Dr May at the meeting.

1. Approval of the agenda [JCTLM-EXEC/11-01]

The agenda was accepted with no changes.

2. Report of 9th JCTLM Executive Committee Meeting

There were no comments on the report of the 9th Executive Committee meeting, which had been finalized in February 2011, and published on the JCTLM website.

2.1 Review of action points arising from the 9th meeting [JCTLM-EXEC/11-02]

Dr Wielgosz summarized the action items that were still outstanding:
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
Dr Wielgosz reported that this issue could not be addressed during the tri-partite meeting in March 2011 in the absence of the representatives of ISO. However, the issue of the status of the ISO 15195 had been addressed at the ISO TC 212 meeting held in October 2011 in Las Vegas, and will be dealt with under the agenda item 10.
Action (A/10-05): JCTLM Secretariat to circulate the revised text for the Declaration of Cooperation amongst the three sponsoring organizations for their approval
This revised text had been circulated for comments amongst the members of the Executive Committee, and the final draft of the modified text of the Declaration of Cooperation [JCTLM-EXEC-11-26] will be presented at the next agenda item.
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.

This action was pending the approval of the revised text of the Declaration of Cooperation by the three sponsoring organizations.

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

The revised document of the Terms of References (ToRs) of the review teams was discussed during the last JCTLM Working Groups' Meeting in Atlanta. There had been no further comments received from the WGs/Leaders of the Review Teams. This issue will be dealt with under agenda item 3.4.2.

Action (A/10-11): Prof. Müller will contact the Austrian Ministry of Health to identify appropriate contact.

Prof. Müller reported that he had been unable to identify a specific contact that was dealing with traceability issues related to the *In Vitro* Diagnostic Directive in Austria. He reported that the Austrian Ministry on Commerce was mainly responsible for the IVD Directive, but only had a small activity in the area as Austria did not have a large IVD industry sector.

Action (A/10-12): Prof. Siekmann will contact the PTB to investigate how Germany deals with IVD Directive's requirements

Prof Siekmann reported that target values were set by the Reference Laboratories which were required by law to participate regularly in EQAS surveys for their accreditation for compliance with ISO 15195, and that the appropriate body was the Ministry of Health in Germany which was dealing with IVD Directive's requirements.

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

The action was completed, and this would not be possible due to issues of copyright.

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

Prof Siekmann reported that the English version of standard describing the developed reference measurement methods for Blood Cell Counting were not yet available, and that these were expected to be published in English in April 2012 according to the recent contact he had with the laboratory in charge of these methods. These nominations which had been reviewed during Working Group Cycle 7 (2010) would remain deferred until this non-compliance was resolved.

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

This issue was discussed during the last Working Groups Meeting in Atlanta in July, where it was decided that the materials and methods listed for HbA1c should be reviewed by the Proteins Review Team Leader, who had not sent any feedback to date.

The members of the committee requested the WG1 Chair to contact D. Bunk to identify whether or not the HbA1c items should be re-reviewed or should remain listed as being of a higher metrological order in the JCTLM database.

Prof Siekmann expressed his concerns on the consequences of not having primary reference material for hemoglobin with a certificate with a stated uncertainty. This had led the Reference Laboratory he had been responsible for to withdraw its HbA1c measurement services.

In the discussion that followed, the Chairman proposed that a closed meeting be organized to enable the reference materials producers, reference measurement methods developers and participants in the HbA1c network to clarify the traceability issue for the HbA1c reference measurement system being listed in the JCTLM database. Prof Siekmann agreed to prepare a

short discussion paper for the Executive outlining the current status of primary calibrators for HbA1c.
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.
Prof Siekmann reported that there were no requests yet for RELA sample to be used in CCQM study, and that some National Metrology Institutes had participated in the RELA Scheme 2011 from the invitation of the PTB.
Dr Phinney reported also that subsequent studies in clinical chemistry were foreseen to be scheduled in the five year plan of the CCQM Organic Working Group, and that coordination for the use of RELA sample could be proposed for these studies and agreed to coordinate these discussions with CCQM OAWG.
Action (A/10-25): EC members to send their comment on the draft for traceability statement by 31 January 2011
This action has not been completed, and will be dealt with under agenda item 6.
Action (A/10-26): JCTLM Secretariat to contact GHTF to request information on the status of GHTF STED document and a response to comments made by the BIPM and the IFCC.
Dr Wielgosz reported that Global Harmonized Task Force (GHTF) had published the Summary Technical Documentation (STED) for demonstrating conformity to the essential principles of safety and performance of *in vitro* diagnostic medical devices in March 2011 on its website. This includes under paragraph 10.1.2.4 a statement on metrological traceability of calibrator and control material values.
The Committee acknowledged that the GHTF STED document would promote the importance of metrological traceability to regulators worldwide although there was no clear reference to JCTLM.
Action (A/10-30): Prof Müller to confirm date and venue for a proposed 2011 JCTLM Stakeholder's meeting.
There was no Stakeholder's meeting in 2011.

