Report of the 12th meeting of the JCTLM Executive Committee
6 December 2013, BIPM, Sèvres, France

List of participants:
Prof. M. Müller (JCTLM Chairman, IFCC)
Dr G. Beastall (IFCC)
Ms R. Robertson (ILAC)
Dr G. Jones (ILAC)
Dr R. I. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr R. Kaarls (CIPM)
Dr K. Phinney (JCTLM WG1 Chair)
Dr H. Schimmel (JCTLM WG1 Chair)
Prof. L. Thienpont (JCTLM WG 2 Chair)
Prof. L. Siekmann (IFCC, JCTLM WG 2 Chair)
Dr S. Maniguet (JCTLM Secretariat, BIPM)

Apologies received:
Dr. M. Milton (BIPM)
Dr. W.E. May (CIPM)

Prof. Müller opened the meeting, and welcomed Ms Robertson who was representing the ILAC at the meeting.

1. Approval of the agenda [JCTLM-EXEC/13-01]

The agenda was approved with no changes.

2. Report of 11th JCTLM Executive Committee Meeting

There were no comments on the report of the 11th Executive Committee meeting, which had been finalized in March 2013, and published on the BIPM JCTLM website.

2.1 Review of action points arising from the 11th meeting [JCTLM-EXEC/13-02]

Dr Wielgosz summarized the action items that were still outstanding:

Action (A/12-01): BIPM to contact the Chair of the CCQM OAWG in order to verify the possibility to address the issue of the use of RELA samples for relevant CCQM comparisons as a permanent item agenda future OAWG meetings.
This action was completed. Dr Phinney reported that CCQM key comparisons for the measurement of creatinine and glucose were planned to be rerun for which the use of RELA samples could be suitable candidate materials.

Action (A/12-02): BIPM/NIST to review the information available in the NIST SRM certificates of analysis, and to draft guidance on the correction factors that CRM user would need to apply for the conversion of mass fraction to concentration values for discussion at the next WG meeting.
Dr Phinney provided two examples of NIST SRM certificates included in the document JCTLM-EXEC/13-17, which would be made available to the JCTLM WGs.

Action (A/12-03): JCTLM Secretariat to liaise with CDC to inform them on the need to clarify to the database user if there were differences in the measurement results obtained in using Abel-Kendall or their improved IDMS method, and to verify the feasibility of a comparative study including patients' sample and spiked steroid samples.
Dr Wielgosz reported that JCTLM Secretariat contacted the CDC, and the CDC provided on 12 December 2013 the following response with regards to the Abel-Kendall method:
"All clinical and public health decision levels are linked to the Abel-Kendall methodology. It is important for patient care and public health activities that this methodology is maintained as reference method. Therefore, CDC and its network laboratories continue to maintain and to operate the Abel-Kendall method as reference measurement procedure. To meet future needs and facilitate a transition to other methodologies, CDC also maintains a GC/MS-based method as reference measurement procedure. Currently, insufficient data exist describing the relationship between Abel-Kendall and GC/MS using patient specimens. CDC is currently working on generating such data. Because of the resources available to us, we are not able to provide you with a timeline as to when this activity will be finished."

In addition, some members of the Committee pointed out that further guidance was needed for criteria for the removal of a reference measurement method from the JCTLM database. The Committee requested that a proposal should be drafted on the required criteria for posting a reference measurement method in the no longer listed higher-order metrological methods for discussion during the next WGs meeting. Dr Phinney agreed to lead this activity in JCTLM WG1.

Action (A/12-07): **WG1 and WG2 Chairs/Secretariat to contact the Blood gases experts of the review team to verify the current status of higher metrological order items for Blood gases reference measurement systems.**
This action was pending further guidance requested by the Electrolytes Review Team on whether they should be investigating the higher metrological order items for blood gases reference measurement systems as a gap analysis, or whether they should provide a list of the existing higher metrological order items. The future activity for the JCTLM review teams will be dealt with under agenda point 3.5.

Action (A/12-08): WG1 Chair/Dr Schimmel to contact Dr C. Jackson to correct the pending issue for the traceability statements and to finalize the nucleic acid review team terms of reference, and to circulate the final version for approval by the Executive Committee.
The term of references for the nucleic acid review team as drafted in the document JCTLM-EXEC/12-05 was discussed during the last WG meeting, and it was agreed that Dr Schimmel, Dr Jackson, and Ms Parkes should propose a final draft for the term of references for the Nucleic Acid review team. The Committee approved the recommendation from the WGs to circulate the final version for the terms of reference among the leaders of review teams for awareness of newly appointed team leaders.

Action (A/12-09): Dr Schimmel, Dr Beastall, Dr Wielgosz, Dr Jones to draft a paper for next JCTLM Executive Meeting on the future structure, funding, and impact of JCTLM
This will be dealt with under agenda point 3.1.

Action (A/12-10): JCTLM Secretariat to liaise with network laboratories with regards to the accreditation issue of the laboratories participating in the Network

Dr Wielgosz reported that the IFCC HbA1c network, the NGSP laboratory network for HbA1c measurements, as well as the CDC CRMLN were contacted. The coordinating laboratories of the two HbA1c networks sent feedback and none of the laboratories participating in their Network would be preparing for accreditation in the short term period.

