

**Report of the 15th meeting of the JCTLM Executive Committee
3-4 December 2015, BIPM, Sèvres, France**

List of participants:

Dr G. Myers (JCTLM Chairman, IFCC)
Dr G. Beastall (IFCC, JCTLM WG-TEP Chair)
Prof L. Siekmann (IFCC, JCTLM WG 2 Chair)
Ms R. Robertson (ILAC)
Dr G. Jones (ILAC)
Dr R. I. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr H. Schimmel (JCTLM WG 1 Chair)
Dr S. Maniguet (JCTLM Secretariat, BIPM)

Apologies received:

Dr K. Phinney (JCTLM WG1 Chair)
Dr. M. Milton (BIPM)
Dr. W.E. May (CIPM)
Dr R. Kaarls (CIPM)

1. Approval of the agenda [JCTLM-EXEC/15-14]

Dr Myers opened the meeting and asked the Committee whether any additional points should be considered for the agenda. The agenda was approved with no changes.

2. Report of 14th JCTLM Executive Committee Meeting

There were no comments on the report of the 14th Executive Committee meeting, which had been finalized in October 2015, and published on the [BIPM JCTLM website](#).

2.1 Review of action points arising from the 14th meeting [JCTLM-EXEC/15-15]

Dr Wielgosz summarized the action items that were still outstanding:

Action (A/15-01): Dr Phinney to circulate examples documenting the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values among WG Chairs for publication on the JCTLM website.

Dr Wielgosz reported that Dr Phinney provided two examples of NIST SRM certificate of analysis that included a mention use of serum densities to convert from mass fraction to concentration values. She had commented that it became common practice for NIST to include a statement of the serum or plasma density in the certificate of analysis. These examples would be made available to the CRM users as a guidance document on the section for [Technical documents](#) of the JCTLM webpage.

Action (A/15-03): Dr Wielgosz to revise the document JCTLM-EXEC/15-03, and the document for the Declaration of Cooperation to describe the new structure, roles and responsibilities of each JCTLM entities and to circulate for comment by the EC members by end of July.

Action (A/15-05): Dr Myers to finalize the document JCTLM-EXEC/15-05 including the revised JCTLM Mission Statement, and circulate it by end of July 2015 for approval by the members of the Executive.

Action (A/15-06): Dr Wielgosz to finalize the revision of the Appendices I, III and IV (JCTLM-EXEC/15-06, and 07) and circulate it by end of July 2015 for comment by the members of the Executive.

Dr Wielgosz reported that the revised text for the document for the Declaration of Cooperation and its Appendices had been circulated to the members of the EC before the meeting, and will be reviewed under the agenda point 3.

Action (A/15-04): JCTLM Quality Systems Review Team to modify JCTLM Quality documents to describe the new organizational structure, and WG Database policies for reviewing the nominations for materials, methods, and services with the participation of RELA Advisor, and to distribute to Executive Members for discussion at next December meeting.

Dr Wielgosz reported that the action was still ongoing, and as a first step towards the full revision of the JCTLM Quality documents the Secretariat produced 'use case' diagrams for describing the current organizational structure and review process for JCTLM as well as the proposed modifications in the structure and the new WG policies for the review process that would be in line with the new Database WG structure. This would be discussed further under agenda 7.

Action (A/15-07): Secretariat to send a letter to the JCTLM Member organizations to inform them of the reclassification in the membership category, and to verify if they wish to remain member of JCTLM after transition period

The action was outstanding, and would be followed up after the approval of the revised text of the Declaration of Cooperation by the sponsoring organizations of JCTLM.

Action (A/15-11): Secretariat to contact the Leader of the Coagulation Factor review team to verify if any new nominations are to be expected for new lot of Coagulation Factors reference material which was delisted as no longer available.

Dr Wielgosz reported that the Secretariat contacted the leader of the Coagulation Factor review team, and that from the response she provided it was clear that there would be no new nominations to be expected for the new lot of Coagulation Factors reference material. She explained that the underlying reason for this was that the material might not fulfill all mandatory requirements of the ISO 15194 which JCTLM uses as a basis for completing the technical assessment of higher-order reference materials.