New Actions (see Annex 1 for full list):
Action (A/11-01): WG1 Chair/Dr Phinney to contact D. Bunk to clarify whether or not the HbA1c materials and methods should be re-reviewed or remain listed.
Action (A/11-02): IFCC to organize a closed meeting in conjunction with the next WGs meetings to clarify the traceability issue regarding the HbA1c reference measurement system components being listed in the database.
Action (A/11-03): Prof Siekmann to prepare a short discussion paper for the Executive outlining the current status of primary calibrators for HbA1c.
Action (A/11-04): Dr Phinney to coordinate discussions within CCQM OAWG on the use of RELA samples for relevant CCQM comparisons

3. JCTLM Framework and Declaration of Cooperation

3.1 Modified text for Membership Obligations and Privileges [JCTLM-EXEC/11-26]

Dr Wielgosz presented the document JCTLM-EXEC/11-26 which modified the text of the Declaration of Cooperation (DoC) between the CIPM, IFCC and ILAC, and of its Appendices III and IV. He summarized the amendments to the text, and highlighted those made after last year meeting, notably the point 5 of the text of the DoC for the JCTLM Structure and Operation which would read that the operating budget for the JCTLM Secretariat would be presented and discussed between the sponsoring organizations at the annual Executive meeting preceding the year for which the budget is set.

The Committee agreed on the final draft of the revised JCTLM Declaration of Cooperation which would be circulated for comments amongst the sponsoring organizations for their approval.

Actions:
Action (A/11-05): JCTLM Secretariat to circulate the revised text for the Declaration of Cooperation amongst the three sponsoring organizations for their approval, and to follow up the action A/10-06 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

Dr W. May had informed the committee of his resignation as co-Chair of the Working Group 1, and had proposed to nominate Dr. K. Phinney from NIST as candidate for WG1 co-Chair position. The Committee thanked Dr. W. May for his work and important contribution over the years in support of the JCTLM.

The procedure for the selection and appointment of the Working Group Chairs for renewable two year periods was followed. The executive committee welcomed the nomination of Dr. Phinney who was appointed as a new co-Chair of WG1, and re-appointed Profs Siekmann, and Thienpont as co-Chairs of WG2. It was further agreed that the re-election of Dr Schimmel as co-Chair of WG1 would be dealt with by email after he had confirmed he was still willing to be candidate for WG1 chairmanship.

Actions:
Action (A/11-06): JCTLM Secretariat to contact Dr. Schimmel to verify if he would be willing to continue in his role as WG1 co-chair.

3.3 JCTLM membership

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/11-03, 27]

Dr Wielgosz presented the documents JCTLM/11-03, and 27, which summarized the review team membership on 19 July 2011 by working group and analyte type, and included a new application for membership of the review team for Drugs. The JCTLM Executive Committee approved the membership application from Dr Brian Keevil from the University Hospital of South Manchester (United Kingdom) for the Drugs WG1 and WG2 Review Teams.

Prof Siekmann expressed his concerns on the lack of active participation of some of the members of the review teams for the review of the submissions, and proposed that their membership be limited in time. The members of Executive Committee agreed on the need to set a renewable five year time periods for review team membership.

Actions:
Action (A/11-07): JCTLM Secretariat to modify the Executive procedure for the appointment of the members of the review teams to include the term for membership of five years renewable for 5 year periods.

Action (A/11-08): JCTLM Secretariat to contact the leaders of the review teams to inform them of the term for membership that would be applicable from January 2012, and request them to confirm the list of their review team members.

3.4.2 Review Team Scope of activities [JCTLM-EXEC/11-31, 32]

Dr Wielgosz reminded the members of the Executive Committee that there were two existing documents. The first document for the review teams' scope of activity which was currently published on the JCTLM website [JCTLM-EXEC11-31] had been drafted by the leaders of the review teams. The second document [JCTLM-EXEC11-32] which had been drafted by C. Jackson and commented during last year executive committee was still pending revision from the review teams.
The Executive Committee requested that the WG1 & 2 chairs should circulate by email these two documents for review by the Review Team Leaders in order to provide an amended version of the review teams' terms of reference for approval at the next working groups' meeting.