Action (A/12-12): BIPM to contact the board of Metrologia to see if it would be possible to expand their electronic service to the publication of reference measurement methods in support of the metrological traceability for laboratory medicine community
Dr Wielgosz reported that the publications team of *Metrologia* concluded that it would be difficult to build a business case to expand their electronic service to publications of modified, improved or newly developed reference measurement methods, as it was not innovative science.
The issue was further discussed, and the committee agreed that it would be a valuable service to the community if the JCTLM would develop a process for reviewing validation data for a modified method with increased performance by experts of the review teams, to enable its publication as well as the publication of the improved service by the JCTLM. The committee requested that WG procedures be revised accordingly.

Action (A/12-14): JCTLM Secretariat to draft a statement on the differences between both versions of the ISO 15194 standard, and indicate that for reference materials reviewed against ISO 15194:2002, verification of the CRM certificate was required to determine the compliance of the CRM with ISO Guide 34 requirements and the consistency between the commutability statement and the intend use stated in the certificate of the CRM.
Dr Wielgosz reported that a draft statement on the differences between both versions of the ISO 15194 standard was included in the document JCTLM-EXEC/13-16, and would be posted on the BIPM JCTLM webpage after circulation for approval by the EC.

Action (A/12-15): JCTLM Secretariat and Dr Jones to review the FAQ document with Dr Jackson and circulate the new version to the members of the Executive Committee for comment.
Dr Wielgosz reported that a revised draft for FAQ document was included in the document JCTLM-EXEC/13-14, and would be posted on the BIPM JCTLM webpage after circulation for approval by the EC.

Action (A/12-16): Secretariat to modify the draft for the updated list of HbA1c measurement methods to merge the Instand database entry with the IFCC HPLC/MS-ESI method which would include the reference Kaiser P. et al. Modification of the IFCC reference measurement procedure for determination of HbA1c by HPLC-ESI-MS, *GMS Ger. Med. Sci.*, 2006, Doc. 06, and to circulate it for comment to C. Weycamp, H. Shimmel, G. Beastall, and P. Kaiser.
This action was completed. Dr Schimmel reported that Dr Kaiser made the request to replace the 2006 reference by another reference published in 2008 Clin Chem 2008;54:1018-22, that described another modified measurement procedure currently used by the IFCC HbA1c Network laboratories. The protein review team was requested to give its view on whether the 2008 publication can replace the 2006 publication (GMS Ger.Med. Sci., 2006, Doc. 06.) in, or whether it should be added as a new reference in the list of publications in IFCC HPLC/MS-ESI method, or whether it would eventually introduce new aspects which have not been looked at so far. There had been no feedback yet from the Proteins team.

Action (A/12-19): JCTLM Secretariat to place the total protein measurement method in the file for no longer listed methods with a reference to the paragraph 3 and Doumas' references 1 and 2 cited in NRSCL RS5-A2.
This action was completed. However, it was pointed out during the last WGs meeting that although the NRSCL RS5-A2 guidance document for total protein method was no longer published by CLSI, it was still technically sound and widely used by the laboratory medicine community. The Committee agreed that a nomination for the total protein measurement method described in the Doumas' references together with appropriate reference to the calibrator involved with the method, should be submitted for review by WG1 at the next review cycle by an institution using the method. Dr Phinney agreed to submit the nomination of the total protein method as used by NIST.

Action (A/12-21): **Dr Jones to submit the paper on the history and function of the JCTLM for publication in the CCLM Journal.**
Dr Jones reported that the manuscript on the history and function of the JCTLM was revised in collaboration with Dr Jackson, and that an extended version of the paper had been drafted with the view to be published on the JCTLM website, and was included in the document JCTLM-EXEC-12-17 for approval by the Executive Committee. He further added that it would have to be further restructured in order to be suitable for submission to peer-review CCLM journal.

Action (A/12-22): **JCTLM Secretariat to comment on the text of the traceability statement and circulate it for comment to the members of the EC.**
Dr Wielgosz reported that the revised text of the traceability statement was corrected for consistency with the ISO17511 metrological traceability statement, and was included in the document JCTLM-EXEC-12-13 for approval by the Executive Committee.
Dr Beastall explained that he would discuss the final version of the traceability statement with the IFCC corporate members before wider distribution to the IVD industry.

New Actions:
Action (A/13-01): JCTLM Secretariat to circulate the information available in the two NIST SRM certificates of analysis to the JCTLM WGs, as the basis for discussion at the next WG meeting on drafting guidance on the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values for discussion at the next WG meeting.

Action (A/13-02): Dr Phinney to draft a proposal to define the required criteria to remove a reference measurement method from the database for discussion at the next WG meeting.
Action (A/13-03): Dr Schimmel (as WG1 co Chair) to finalize the document for the review team terms of reference, to circulate the final version among the Review teams, and to send it for approval by the Executive Committee.