The committee commented that this would create a gap of higher-order reference material in the blood coagulation field, although the approach used for producing this plasma material was most probably compliant with that described in ISO 15194.

Action (A/15-17): Secretariat to forward for review by Dr Schimmel three outstanding membership applications for Proteins team activity.

Dr Schimmel informed the committee that he reviewed the three applications for membership for the Proteins team, and of these that he recommended the appointment of two new members having appropriate expertise for contributing in the proteins team. He said he would circulate his recommendations to the members of the EC for their approval after the meeting.

Action (A/15-19): Dr G. Jones to provide BIPM with his presentation for distribution to the CCQM EAWG to see if they wish to nominate their materials included in the traceability statement of the IVD assay providers.

Dr Wielgosz proposed to follow up this action, and said that it would be valuable to raise the issue of the need for materials in pH and electrolytes for the clinical community at the

meeting of the CCQM-EAWG in April 2016 at the BIPM. The committee agreed with this proposal, and Dr Jones agreed to identify a list of analytes in the blood gases area and electrolytes area where traceability to NMI reference materials was presumed to exist but no material were listed in the JCTLM database.

Action (A/15-20): Dr G. Jones to respond to Dr K. Phinney and to propose a fast track review of the new batch of a previously listed reference material providing that the material was stable and that there was no drift in claiming traceability to the first batch.

Dr Phinney reported in an email to JCTLM that the issue regarding the submission for review of the new batch of a previously listed reference material was still under discussion at NIST. She indicated that they prepare extensive internal reports describing preparation and value assignment of each of their CRMs, and these could potentially be converted into an external certification report. They have a new Special Publications 1200 series that might be appropriate. Initial implementation would take a little time for those materials already available because existing reports would need to be modified with agreement on content to be presented externally, but going forward, the process should be faster for additional replacement materials. They were working with their laboratory office to move this concept forward.

Action (A/15-23): Dr Wielgosz and Beastall to draft a proposal for an agenda for a JCTLM/IVD Symposium/Satellite meeting at the IFCC meeting in Athens in June 2017.

Dr Beastall informed the committee that the Satellite meetings' programme at the IFCC meeting in Athens was already complete at the time he discussed with the IFCC SD, and proposed an alternative that would be to send a proposal for an Educational Workshop. The committee agreed with this proposal.

New Actions:

Action (A/15-24) : Secretariat to publish as a Technical document on the JCTLM webpage the examples for NIST SRM certificate of analysis including the mention use of serum densities to convert from mass fraction to concentration values.

Action (A/15-25) : Dr Schimmel to circulate for approval to the EC his recommendations for the appointment of two new members of the review team for Proteins, and Secretariat to update the list of members of the teams accordingly.

Action (A/15-26) : Dr Wielgosz/Dr Jones to draft a presentation for the April 2016 CCQM EAWG meeting regarding the need for reference materials in pH and electrolytes for the clinical community.

Action (A/15-27) : Dr Beastall to draft a proposal for a JCTLM Educational Workshop at the IFCC meeting in Athens in June 2017

3. Revision of JCTLM Declaration of Cooperation Document [JCTLM-EXEC/15-16]

3.1 Mission Statement and Structure and Operation Statements

3.2 Appendix I and II: List of JCTLM Members and WGs

Dr Wielgosz presented the document JCTLM-EXEC/15-16 which modified the text of the Declaration of Cooperation (DoC) between the CIPM, IFCC and ILAC, and of its Appendix I and II. He summarized the amendments to the text, and highlighted those made after last meeting in June 2015. This also included an amendment to the text relating to the JCTLM Structure and Operation which would read that additional organizations could be invited to

join the Executive Committee provided they fulfilled the conditions set out in the Appendix IV [JCTLM-EXEC/15-18].