Action
Action (A/11-09): WG1 & 2 Chairs to circulate by email to the review team leaders the two documents of the review teams' Terms of Reference for their comments by June 2012, and to provide the final draft of the ToRs for its approval during next WGs meeting in July 2012.

3.5 Funding of the JCTLM Secretariat [JCTLM-EXEC/11-34]

Dr Wielgosz presented the document JCTLM/11-34 which summarized the activities, the resources and the costs of the JCTLM Secretariat for 2011. He further added that this latter document as well as the invoice which was sent in November 2011 to the IFCC was based on the time sheet record in use at the BIPM. The operating costs of the JCTLM Secretariat included the tasks related to the organization of JCTLM Executive meeting and related documentation, the processing of JCTLM submissions and reviewed nominations, the development and the maintenance of JCTLM Database, the activity for liaison with external organizations related to JCTLM, the organization and attendance to the WGs meeting, the drafting of the report meetings. The effective cost for 2011 JCTLM Secretariat appeared to be in line with that foreseen and presented in the document JCTLM EXEC 10-24 which was 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 for inflation.

3.6 JCTLM Database

Dr Maniguet gave an update on the JCTLM Database which currently lists 247 Certified Reference Materials (CRMs), 152 Reference Measurement Procedures (RMPs) and 86 Reference Measurement Services (RMSs) with the publication of the 20 new entries for reference materials and 6 for methods approved during last year's meeting. A feedback user form was developed and posted onto the database website at the beginning of December further to the request of the Executive Committee during its last meeting. The data extracted from this customer survey would only be processed to identify the specific/potential needs and concerns regarding materials, methods or laboratory services in the field of laboratory medicine, and to highlight the appropriateness of the information available from the database website. A number of future developments were proposed for next year, which would responds to requests made during the past WGs meetings. These included the addition of a frequently asked question page, a beginners' guidance webpage for organizations submitting nominations for the first time, and a webpage to highlight the benefit of claiming traceability

to JCTLM database entries. These pages would be drafted for discussion during the next WGs meeting. Future improvements to the database which would require the modification of the web system were also proposed in response to requests from database users. The first development which was foreseen would allow the download of all entries for materials, methods or services. The second development would remove the duplication of publication of measurement methods which could apply to materials of the same kind. The latter modification will be done in collaboration with the WG2 Chairs.

Prof. Siekmann commented that there were reference measurement methods published with the arbitrary statement for the uncertainty "The expanded uncertainty is a relative one" which was not relevant and should be removed. The Executive Committee agreed on the removal of the comments where appropriate.
Prof. Siekmann further added that the expanded uncertainties declared in the JCTLM database for some reference measurement laboratory services were not consistent with the scope of accreditation stated in the certificates, and that could be confusing when for instance the German or Italian accreditation bodies requested that a minimum value be stated for the uncertainty. Dr Maniguet replied that the JCTLM Secretariat was not allowed to modify the data submitted by the laboratory when approved for listing by the Executive. However, the services of the laboratories which had been accredited after their publication in the JCTLM database were reviewed for consistency with that stated in the certificate, and the values for the measurement and uncertainty ranges were modified in line with that of the certificate when the laboratory had agreed with the update. Dr Wielgosz proposed that the existing WG2 procedure should be modified to include the requirement for the uncertainty stated in the JCTLM database to match that given in the laboratory's scope of accreditation. The Committee agreed with the proposal.

Prof. Siekmann commented that the clinical chemistry community used concentration in the description of the measurand rather than the mass fraction which was preferred by the National Metrology Institutes producing reference materials. Dr Phinney stated that the current practice at NIST was to produce the certified value as a mass fraction, and then to perform density measurements so that the value could be expressed as a concentration as preferred by their users.
The committee proposed that this issue be addressed in a paper to the NMIs.

Prof. Thienpont commented that there was a need for improvement with regards to consistency in the analyte names listed in the database. Dr Maniguet replied that the reviewed data were published as approved for listing, but that synonyms could easily be added to the database to ensure consistency in search results.

Actions:
Action (A/11-10): JCTLM Secretariat to remove arbitrary comment stating that the expanded uncertainty is a relative one where appropriate in the JCTLM list for methods.
Action (A/11-11): JCTLM Secretariat/WG2 chair to modify the WG2 procedure to include the requirement for consistency of the expanded uncertainty ranges in the database with that stated in the accreditation certificate.
Action (A/11-12): Prof. Siekmann to draft a paper addressing the issue on the use of the concentration versus the mass fraction**.**
Action (A/11-13): JCTLM Secretariat/Prof Thienpont to review the analyte names in the database to improve the consistency of the information provided to the user.