Action (A/13-04): JCTLM WG Chairs and Quality Review Team to develop a process for the review of modified methods and their validation data to enable publication and listing of the method and service related to it.
Action (A/13-05): NIST/Dr Phinney to submit a nomination for the total protein measurement method described in the Doumas' reference together with appropriate reference to the calibrator involved with the method for review by WG1 at the next review cycle.

Action (A/13-06): Dr Beastall to discuss the final document for the traceability statement with the IFCC corporate members before JCTLM can proceed to its distribution to the IVD industry.

3. JCTLM Framework and Declaration of Cooperation

3.1 **Future structure funding and impact of the JCTLM**

Dr Wielgosz reported that there were currently twenty-six organizations that are members of the JCTLM, and that in accordance with the revised text of the Declaration of Cooperation (DoC) published in April 2013, the members would be expected starting from December 2014 to report regularly (every 2 years) on their activity in support of the JCTLM.
He presented also the document JCTLM-EXEC/13-21 which included a flowchart on the time and resources spent for JCTLM activities including the solicitation, nomination and review process of entries into the JCTLM Database y and other related activities, and how these activities were split between the WG, Executive and Secretariat. In the discussion that followed the Committee agreed that the member organizations should be informed that the participation of their experts in the activity of the review teams was a key requirement for continuing and expanding the activity of the JCTLM. It was requested that a call for nominations of experts should be launched at the beginning of 2014 which would specify the fields for which volunteers were required.

The JCTLM Members and Stakeholders meeting held on 4 and 5 December 2013 discussed possible future directions for JCTLM. This discussion was developed further by the JCTLM Executive (6 December), which established an ad-hoc WG on JCTLM Structure, to explore options for the future evolution of the JCTLM Organizational Structure, to best meet the future challenges expected to be faced by the JCTLM.
Dr Beastall agreed to chair the ad-hoc WG, with the following other members participating: Dr Jones, Dr Kaarls, Dr Wielgosz, Dr Schimmel, and Prof Muller (confirmed after the meeting). The ad hoc WG would develop a draft paper for further discussion and action at the next Executive meeting in December 2014.

Actions:
Action (A/13-07): JCTLM Secretariat in consultation with the WG Chairs to contact JCTLM member organizations to request them to nominate volunteers to participate in existing Review Teams when required and new ones when these are formed.
Action (A/13-08): Ad-hoc WG (Dr Beastall, Dr Jones, Dr Kaarls, Dr Wielgosz, Dr Schimmel, Prof Muller) on JCTLM Structure, funding and impact to draft a document proposing future options for the evolution of the JCTLM, for discussion at the Executive Meeting in December 2014.

3.2 Representation on the Executive

Dr Wielgosz reminded the Committee that the term of the JCTLM President would come to an end at the next Executive meeting at the end of 2014, and that the procedure to elect a new President of the Committee would be followed, which would require the Secretariat to inform the JCTLM sponsoring organizations for the need to nominate candidates for the post of JCTLM President.
He added that the JCTLM Secretariat host organization would need to be re-elected in two years time.

Action:
Action (A/13-09): JCTLM Secretariat to contact IFCC, BIPM and ILAC on 1 June 2014 for nominations for JCTLM President.

3.3 JCTLM WG Chairs

Dr Wielgosz reminded the committee that the procedure for the selection and appointment of the Working Group Chairs for renewable two year periods was followed, as the term of the WG1 and WG2 Chairs had come to an end in December 2013. The Executive Committee re-appointed Drs Phinney and Schimmel as co-Chairs of WG1 as well as Profs Siekmann, and Thienpont as co-Chairs of WG2.

He further explained that the Secretariat has had to deal with issues outside of its scope of activity with regards to that described in the procedure document JCTLM Exe-P-01, and P-02. From the discussion that followed, the Committee agreed that the tasks for WG Chairs and Secretariat should be reviewed, and requested that the relevant procedure documents should be revised to clarify their activities, respectively.

Action:
Action (A/13-10): Dr Wielgosz/WGs Chairs to review the tasks for WG Chairs and Secretariat, and to revise the procedure document JCTLM Exe-P01, and P02.

3.4 JCTLM membership

Dr Wielgosz informed the Committee that one organization had applied for membership of the JCTLM, the Health Sciences Authority (HSA) from Singapore.The Committee reviewed the application JCTLM-EXEC/13-04 and approved the JCTLM membership of HSA.

Action:
Action (A/13-11): Secretariat to write to HSA to confirm the Executive's approval of membership.

3.5 JCTLM Working Groups

3.5.1 Review of JCTLM Review Teams and RT Members

Dr Wielgosz presented the document JCTLM-EXEC/13-03 which included a new application for membership of review teams. The JCTLM Executive Committee approved the membership application from Dr Neil Almond from the National Institute for Biological Standards and Control (NIBSC) for the Nucleic Acid WG1 and WG2 Review Team.