3.3 Appendix IV: Participation of organizations in the JCTLM [JCTLM-EXEC/15-18]

Dr Wielgosz presented the document JCTLM-EXEC/15-18 which modified the text of Appendix IV to open the JCTLM Executive Committee Member Status to international governmental and non-governmental organizations having technical competence in the field or a subspecialty, and organized the JCTLM Membership in two categories of members: JCTLM National and Regional Members being defined as national and regional organizations that adhere to and/or contribute to the activities of the International Organizations that are members of the JCTLM Executive Committee and that have expertise in traceability in laboratory medicine and demonstrate a willingness to provide experts for JCTLM Working Groups and Review Teams; and in addition JCTLM Stakeholder Members being defined as properly constituted “non-profit” and “for-profit” organizations, with interest, expertise and a demonstrable record of working to reduce the between method variability in laboratory medicine measurements and a commitment to promote the JCTLM database and activities.

3.4 Appendix III: JCTLM Framework and database [JCTLM-EXEC/15-17]

Dr Wielgosz presented the document JCTLM-EXEC/15-17 which included the revised text of Appendix III. He pointed out the amendments to the text which would reference the Quality manual of the JCTLM and no longer all relevant ISO Standard and Guides used by JCTLM in its review process. The relevant standards with which compliance is evaluated were listed in the Quality Manual of the JCTLM Working Group, and the list updated when necessary.

The Committee proposed minor modifications for the revised text of the JCTLM Declaration of Cooperation between the CIPM, IFCC and ILAC, and of its Appendices I to IV, and requested that the final draft should be circulated amongst the members of the EC for their comment, and amongst the sponsoring organizations for their approval by the end of January 2016. The action A/15-07 would be followed up to inform the JCTLM Member organizations of the new membership categories, and to verify if they wish to remain members of the JCTLM.

Action (A/15-28): Secretariat to finalize the draft of the revised text of the JCTLM Declaration of Cooperation between the CIPM, IFCC and ILAC, and of its Appendices I to IV for final approval by the members of the sponsoring organizations by January 2016.

4. Progress with identifying potential JCTLM Executive Committee Organizations

The members of the Committee noted that the JCTLM Members’ and Stakeholders’ Meeting held during the week was attended by representatives from international organizations with which the JCTLM should work more closely. The International Council for Standardization in Haematology (ICSH), the World Health Organization (WHO) and SoGAT presented their approach for standardization in their fields. In the discussion that followed it was agreed that the step forward would be to hold a meeting with representatives from those international organizations involved in developing measurement standards within laboratory medicine including in the field of molecular genetics, haematology and infectious diseases.

In addition, the Committee welcomed the proposal from the Chairman of the ICSH who invited a JCTLM representative to attend their General Assembly meeting in October 2016.

Action (A/15-29): JCTLM to develop a proposal for initiating meeting with representatives of those international organizations involved in developing measurement standards within laboratory medicine, with a view to developing a closer working relationship with the JCTLM.

Action (A/15-30): Dr Beastall and Dr Jones to draft a working document for discussion at the ICSH General Assembly in October 2016.

5. Reports from JCTLM Member Organizations: Feedback and Comment [JCTLM-EXEC/15-27]

Dr Wielgosz reported that the Secretariat contacted the twenty six member organizations to remind them to send their biennial activity reports, and of these 10 returned a written report and/or volunteered to present their activity at the JCTLM Members' and Stakeholders' meeting. The Committee acknowledged the quality of the reports provided and the level of involvement of the member organizations in presenting their activities in support of the JCTLM at their meeting. The committee requested that these documents be made available on the JCTLM website. Dr Wielgosz confirmed that the meeting presentations would be accessible from the website unless otherwise stated by the representative of the organization at the meeting, and that the agreement from the organizations would need to be sought prior posting their written report onto the website. The committee agreed with this approach.

Dr Myers pointed out the need to provide more guidance to the member organisations on the format and content of the biennial report, and proposed to provide them with a template (pro forma) report. The committee agreed with this proposal, and commented that this approach could be applied also to the members' presentations.

Dr Myers commented that CNAS (China) submitted a number of questions in its activity report, and agreed to respond to the organization.