4. JCTLM WG1

4.1 Report of the JCTLM WG1, 2 and 3 meeting, July 2011, Atlanta US [JCTLM-EXEC/11-04, 30, 35]

Dr Wielgosz presented the document JCTLM EXEC/11-04 which described the issues and actions raised during the discussions with WGs in July, and JCTLM-EXEC/11-35 which included the comments from D. Armbuster on the WGs meeting outcomes. The following outstanding issues were discussed:

(Issue 3) An improved statistical test/approach for testing of commutability needs to be developed

Prof. Thienpont said that she had been involved in the development of the CLSI guideline C53 on commutability, and was not aware if there was currently a statistical group working on commutability. However, she added that the main issue with commutability measurement results resided with finding an adequate procedure (and criteria) for assessment of samples that are related to each other, for example, a set of 5 samples intended for recalibration of an assay. For obvious reasons it makes no sense to assess the commutability of each sample separately, but as a set, which requires different criteria. In the discussion that followed it was said that the commutability issue could to be dealt with jointly by the appropriate CLSI Sub-Committee, and the IFCC Scientific Division, and that the contribution from the NMIs could be helpful for statistical issues. Meanwhile, Prof. Thienpont heard that the CLSI EP14-A2 is under revision.

(Issue 6) Reference to the validation protocol guidance given in Clinical Chemistry maybe useful for those preparing publications

(Issue 8) Further guidance on submissions maybe useful including a mandatory requirement to read the relevant ISO standards so that an assessment on whether to submit a nomination can be made by the nominating institute

It was suggested that the reference to the validation protocol guidance in Clinical Chemistry, as well as the statement that nominations would have to fulfil ISO 15194 &15193 requirements would be included in the beginner's guidance webpage that would be proposed on the JCTLM webpage.

(Issue 9) Suggestions on further information for those submitting nominations for the first time, included development of: a JCTLM beginner's pack, frequently asked questions section, and an explanation of the value of listing in the JCTLM database

The issue will be addressed by the Secretariat. From D. Armbuster's comments, Dr Phinney agreed that her July 11 presentation be posted on the website as an example of a correctly completed submission.

(Issue 10) The link between patient safety and traceability of measurement results needs to be raised and explained as this is not sufficiently promoted at the moment

The BIPM, the NIST and the IFCC expressed their interest in participating in a possible study on the economic and patient safety impact from the lack of traceability. Dr Beastall suggested that he would draft the Term of Reference/key aims for the study prior to advance further in the study specifications.

(Action 1): the two terms of reference (ToR) documents for Review Teams to be circulated to Review team Leaders and ToRs harmonized and final document developed with WG Chairs.

This was discussed under previous agenda item.

(Action 3): HbA1c nomination to be treated in Cycle 8 review due to late submission/ modification of submission

(Action 4): Proteins Review Team Leader (Dr D. Bunk) to resolve issues related to Total Protein Nomination and HbA1c methods and materials comments and nominations
The committee asked Dr. Phinney to contact Dr Bunk to seek for feedback on the review of the Protein nominations.
(Issue 18): ISO 17511 does not deal appropriately with purity determinations for primary calibrators and needs to be modified
Dr Wielgosz said that a paper on metrological approaches to purity was being drafted by the BIPM, as this was currently in the work programme of the Chemistry Department. This and the comparison programme on primary calibrators led by the BIPM would provide input for the redrafting of ISO 17511.
(Action 6): Progress on Harmonization activities (www.harmonization.net) to be discussed at the JCTLM Executive meeting and led by IFCC
The action will be dealt with under agenda point 4.7.
(Issue 24) Marketing of JCTLM is limited and the relevance of the work needs to be explained and impact/case studies added
This was dealt with in the previous Issue 10.
(Issue 25) Branding and relevance of JCTLM can be raised by the adoption of statement's by manufacturers that their test results are traceable to JCTLM listed materials/measurement service results.
The AACC Industry Division had expressed an interest in promoting the JCTLM brand, and that this could be discussed further with industry representatives during the AACC Meeting in July 2012.
The Committee agreed that the draft statement on traceability would be based on the JCTLM EXEC/10-31 which described recommendations on statements regarding the JCTLM and traceability that could be used in industrial packages.