He reported further to the Committee that Dr Jackson informed the JCTLM WGs of his resignation as leader of the WG1 Quality Systems review team on 1st of January 2014, and that Dr Sharpless wrote to the JCTLM that she would withdraw from her participation as a member of the Vitamins and WG1 Quality Systems JCTLM review teams. Dr Tai from NIST who was willing to replace her as a new member for the Vitamins review team, would send her application form for JCTLM membership for approval by the EC.
The Committee appointed Dr Wielgosz as the new Quality Systems review team leader, and Drs Robertson and Maniguet as new members of the WG1 Quality Systems review team, and requested that an additional member be recruited for the team.

The review team leader for Drugs had informed JCTLM that two members, Dr Jones and Dr Keevil, would no longer be able to participate in the review team, and that additional members would need to be recruited.
The committee reviewed further the review team membership by working group and analyte type and requested that a call for nominations among the JCTLM member organizations be launched for experts for the following review teams: Drugs, Non-electrolyte metals, Non-peptide hormones, Proteins and Vitamins. In addition, Dr Beastall agreed to contact the leader of the review team for Coagulation factors to verify if it would be possible to contact the ICSH for candidates. Dr Wielgosz agreed as well to contact Dr Giroud to clarify the current status for microbial serology review team.
The committee pointed out the need to extend the WGs' activity to new biological measurements, and requested the WGs to consider the establishment of new review teams for cell typing, , allergens, pathogens, or microbiology. The role of these new teams would in the first instance be focused on soliciting nominations of possible entries for the JCTLM database.

Actions:
Action (A/13-12): Secretariat to update the list of review team leaders and members, and to contact new review team members informing them of their approved nominations.
Action (A/13-13): Dr Beastall to contact the leader of the review team for Coagulation factors to verify if it would be possible to contact the ICSH for potential candidates for review team membership.
Action (A/13-14): Dr Wielgosz to contact Dr Giroud to verify the current status for microbial serology review team, and to clarify if it would be appropriate to rename the review team to ensure a better visibility of the metrological traceability in the field of biological measurements.

3.5.2 Review Team Scope of activities

The document JCTLM-EXEC/12-05 which included the last version for Terms of reference for the review teams was dealt with under the agenda point 2.1, see Action (A/13-03).

3.6 Funding of the JCTLM Secretariat

Dr Wielgosz reported that the invoice which was sent in November 2013 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 2013 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 2011 to 2015 that was produced based on that of 2010 with an increase of 2% per year for inflation.

Dr Beastall could only confirm that the IFCC would continue to fund half of the operating costs for the JCTLM Secretariat until and including 2014, when his term as President of the IFCC would come to an end. It was noted that the funding of the JCTLM Secretariat from 2016 onwards would depend on the outcomes of discussions among the sponsoring organizations based around the proposals put forward by the ad hoc WG on JCTLM Structure.

3.7 JCTLM Database

In March 2013, thirty-nine measurands for certified reference materials, 2 reference measurement methods, and 5 reference measurement services were published following the approval by the Executive Committee of nominations reviewed during WG1 cycle 9 and WG2 cycle 7. There were two Thrombocyte methods covering two levels concentrations that were approved for publication in the JCTLM Database after the submission of the English version of the standards DIN 58932-1 describing the measurement method and the publication on Blood Cell Concentration (J. Lab Med 2012; 36(1):25-35).

In April 2013, twelve reference measurement services from 1 reference laboratory were reinstated after receipt of the copy of its accreditation certificate for compliance with ISO 15195 and ISO/IEC17025 as a calibration laboratory.

In March 2013, the file for the "List of reference measurement methods no longer available in the JCTLM database" that can be downloaded from the JCTLM database website was created to include the total protein measurement method. This update was discussed further during the WGs meeting and the EC meeting under agenda point 2.1 that decided the action (A/13-05).

The current status of the database as of December 2013 was as follows:
- 299 certified reference materials (CRMs) amongst which 33 are in List II (i.e. Reference Materials value assigned using an internationally agreed protocol), and 3 are in List III (i.e. Reference Materials for nominal properties),
- 160 reference measurement methods covering 76 analytes, and
- 92 reference measurement services covering 33 analytes. These services are delivered by 9 reference laboratories accredited for compliance against ISO 15195 and IEC/ISO 17025 as calibration laboratories, and by 2 National Metrology Institutes (NMI).

The content management system and the web system of database had been modified to allow the search for methods by their JCTLM identifier numbers, and this new functionality was implemented in January 2014.

The Committee pointed out that there was a need to update the generic presentation of the JCTLM to include the current number of measurands covered for materials, methods, and services.

Action:
Action (A/13-15): JCTLM Secretariat to update the generic presentation of the JCTLM to include the current number of measurands covered for materials, methods, and services.

4. JCTLM Documents

4.1 Comparison of ISO 15194: 2002 vs. ISO 15194: 2009 [JCTLM-EXEC/13-15, 16]

4.2 JCTLM Frequently Asked Questions [JCTLM-EXEC/13-14]

4.3 Traceability statement related to the JCTLM [JCTLM-EXEC/13-13]

4.4 History and activities of the JCTLM [JCTLM-EXEC/13-22]

The JCTLM documents JCTLM-EXEC/13-13, 14, 16 and 22 were presented and discussed under agenda point 2.1, and the Committee commented that its members would review these further by the 15th of January 2014 before their publication onto the JCTLM webpages.