Action (A/15-31) : Secretariat to write to the JCTLM Member organizations having provided a written report for their activity related to JCTLM to verify if they wish to render it public

Action (A/15-32) : Secretariat to draft a template (pro forma) for the written activity reports to be submitted on a biennial basis by the JCTLM member organizations

Action (A/15-33) : Dr Myers to draft responses to the questions that CNAS (China) submitted in its activity report for comment by the EC.

6. Report from the JCTLM WG on Traceability Education and Promotion

Dr Beastall was appointed Chairman of the JCTLM WG on Traceability Education and Promotion (WG-TEP) following the meeting in June 2015.

He proposed that as a follow up to the Members' and Stakeholders' meeting, an evaluation form for the meeting be circulated, as well as a request for suggestions for the next meeting in 2017.

The committee agreed with his proposal.

He reported on the outcome of the inaugural meeting of the WG-TEP held on 2 December 2015 at the BIPM, and acknowledged the high attendance and active participation of the WG members at this first meeting. The Terms of Reference of the WG-TEP were approved by the members of WG during the meeting. He presented the document JCTLM-EXEC/15-38 which included the list of actions and decisions from the first meeting.

The Executive reviewed this document and agreed on the WG recommendation to host the

next biennial JCTLM Members' and Stakeholders' Meeting at the BIPM in 2017. The programme of the meeting would be finalized by December 2016.

Dr Beastall reported also that in the short term action plan the members of the WG were requested to submit five concepts about traceability that could be used to prepare promotional materials. Those concepts would then be developed into 10 -20 vector graphics which would illustrate basic concepts related to traceability for demonstrating the impact/importance of traceability on patients' measurement results. He further invited the members of the Executive to contribute to this list of concepts.

He added that the WG-TEP would be involved in producing text for the next issue of the JCTLM Database Newsletter, and that the 2016 Issue would be edited by the BIPM using the 2015 Issue template. The extension of its content and the modification of its format would be proposed for future editions of the newsletter notably when an editor would have been selected amongst the members of the WG.

Dr Beastall informed the committee of the approach proposed by the WG-TEP to investigate the cost and the options for producing either a portal or a new website on traceability. Although the WG's preferred option for hosting the traceability website was seen as the BIPM, the representative from the BIPM, the IFCC and the ICHCLR (managed by AACCC) agreed to investigate the cost for such a development inside their respective organizations.

The Executive supported the approach from the WG.

The Executive encouraged the WG-TEP to contact EQAS organisers and raise the issue of the importance and impact of metrological traceability to their schemes.

Action (A/15-34): Secretariat to send an evaluation form for the 2015 members' and stakeholders' meeting to all participants

Action (A/15-35): Secretariat to contact the participants in the 2015 Members' and Stakeholders' meeting to invite them to send their suggestions for the next meeting in 2017

7. JCTLM Database WG Structure and Processes

7.1 Composition and meetings of the WG

Dr Myers reported to the members of the Committee that the WG meeting which was held on 2 December 2015 had been successful with regards to feedback and discussions on the nominations reviewed during the 2015 review cycle, and also with regard to the new JCTLM WG structure which was trialled during this review cycle. The Vice Chairs of the Database WG and the leaders of the review teams reported on the review teams' recommendations proposed for each of the submitted nominations reviewed.

Dr Myers commented that although the main focus of the meeting was to validate and harmonize review recommendations, it would be valuable that each of the review teams could report on the state of the art of standardisation activity in their field of expertise. The Committee agreed with the approach and requested that the leaders of the review team should be contacted to present an "environment scan" for the field of their team activity at the next Database WG meeting.

Action (A/15-36): Secretariat to contact the leaders of the review teams to request them to present an “environment scan” in regard to the standardization activity covering their team’s scope of activity, at the next Database WG meeting.

7.2 Review and proposals for changes to Review Teams and their Membership

Dr Wielgosz informed the Committee that the Database WG reviewed the membership of the JCTLM review teams during its meeting, and made the recommendation to launch a call for nominations of experts in the fields of Drugs, Electrolytes and Blood Gases, Metabolites and Substrates, Proteins and Vitamins.