Actions:
Action (A/11-14): Dr Beastall to draft the aims and structure of a possible study on the impact of metrological traceability in laboratory medicine and clinical chemistry.
Action (A/11-15): Dr Phinney to contact Dr Bunk to seek for feedback on the review of the Proteins nominations
Action (A/11-16): The Executive Committee to comment on the document JCTLM EXEC/10-31 by the 15th of January 2012

4.2 Approval of Cycle VIII 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 for review to WG1. There was one nomination for reference measurement method for HbA1c which had been submitted for review cycle 7. In addition, there were forty nominations for reference materials for five groups of analytes, and seven nominations for reference measurement methods for five groups of analytes which had been submitted for review cycle 8.

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 Drugs [JCTLM-EXEC/11-05, 33]

There were three nominations for reference materials for Drugs. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database.

It was noted that the two nominations for serum digoxin reference materials from LGC were recommended for approval although these were not yet released as the completion of the procedure for ERM-approval was due to the end of December. The Committee stated that the materials would not be listed if those were not available by January 2012.

4.2.2 Electrolytes [JCTLM-EXEC/11-06, 25]

There were three nominations for reference materials for Electrolytes, which were re-submissions after last year's review cycle. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database.

It was noted that CENAM had provided the English translations of the supporting review documents in response to last year review team's comments.

4.2.3 Enzymes [JCTLM-EXEC/11-07, 08]

There was one nomination for reference measurement method for ALP, which was recommended for approval and listing in the database.

4.2.4 Non-electrolyte metals [JCTLM-EXEC/11-09, 10]

There were eight nominations for reference materials for Non-electrolyte metals. All of these had been reviewed, and three entries from the LGC ERM-DA120a as well as two entries from the NIST reference material SRM 955c were being recommended for approval and publication in the JCTLM database.

4.2.5 Metabolites and substrates [JCTLM-EXEC/11-11, 12, 13, 14]

There were twenty-five nominations for reference materials, and one nomination for a reference measurement method for Metabolites and Substrates. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database.

It was noted that some of the members of the review teams commented that the certificate of analysis for the SRM 972 Vitamin in human serum reference material from the NIST needed a more definitive statement on commutability. The committee commented that the commutability statement from the producer was an ISO 15194:2009 requirement, and that its members would review further these nominations by the 15th of January 2012.

Prof. Siekmann explained that the Cholesterol ID GC MS reference measurement method nomination was a submission from the CDC, and that they may wish to with draw their previous Abel-Kendall method listed for Cholesterol measurement.

Dr Wielgosz stated that he would review the stability information related to submitted amino acid materials and make any comments by 15th of January.

Actions

Action (A/11-17): JCTLM Secretariat to contact CDC to verify if they wish to withdraw their Abel-Kendall reference measurement method for Cholesterol from the JCTLM database after publication of their improved method.

Action (A/11-18): The BIPM to review stability information related to submitted amino acid materials

4.2.6 Non-peptide Hormones [JCTLM-EXEC/11-15, 36, 37]

There were three nominations for reference measurement methods for Non-Peptide Hormones. All of these had been reviewed, and of these one for free thyroxine measurement method was being recommended for approval and publication in the JCTLM database.

It was noted the two remaining nominations had not been recommended as there had not been published yet.

Prof Thienpont commented that there must have been a misunderstanding for the Cortisol reference measurement method nomination submitted by the University of Ghent laboratory for review cycle 8. It was never their intention to nominate the ID-LC/tandem MS procedure for listing in the database. She explained that the JCTLM WG1-02-F-02 file submitted together with the supporting validation report was meant to provide evidence for the modified /updated Cortisol reference measurement service that could be delivered by the University of Ghent laboratory.
The Committee stated that these should be returned to the review team for review.

4.2.7 Nucleic acids [JCTLM-EXEC/11-16] (Review report not yet available)

There was one nomination for reference material for Nucleic acid, and the review was still ongoing.

4.2.8 Proteins (Cycle VII) [JCTLM-EXEC/11-17] (Review reports not yet available)

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

4.2.9 Vitamins [JCTLM-EXEC/11-1, 36, 37]

There were two nominations for reference measurement methods for Vitamins. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database.

The Committee agreed to send further comments on the WG1 recommendations to the JCTLM Secretariat by 15 January before final approval.

Actions
Action (A/11-19): Executive Committee to send their comments on the RT recommendations by the 15 January 2012

4.3 Delisting of RMs and RMPs

There had been no reference materials delisted since the 9th Executive Committee meeting.

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

Dr Wielgosz confirmed that the new call for nominations for Reference Materials, and Methods would be launched on the 1st of February 2012, with a deadline for submissions in May 2012.

4.5 WG1 quality/ procedure manual

There had been no requests for modifications/updates to the WG1 Quality Manual since the 9th Executive Committee meeting.

4.6 Availability of ISO standards

This was dealt with under agenda point 2.1.