Action:
Action (A/13-16): EC to comment on the final draft document JCTLM-EXEC/13-13, 14, 16, and 22 by the 15th of January 2014, for their publication on the JCTLM webpages.

5. JCTLM WG1

5.1 Approval of Cycle 10 RM and RMP nominations

Drs Schimmel and Phinney reported to the members of the committee that the WGs meeting which was held on 3rd December 2013 had been fruitful with regards to feedbacks and discussions on the nominations reviewed during the review cycle in 2013. There had been a large number of nominations submitted, and reviewed, but there was still a need for further harmonization of the review and the findings among the review teams for the last review cycle. One of the important issues that was raised was the quality of the supporting documentation provided by the nominator of certified reference materials which had been not sufficient for a number of submissions in order for the review team to complete properly the review. WGs recommended that the review process should be modified so that the nominating organization would have to demonstrate compliance with respect to the requirements laid down in the standard ISO 15194, rather than simply declaring deviations from the requirements of the standard. The change of the existing nominating process should ensure that the nominating organization would provide the review team with the appropriate documentation to carry out a review effectively.
The Committee approved the WGs recommendation to modify the nomination process for certified reference materials and reference methods.

The Executive Committee also discussed what feedback could be provided from the review process if issues were raised with the outputs of accredited CRM producers. It was agreed that the CRMs would continue to be reviewed by the processes described in the JCTLM quality manual. This process allowed nominating CRM producers to make appeals to the Executive Committee if they disagreed with the outcome of the review process. If this was related to an accreditation issue, this would allow ILAC to advise directly on how to proceed.

There were fifty-eight nominations for reference materials for seven groups of analytes, and twelve nominations for reference measurement methods for four groups of analytes which had been submitted for review cycle 10.

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

5.1.1 Drugs (Cycle 10) [JCTLM-EXEC/13-24, 25]

There were six nominations for reference materials, and seven nominations for reference measurement methods for Drugs. All of these had been reviewed, of these one reference material, and five reference measurement methods were being recommended for approval and publication in the JCTLM database.
It was noted that for one of the method, the review team recommended its listing with the provision of the presentation of material documenting that the corrections have been made according to review findings.

There were two additional reference measurement method nominations for purity measurement for which the review team decided to defer the final decision for publication to the EC, although they had not observed any critical/major non compliance with respect to the requirements of the ISO 15193 standard. The Committee concluded that this method was of a higher metrological order, and that it should be listed under a new category which would appear in the JCTLM webpages in a dedicated box for guidance on approaches for primary calibrator purity determinations. This type of method was applicable to many analytes, and the Executive did not believe it would be in the interest of the users of the database to solicit nominations for purity determination methods applied to individual analytes. The committee further agreed that the JCTLM Database would not list methods for purity determination of primary calibrators for individual analytes, but further methods that were submitted could be considered for listing in the 'Metrological approaches to purity determination for Primary Reference Materials'.

5.1.2 Electrolytes (Cycle 10) [JCTLM-EXEC/13-08]

There were three nominations for one certified reference materials for Electrolyte. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database. The review team made these recommendations with the provision that the corrective actions be made by the producer according to review findings.

5.1.3 Non-peptide hormones (Cycle 10) [JCTLM-EXEC/13-27, 28]

There were nineteen nominations for certified reference materials, and two nominations for reference measurement methods for Non Peptide Hormones. All of these had been reviewed, of these none of the reference materials were recommended for listing, one method was deferred to the next review cycle due to the lack of publication, and the second measurement method nomination for purity determination was deferred to the Executive. It followed from the decision made by the EC under agenda point 5.1.1, that the nominated method nomination would appear in the guidance box on 'Metrological approaches to purity determination for Primary Reference Materials'.

5.1.4 Metabolites and substrates (Cycle 10) [JCTLM-EXEC/13-18, 19]

There were ten nominations for reference materials, and two nominations for reference measurement methods for Metabolites and Substrates. All of these had been reviewed, and five reference materials as well as two measurement methods were being recommended for approval and publication in the JCTLM database.

5.1.5 Proteins (Cycle 10)

There was one nomination for reference material, and one nomination for reference measurement method for Proteins. The review team leader had not sent any feedback until December 2013, and Dr Phinney agreed to contact him to clarify the review status for these nominations.

5.1.6 Vitamins (Cycle 10) [JCTLM-EXEC/13-09]

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

The committee commented that its members would further review these recommendations.

Actions:
Action (A/13-17): WG1 Quality System review team to modify the WG1 procedures to include the process for demonstration of compliance with ISO 15194 for nominating certified reference materials to JCTLM, and with ISO 15193 for nominating reference methods to JCTLM.
Action (A/13-18): JCTLM Secretariat to circulate for further review the review reports for specific nominations among the review teams for Drugs, Non-Peptide hormones, Metabolites and Substrates, and Vitamins.
Action (A/13-19): WG1 Chairs to review the nominations and harmonize the review reports for WG1 Cycle 10 nominations.
Action (A/13-20): Executive Committee to send their comments on the RT recommendations by the 15 January 2014
Action (A/13-21): Dr Phinney to contact the leader of the Proteins team leader to clarify the status of the review of WG1 and WG2 nominations

5.2 Delisting of RMs and RMPs

There had been no certified reference materials that were delisted from the database in 2013. The delisting of the total protein method was reported under agenda point 2.1.