He further added that the leader of the team for Blood Grouping had agreed on the extension of the scope of activity of the team to Cell Typing, and had informed the JCTLM of her resignation as leader of the team in March 2016. This change was discussed at the meeting of the Database WG which made the proposal to merge the activity of the review team for Blood Grouping and Blood Cell Counting to form the Blood Cell Counting and Typing team. The Committee agreed with the recommendation of the WG and requested that the members of the current Blood grouping be contacted to verify if they were willing to continue to be active in this team.

The Committee recognized the need to formally approach the ISTH to verify if they wish to participate in the Coagulation factor review team activity.

Prof. Siekmann said that he informed the Database WG that he would withdraw his participation as member of the Drugs and Metabolites and Substrates team at the end of 2015, and would propose experts for his replacement in both groups in January 2016.

Dr Schimmel reminded the committee that Dr Bunk resigned as leader of the Proteins team in October 2015, and that he took over the activity of the review team and undertook the review of the Protein nominations submitted for review in 2015. Dr Schimmel agreed to act as interim Leader of the Proteins team until December 2016 when a new leader would be appointed.

The Committee thanked Dr Bunk for his important contribution in the JCTLM activity.

Action (A/15-37): Secretariat to contact the members of the Blood Grouping team and Blood Cell Counting team to announce the proposal to merge the teams, and to verify if they wish to continue to participate in the newly renamed Blood Cell Counting and Typing team.

Action (A/15-38): Secretariat to launch a call for experts in the field of Drugs, Electrolytes and Blood Gases, Metabolites and Substrates and Vitamins.

Action (A/15-39): Secretariat to contact the leader of the review team for Non Electrolytes Metals to verify the status of the team and whether a call for experts would be needed.

Action (A/15-40): Dr Wielgosz in consultation with Leader of the Coagulation factor review team to identify the appropriate contact person within the ISTH organization who could provide guidance on the ISTH involvement in the Coagulation factor review team activity

7.3 Revision of the JCTLM WG Quality Manuals [JCTLM-EXEC/15-36]

Dr Maniguet presented the document JCTLM-EXEC/15-36 which included ‘use case’ diagrams that described firstly the management scheme for the appointment of the JCTLM entities involved in the nomination and review process, and secondly the management scheme of the review of reference materials, methods, and services of a higher metrological order.

She highlighted the proposed modifications resulting from the implementation of the new WG structure, and new JCTLM policies for the review of the review teams' recommendations for listing nominations in the database, and the approval by the Executive Committee which would be based on the reports made by each of the three Analyte WG Chairs at the annual meeting.

The Committee approved the proposed modifications for the new WG policies for the review process which would be included in the JCTLM Procedures. The action A/15-04 would be followed up to modify JCTLM Quality documents to describe the new organizational structure, and WG Database policies for reviewing the nominations for materials, methods, and services with the participation of RELA Advisor, and to distribute to Executive Members for comment and approval by end of April 2016.

8. Timetable for finalization and approval of documents

8.1 Declaration of cooperation document

It was agreed during the meeting that the final draft of the revised text of the Declaration of Cooperation would be circulated to the members of the Executive for their final comment, and to the JCTLM sponsoring organizations by end of January 2016 for their final approval.

8.2 WG quality manuals

It was agreed during the meeting that the JCTLM Quality System Review Team would revise the set JCTLM procedures for describing the new structure and governance, and circulate the draft documents to the members of the Executive for their comment, and final approval by 30 April 2016.

9. JCTLM Governance

9.1 Representation on the Executive

The Committee recognized the need to coordinate the appointment of the JCTLM Chairperson and Secretariat, and agreed that the future selection of the Chairperson and the organization acting as Secretariat should be done at the same time period and that their term of a two year period renewable would remain unchanged.