4.7 Update on AACC Harmonization Initiative [JCTLMWG/11-18]

Dr Beastall reported on the progress on harmonization activities since the 9th Executive Committee meeting, notably the launch of a website, and the establishment of WGs for the process and the governance. The next meeting of the WGs in the Harmonization initiative was going to be held in May 2012 in Washington DC.

During the discussion that followed the Committee agreed that the update on the AACC Harmonization Initiative should be a permanent agenda item for future EC meetings. Also the Committee agreed that JCTLM should increase its involvement in the harmonization process. It was proposed that a JCTLM representative should attend the meeting in May as an observer.

Actions

Action (A/11-20): Dr Beastall to contact the secretariat of the Harmonization Executive and request an invitation for the JCTLM (represented by Dr Wielgosz) to attend the AACC Harmonization meeting in May 2012 to ensure the linkage/liaison between both the harmonization and standardization processes.

5. JCTLM WG 2 – Reference Measurement Laboratories

5.1 Update on status of accreditation of Reference Measurement Service Providers

Dr Maniguet referred to the document JCTLM-EXEC/10-17, and updated the Committee on the status of accreditation of Reference Measurement Service Providers for which the services were pending accreditation at the 9th Executive Committee meeting. One laboratory had been accredited in September 2011 for compliance to ISO 17025 and 15195 as calibration laboratory for all its 12 remaining services listed in the database. Two other laboratories were still in the process of getting accreditation as of 08 December 2011.
The Committee stated that the laboratories that do not fulfill the requirement for accreditation by the set deadline of 1 January 2012, would be delisted from the JCTLM database. It was further added that those laboratories would be directly re-instated in the database following the receipt of the accreditation certificate.

Actions

Action (A/11-21): JCTLM Secretariat to remove the reference measurement services from the JCTLM Database for the laboratories which have not provided a copy of their certificate of accreditation by 1 January 2012.

5.2 Approval of Cycle V Laboratory RMS nominations [JCTLM-EXEC/11-21]

Dr Maniguet presented the nominations for reference measurement services, which had been submitted for review as part of WG2 review cycle 6. There were five nominations for services for four groups of analyte.

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

5.2.1 Enzymes [JCTLM-EXEC/11-22]

There was one nomination for ALP reference measurement service which had been submitted by the CIRME (Italy). It had been reviewed, and was being recommended for approval and publication in the JCTLM database.

5.2.2 Metabolites and substrates [JCTLM-EXEC/11-23]

There was one nomination for a triglycerides reference measurement service. The laboratory making the submission was in the process of getting accreditation during the review process. The submission had been reviewed, and was not being recommended for approval and publication in the JCTLM database.

It was noted that it was not clear to the review team whether or not the purity of the primary reference material purchased from a commercial company had been verified by the laboratory, which would prevent the listing of the service. The Committee asked the Secretariat to contact the service provider to clarify the purity issue.

5.2.3 Non-Peptide Hormones [JCTLM-EXEC/11-37]

There was one nomination for a free thyroxine reference measurement service which had been submitted. The laboratory was in the process of getting accreditation during the review process. The submission had been reviewed, and was being recommended for approval and publication in the JCTLM database.

5.2.4 Vitamins [JCTLM-EXEC/11-24]

There were two nominations for a hydroxyvitamin-D3 and D2 reference measurement service which had been submitted. The laboratory was in the process of getting accreditation during the review process. Both nominations had been reviewed, and were not being recommended for approval and publication in the JCTLM database.
It was noted the major non-compliance listed in the review arose from the lack of the laboratory's participation in an interlaboratory comparison program. The Committee agreed that the review team should reconsider its non-recommendation for listing. There was that there no existing RELA schemes for hydroxyvitamins, but the laboratory had found a valuable alternative which should be considered by the review team Prof Siekmann replied that a RELA Scheme for Vitamins measurand could be opened if a request was expressed from a laboratory.

The committee approved the remaining recommendations for WG2 nominations.

Actions:
Action (A/11-22): JCTLM Secretariat to clarify the issue of the purity of the primary calibrator with the nominator of the triglycerides reference measurement service
Action (A/11-23): JCTLM Secretariat to contact Vitamins review team and inform them of the EC's comments.

5.2.5 Accreditation deadline and actions

The issue was dealt with under agenda item 5.2.1

5.2.6 Update on IFCC EQAS results

Prof. Siekmann updated the committee on the IFCC EQAS results, and noted that the number of laboratories participating had increased. For example, fifty laboratories had participated in RELA 2010, which resulted in a total of 250 results with five results by laboratory. He

believed that a number of laboratories that had participated were still developing their reference measurement services, which would explain why they had not yet made nominations to be included in the JCTLM Database.