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

5.4 Dr Wielgosz confirmed that the new call for nominations for Reference Materials, and Methods would be launched on the 15th of February 2014 (with the provision that the revision of the WG1 procedures was completed), with a deadline for submissions in May 2014. WG1 quality/ procedure manual (Review and Update)

This was dealt with under agenda point 5.1. (see action A/13-17)

6. JCTLM WG 2 – Reference Measurement Laboratories

6.1 Approval of Cycle 8 Laboratory RMS nominations

Dr Maniguet presented the nominations for reference measurement services, which had been submitted for review as part of WG2 review cycle 8. There were 12 nominations for services for three 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.

6.1.1 Enzymes [JCTLM-EXEC/13-08]

There were seven nominations for enzymes reference measurement services submitted by two reference laboratories. All had been reviewed, and were being recommended for approval and publication in the JCTLM database.

6.1.2 Metabolites and substrates [JCTLM-EXEC/13-20]

There were three nominations for reference measurement services for Metabolites and substrates submitted by one reference laboratory. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database.

6.1.3 Proteins

There was one nomination for reference measurement service for protein submitted by one reference laboratory. The review team leader had not sent any feedback until December 2013, and Dr Phinney agreed to contact him to clarify the review status for the nomination.

6.1.4 Vitamins [JCTLM-EXEC/13-10]

There were two nominations for reference measurement services submitted by one reference laboratory which were deferred from review cycle 6. All of these had been reviewed after the laboratory provided its certificate of accreditation and additional results for its participation in an inter-laboratory comparison scheme for vitamins, and were being recommended for approval and publication in the JCTLM database.

The Committee would review these recommendations by the 15th of January 2014.

6.1.5 Update on IFCC EQAS results

Prof. Siekmann reported that the Vitamins RELA Scheme was now available further to the request from one reference laboratory.

6.1.6 Re-review of database entries – (based on once every 3 year EQAS participation requirements)

Dr Maniguet presented the document JCTLM-EXEC/13-05, which included the reference measurement services that were re-reviewed with regards to the RELA participation in 2010, 2011, and 2012, of the laboratories providing these services for each measurand listed and for each group of measurands, and with regards to their accreditation status as at October 2013. Prof Siekmann reported that there were eleven reference measurement services from three laboratories for which the participation of the laboratory in RELA scheme was not compliant with the current JCTLM requirement. The committee requested that these laboratories should be reminded that they would have to participate in the next year RELA scheme, if they wish that their services remain listed after 1st January 2015.

Action (A/13-22): JCTLM Secretariat to contact the three laboratory service providers having not participated sufficiently regularly in RELA scheme from 2010-2012, and to remind them that they would need to participate in the next RELA scheme by the end of 2014 if they wish that their services remain listed in the database after the 1st January 2015.

6.2 Progress / plans for Cycle IX call for Laboratory RMSs

The new call for nominations for Reference Measurement Services would be launched in February 2014 in parallel to the call for Reference Materials and Methods.

6.3 WG2 quality/ procedure manual

Prof Siekmann presented the document JCTLM-EXEC/13-06 which included the draft for the revised procedure document JCTLM WG2-P-03 b, and that was modified to extend the criteria of acceptance of improved reference measurement service from a provider that would have improved /modified a formerly listed reference measurement procedure without

additional publication, with the provision that the basic principle of the measurement procedure (e.g. IDMS) was maintained, and that the modified procedure was approved by the accreditation body.
The Committee approved this modification which was complementary to the EC decision to publish the improved method validation data in the JCTLM Database (see Action (A/13-04)).

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

Dr Wielgosz presented the document JCTLM-EXEC/13-11, which included a letter received from Prof Schumann from the RfB calibration laboratory in Germany, who requested that the board of JCTLM should take notice of some problems having influence on the existing accreditation of its calibration laboratory and/or the capability of competing. The first issue that he was addressing to the EC was the lack of availability of two NIST certified reference materials after a batch was sold out. The committee commented that the issue regarding the supply of CRMs should be dealt with the supplier of certified reference materials. The second issue that he was addressing to JCTLM, together with Dr Kessler, was the inconsistencies they observed in the descriptions of the measurement uncertainty as depicted on the BIPM/JCTLM list for services for Enzymes. The committee requested that the expression of the uncertainty for the enzymes measurement services should be sent for review to the Enzymes review team leader.

Action (A/13-23): JCTLM Secretariat to contact the Enzymes review team leader to verify if any corrections would be required to harmonize the expression of the expanded uncertainty of the enzymes reference measurement services among the service providers.

8. Liaison with ISO TC 212 [JCTLM-EXEC/13-23]

8.1 Revision of ISO 17511:2003 [JCTLM-EXEC/13-12]

Dr Wielgosz presented the document JCTLM-EXEC/13-23, which included the ISO/TC212/WG2 convenor's report and resolutions from the ISO TC 212 meeting held in Singapore in November 2013. He pointed out that WG2 reviewed portions of the revised text (internal working draft) for ISO 17511, including extensively revised descriptive figures of traceability schemes and that numerous recommendations and changes were agreed.
A new draft for ISO 17511 was being developed with the appointment of two drafting teams. The first team would be dealing with the chapter on terms and definitions, and a second team with further revisions to substantive text and figures, notably with inclusion of the measurement harmonization concept.

8.2 Revision of ISO 15195

Prof Siekmann reported that the revised text of ISO 15195 was being drafted for consistency with the VIM3, and that he had still received no feedback from the ISO secretariat for possible inclusion of the IEC/ISO 17025 as normative reference in ISO 15195. The Committee requested that JCTLM secretariat should liaise with ISO Secretariat regarding this issue.
Dr Wielgosz reported at its last meeting the ISO TC 212 WG2 agreed to support a stakeholder's workshop in collaboration with JCTLM, to engage key constituencies (especially accreditation bodies) to assist in further developing the document with appropriate input and consultation of major stakeholders.

8.3 Other work items in ISO TC 212

During the JCTLM members and stakeholder meeting (4-5 December), Dr G Miller presented that one of the possible outcomes from the harmonisation project would the listing by JCTLM. Dr Beastall pointed out that the harmonization project materials/outcomes would need to be more clearly defined if JCTLM was expected to be involved in the project.
The committee requested Prof Thienpont should liaise with the harmonization project team at their next meeting in February 2014, to clarify the items that were expected to be nominated for listing in the JCTLM database.

Action (A/13-24): JCTLM Secretariat to contact the ISO Secretariat to clarify whether or not it would be possible that the IEC/ISO 17025 standard be included as normative reference in the ISO 15195 which was being revised.
Action (A/13-25): Prof Thienpont to liaise with the AACC harmonization project team at their next meeting in February 2014 to clarify/define the items that would come out from their project and that were anticipated for nomination for listing in the JCTLM database.

9. Liaison with the EC

9.1 Update on revision to the IVD Directive [JCTLM-EXEC/12-13]

Dr Schimmel reported that the revised text of the EC Directive on IVD medical devices was being considered by the European parliament, and that there was no clear timeline for the publication of the revised IVD directive.

10. Liaison with the WHO

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

Dr Beastall informed the committee that there had been contact with the WHO, and that they had shown specific interest in the JCTLM, with representatives attending the meetings held over the last few days.

11. Report from related activities/meetings

There were no reports on related activities/meetings.

12. Publicity for the JCTLM

The Committee agreed that a newsletter should be sent to the members of the JCTLM to reflect the update of the JCTLM database, revision & publication of the text of the IVD Directive, and related harmonized standards as well as to announce the future Workshop & Stakeholder meetings The ILAC Liaison offered the expertise of the ILAC Marketing and Communications Committee to assist JCTLM with its publicity needs. This was seen as one non-monetary way that ILAC could assist the activities of JCTLM.

It was noted that assistance may be required with:
- Preparation of a newsletter;
- Materials for conference booths;
- Short PowerPoint on “what is JCTLM”.

JCTLM will also need to prepare some form of communication in 2014 about changes to the database and a few other issues. It was made clear that just how ILAC can help through its MCC will need to be discussed with the Secretariat to start and then the Executive.

Action (A/13-26): JCTLM Secretariat to send to ILAC Secretariat existing leaflet, poster and presentation, and to liaise with them in order to produce a template for the JCTLM Newsletter which would be sent on an annual basis to JCTLM, IFCC and ILAC list of contacts.

13. Future meetings of the JCTLM

13.1 Coordination of meetings with IFCC CTLM, CIRME, others

13.2 Meetings for 2014 and 2015 (with AACC, July 2014 Chicago; with EuroMedLab Paris June 21-25, 2015)

It was proposed that the JCTLM WGs meeting would be held in December 2014 at the BIPM.

In addition, Dr Müller agreed to contact the international conference organisers of EuroMedLab in Paris that would be held in June 2015 to verify the possibility for the venue of WGs meeting as well as the feasibility to hold a JCTLM joint Workshop on ISO 15195.

The possibility of running a "workshop for Reference Laboratories and accreditors of ISO 15195 laboratories" was discussed. The importance of staging this where those who most need to come would already be attending was also discussed. Current plans for IFCC meetings were not seen to be events at which accreditation bodies would be attending. It was noted that ILAC or regional cooperation meetings might offer a better possibility but this would need to be planned. It was agreed this matter would be referred to ILAC for consideration.

13.3 JCTLM Symposium and Stakeholder meetings (2015/2016)

The 13th meeting of the JCTLM Executive would be held at the BIPM on the 4th and 5th December 2014, and preceded by a meeting of the JCTLM WGs on 3rd December 2014.

It was agreed that depending on the JCTLM meetings agreed in June 2015, a JCTLM Members and Stakeholders meeting could be held at the BIPM on 1-2 December 2015, and it would be followed by a WGs meeting on the 3rd December as well as a JCTLM Executive meeting on the 4th December 2015.