He further proposed that the JCTLM and IFCC RELA websites promote each othes, as their activities were closely related. It was agreed that the IFCC RELA webpage would include the JCTLM logo with text explaining that ”Participation in the RELA Scheme satisfies a requirement for JCTLM listing of Reference Measurement Services”. The link to the IFCC RELA webpage from the JCTLM webpage would need to be reorganized with some recent RELA information.

Actions:
Action (A/11-24): Prof Siekmann to add the JCTLM logo and appropriate text to the IFCC RELA website.

5.2.7 Re-review of database entries –post accreditation deadline (2012) and with modified ILAC participation requirements

Dr Wielgosz reported that the laboratories had been informed 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.

5.2.8 Progress / plans for Cycle VII call for Laboratory RMSs

Dr Wielgosz confirmed that the new call for nominations for Reference Measurement Services would be launched in February 2012 in parallel to the call for Reference Materials and Methods.

5.3 WG2 quality/ procedure manual

There had been no requests for update to the WG2 procedure manual during the year.

5.4 Revision of ISO 15195

Prof Siekmann reported that the review of the ISO 15195 was expected with the re-launch of the activity of ISO TC 212 following the appointment of a new Chairman. However, so far the ISO Secretariat had not agreed to include ISO/IEC 17025 as normative reference in ISO 15195, which meant that services should be accredited for both standards (as appropriate for the scopes).

6. JCTLM WG3 - Publications

6.1 Update on activities

Dr Jones presented a list of headings for the first position paper he had agreed to write on the history and function of the JCTLM. He agreed to provide a full text version for contributors’ comments by the 15th of February 2012. It was proposed to submit this paper for publication in the CCLM Journal.

He then went on to discuss JCTLM EXEC/11-30 and the CLSI Project C59-P2 on Metrological Traceability, and outlined key points on the revised document. The BIPM and the IFCC commented that they had not had the possibility to read the document in detail. In the discussion that followed, the committee commented that there were inconsistencies with respect to the ISO 17511 document and related standards and requested Dr Jones to report these back to CLSI.

Action
Action (A/11-25): Dr Jones to distribute the draft of the position paper for contributors' comments by the 15th of February.
Action (A/11-26): Dr Jones to report back to CLSI the comments from the EC arising from the revision of the Metrological Traceability CLSI Project C59-P2 document

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

8.1 Correspondence from DG Enterprise

There were no documents from DG Enterprise.

8.2 Liaison with the Global Harmonization Task Force (GHTF) [JCTLM-EXEC/11-19]

This issue was dealt with under 2.1

9. Liaison with the WHO

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

Dr Beastall informed the committee that IFCC SD representative had a meeting in October 2011, and received no further feedback to date from the WHO. He further added that he would contact WHO with regards to their planned Workshop on Commutability.
Dr Wielgosz reported that the BIPM was continuing its collaboration with the NIBSC on the mass fraction content of insulin within a pure insulin material.

10. Liaison with ISO TC 212[JCTLM-EXEC/11-28, 29]

Dr Wielgosz reported that Dr Greenberg was appointed as new chair of ISO TC 212 WG2, and presented the document JCTLM-EXEC/11-28, and 29 which included the ISO TC 212 Convener's reports. The comments received from the systematic review of ISO 17511 would be evaluated to determine if the revision was appropriate.

11. Report from related activities/meetings

There were no reports on related activities/meetings.

12. Publicity for the JCTLM

There was no further discussion of this topic.

13. Future meetings of the JCTLM

13.1 Meetings for 2012 and 2013

It was proposed that the JCTLM Working Groups meeting be held preceding the AACC meeting in July 2012 in Los Angeles. The date of 14 July was retained for meetings with a morning session for the WGs, and a closed meeting to discuss HbA1c reference measurement systems in the afternoon. The date of 15 July was retained for discussion with industry on the traceability statement.

The 11th meeting of the JCTLM Executive would be held at the BIPM on 6 and 7 December 2012.

13.2 JCTLM Symposium and Stakeholder meetings for 2012/2013

It was proposed to hold a Stakeholder meeting in conjunction with EUROMEDLAD in Milan in May 2013.

Actions

Action (A/11-27): Prof Müller to contact Prof Panteghini to see if a JCTLM Stakeholder meeting can be scheduled in conjunction with the EUROMEDLAB 2013 meeting.