14. Close

The Chairman closed the meeting on 7 December at 17:00

S. Maniguet (23 December 2013)
Revised: 07/02/14, 24/02/14

Annex 1: Summary List of Actions

Actions from the 12th Executive Meeting:

Action (A/13-01): JCTLM Secretariat to circulate the information available in the two NIST SRM certificates of analysis to the JCTLM WGs, as the basis for discussion at the next WG meeting on drafting guidance on the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values.
Action (A/13-02): Dr Phinney to draft a proposal to define the required criteria to remove a reference measurement method from the database for discussion at the next WG meeting.
Action (A/13-03): Dr Schimmel (as WG1 co Chair) to finalize the document for the review team terms of reference, to circulate the final version among the Review teams, and to send it for approval by the Executive Committee.
Action (A/13-04): JCTLM WG Chairs and Quality Review Team to develop a process for the review of modified methods and their validation data to enable publication and listing of the method and service related to it.
Action (A/13-05): NIST/Dr Phinney to submit a nomination for the total protein measurement method described in the Doumas's reference together with appropriate reference to the calibrator involved with the method for review by WG1 at the next review cycle.
Action (A/13-06): Dr Beastall to discuss the final document for the traceability statement with the IFCC corporate members before JCTLM can proceed to its distribution to the IVD industry.
Action (A/13-07): JCTLM Secretariat in consultation with the WG Chairs to contact JCTLM member organizations to request them to nominate volunteers to participate in existing Review Teams when required and new ones when these are formed.
Action (A/13-08): Ad-hoc WG (Dr Beastall, Dr Jones, Dr Kaarls, Dr Wielgosz, Dr Schimmel, Prof Muller) on JCTLM Structure, funding and impact to draft a document proposing future options for the evolution of the JCTLM, for discussion at the Executive Meeting in December 2014.
Action (A/13-09): JCTLM Secretariat to contact IFCC, BIPM and ILAC on 1 June 2014 for nominations for JCTLM President.
Action (A/13-10): Dr Wielgosz/WGs Chairs to review the tasks for WG Chairs and Secretariat, and to revise the procedure document JCTLM Exe-P01, and P02.
Action (A/13-11): Secretariat to write to HSA to confirm the Executive's approval of membership.
Action (A/13-12): Secretariat to update the list of review team leaders and members, and to contact new review team members informing them of their approved nominations.
Action (A/13-13): Dr Beastall to contact the leader of the review team for Coagulation factors to verify if it would be possible to contact the ICSH for potential candidates for review team membership.
Action (A/13-14): Dr Wielgosz to contact Dr Giroud to verify the current status for microbial serology reference measurement systems, and to clarify if it would be appropriate to rename the review team to ensure a better visibility of the metrological traceability in the field of biological measurements.
Action (A/13-15): JCTLM Secretariat to update the generic presentation of the JCTLM to include the current number of measurands covered for materials, methods, and services.
Action (A/13-16): EC to comment on the final draft document JCTLM-EXEC/13-13, 14, 16, and 22 by the 15th of January 2014, for their publication on the JCTLM webpages.
Action (A/13-17): WG1 Quality System review team to modify the WG1 procedures to include the process for demonstration of compliance with ISO 15194 for nominating certified

reference materials to JCTLM, and with ISO 15193 for nominating reference methods to JCTLM.

Action (A/13-18): JCTLM Secretariat to circulate for further review the review reports for specific nominations among the review teams for Drugs, Non-Peptide hormones, Metabolites and Substrates, and Vitamins.

Action (A/13-19): WG1 Chairs to review the nominations and harmonize the review reports for WG1 Cycle 10 nominations.

Action (A/13-20): Executive Committee to send their comments on the RT recommendations by the 15 January 2014

Action (A/13-21): Dr Phinney to contact the leader of the Proteins team leader to clarify the status of the review of WG1 and WG2 nominations

Action (A/13-22): JCTLM Secretariat to contact the three laboratory service providers having not participated sufficiently regularly in RELA scheme from 2010-2012, and to remind them that they would need to participate in the next RELA scheme by the end of 2014 if they wish that their services remain listed in the database after the 1st January 2015.

Action (A/13-23): JCTLM Secretariat to contact the Enzymes review team leader to verify if any corrections would be required to harmonize the expression of the expanded uncertainty of the enzymes reference measurement services among the service providers.

Action (A/13-24): JCTLM Secretariat to contact the ISO Secretariat to clarify whether or not it would be possible that the IEC/ISO 17025 standard be included as normative reference in the ISO 15195 which was being revised.

Action (A/13-25): Prof Thienpont to liaise with the AACC harmonization project team at their next meeting in February 2014 to clarify/define the items that would come out from their project and that were anticipated for nomination for listing in the JCTLM database.

Action (A/13-26): JCTLM Secretariat to send to ILAC Secretariat existing leaflet, poster and presentation, and to liaise with them in order to produce a template for the JCTLM Newsletter which would be sent on an annual basis to JCTLM, IFCC and ILAC list of contacts.