14. Any other Business

Prof Muller together with the other Members of the Executive expressed their thanks to Dr Willie May of NIST for his outstanding contribution to the JCTLM, both for his work in establishing the Committee and in acting as Chair of JCTLM WG 1.

15. Close

The Chairman closed the meeting on 9 December at 13:30.

S. Maniguet (BIPM) 21/12/11
Revised R. Wielgosz (BIPM) 23/01/12

Revised 09/03/12

Annex 1: Summary List of Actions

Actions from the 10th Executive Meeting

Action (A/11-01): WG1 Chair/Dr Phinney to contact D. Bunk to clarify whether or not the HbA1c materials and methods should be re-reviewed or remain listed.

Action (A/11-02): IFCC to organize a close meeting in conjunction with the next WGs meetings to clarify the traceability issue regarding the HbA1c reference measurement system components being listed in the database.

Action (A/11-03): Prof Siekmann to prepare a short discussion paper for the Executive outlining the current status of primary calibrators for HbA1c.

Action (A/11-04): Dr Phinney to coordinate discussions within CCQM OAWG on the use of RELA samples for relevant CCQM comparisons

Action (A/11-05): JCTLM Secretariat to circulate the revised text for the Declaration of Cooperation amongst the three sponsoring organizations for their approval, and to follow up the action A/10-06 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.

Action (A/11-06): JCTLM Secretariat to contact Dr. Schimmel to verify if he would be willing to continue in his role as WG1 co-chair..

Action (A/11-07): JCTLM Secretariat to modify the Executive procedure for the appointment of the members of the review teams to include the term for membership of five years renewable for 5 years periods.

Action (A/11-08): JCTLM Secretariat to contact the leaders of the review teams to inform them of the term for membership that would be applicable from January 2012, and request them to confirm of the list of their review team members.

Action (A/11-09): WG1 & 2 Chairs to circulate by email to the review team leaders the two documents of the review teams' Terms of Reference for their comments by June 2012, and to provide the final draft of the ToRs for its approval during next WGs meeting in July 2012

Action (A/11-10): JCTLM Secretariat to remove arbitrary comment stating that the expanded uncertainty is a relative one where appropriate in the JCTLM list for methods.

Action (A/11-11): JCTLM Secretariat/WG2 chair to modify the WG2 procedure to include the requirement for consistency of the expanded uncertainty ranges in the database with that stated in the accreditation certificate.

Action (A/11-12): Prof. Siekmann to draft a paper addressing the issue on the use of the concentration versus the mass fraction**.**

Action (A/11-13): JCTLM Secretariat/Prof Thienpont to review the analyte names in the database to improve the consistency of the information provided to the user.

Action (A/11-14): Dr Beastall to draft the aims and structure of a possible study on the impact of metrological traceability in laboratory medicine and clinical chemistry.

Action (A/11-15): Dr Phinney to contact Dr Bunk to seek for feedback on the review of the Proteins nominations

Action (A/11-16): The Executive Committee to comment on the document JCTLM EXEC/10-31 by the 15th of January 2012

Action (A/11-17): JCTLM Secretariat to contact CDC to verify if they wish to withdraw their Abel-Kendall reference measurement method for Cholesterol from the JCTLM database after publication of their improved method.

Action (A/11-18): The BIPM to review stability information related to submitted amino acid materials

Action (A/11-19): Executive Committee to send their comments on the RT recommendations by the 15 January 2012

Action (A/11-20): Dr Beastall to contact the secretariat of the Harmonization Executive and request an invitation for the JCTLM (represented by Dr Wielgosz) to attend the AACC Harmonization meeting in May 2012 to ensure the linkage/liaison between both the harmonization and standardization processes.
Action (A/11-21): JCTLM Secretariat to remove the reference measurement services from the JCTLM Database for the laboratories which have not provided a copy of their certificate of accreditation by 1 January 2012.
Action (A/11-22): JCTLM Secretariat to clarify the issue of the purity of the primary calibrator with the nominator of the triglycerides reference measurement service
Action (A/11-23): JCTLM Secretariat to contact Vitamins review team and inform them of the EC's comments.
Action (A/11-24): Prof Siekmann to add the JCTLM logo and appropriate text to the IFCC RELA website.
Action (A/11-25): Dr Jones to distribute the draft of the position paper for contributors' comments by the 15th of February.
Action (A/11-26): Dr Jones to report back to CLSI the comments from the EC arising from the revision of the Metrological Traceability CLSI Project C59-P2 document
Action (A/11-27): Prof Müller to contact Prof Panteghini to see if a JCTLM Stakeholder meeting can be scheduled in conjunction with the EUROMEDLAB 2013 meeting.