9.2 JCTLM WG Chairs

Dr Wielgosz reminded the committee that the term of the WG Chairs had come to an end in December 2015, and that in accordance with the approval of the change of the structure of the WGs, three vice Chairs of the Database WG were to be appointed during the meeting, giving each responsibility for a group of analytes. The Executive Committee confirmed Dr Phinney, Dr Schimmel and Prof Siekmann as Vice Chairs of the Database WG for a renewable two year period, and assigned review teams to each Analyte Group as follows:

Prof Siekmann was appointed Chair of the Analyte Group which would include Drugs, Metabolites and Substrates, and Non-Peptide Hormones Review Teams;

Dr Schimmel was appointed Chair of the Analyte Group which would include Coagulation Factors, Enzymes, Proteins, Nucleic Acid, Infectious diseases, Blood cell counting and typing Review Teams;

Dr Phinney was appointed as Chair of the Analyte Group which would include Vitamins, Non Electrolytes Metals, and Electrolytes and Blood Gases Review Teams.

The Committee decided to modify the term for review team membership and leadership to a renewable two year period, consistent with all other appointment periods in the JCTLM. These modifications in the term for membership would be included the JCTLM Quality procedures.

9.3 JCTLM membership

There were no applications of JCTLM membership this year.

The members of the Committee supported to the initiative to draw a list of prospective members of the JCTLM which would be based on each sponsoring organizations' membership list contact list; the NMIs/DIs for the BIPM, Members of the IFCC, and the National accreditation bodies for the ILAC.

Action (A/15-41): Dr Myers to draft of a list of prospective JCTLM Member organizations by February 2016 after consultation with the BIPM, ILAC and IFCC.

9.4 Funding of the JCTLM Secretariat

Dr Wielgosz noted that the costs related to running the JCTLM Secretariat were in line with those foreseen and presented in the document JCTLM-EXEC/10-24 which provided cost estimates for JCTLM Secretariat activities for 2011 to 2015 that was produced based on that of 2010 with an increase of 2% per year for inflation. The cost of the JCTLM Secretariat for 2015 would be shared equally between IFCC and BIPM for 2015. The running cost for 2016 was estimated as the same as for 2015, corrected for inflation. It was agreed that BIPM and IFCC would again share the JCTLM Secretariat costs on a 50:50 basis for 2016.

Action (A/15-42): BIPM to provide to the IFCC by the end of December 2015 the invoice for 50% of the running costs of the JCTLM Secretariat

9.5 JCTLM Database

Dr Maniguet presented the updates of the JCTLM Database carried out from December 2015 to December 2016. She highlighted the updates of the content of the database, the development of the system and web application and the numbers of visits to the website.

In February 2015, 13 entries for certified reference materials, 9 reference measurement methods, and 30 reference measurement services were published in the JCTLM Database following the approval by the Executive of nominations reviewed during WG1 cycle 11 and WG2 cycle 9.

The current status of the database as of December 2015 was as follows:

- 295 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),
- 176 reference measurement methods covering 80 analytes, and
- 133 reference measurement services covering 39 analytes. These services were delivered by 14 reference laboratories accredited for compliance against ISO 15195 and IEC/ISO 17025 as calibration laboratories, and by 2 National Metrology Institutes (NMIs).

The back office and front office of the database application were updated to enable the system to publish the service delivered by a laboratory which was based on a modified listed method, and to publish the reference of the validation report of the modified method in addition to the reference of the method which was modified and used by a provider to deliver its measurement service. The technical developments of the system were done by an external company.

A pop-up window was published from mid-November 2014 to mid-February 2015 on the JCTLM database website in order to investigate who were the users of the database and what information they were looking for. There were 85 responses collected that showed that the users were in majority coming from the clinical laboratories (34%), IVD industry (20%), Reference laboratories (19%) and from the NMIs/DIs and reference material producers (6%). Visitors were interested in: information on reference materials (48%), methods (33%) and information on service providers (14%).

The number of visits for the JCTLM Database website was investigated over the year, and the log analysis which was carried out using new software showed that the number of visits was 0 1400 on average per month.

The second issue of the JCTLM Database Newsletter was produced in collaboration with the UKAS' Office Marketing, and was distributed in March 2015 as a PDF by email to the JCTLM contact list. Its content covered the following topics: New entries in the database Content of the database, Call for nomination announcement, Call for experts nominations, Quality Manual Modifications, Meeting announcement. Future Newsletters would be the task of the WG-TEP which would select amongst its members an editor of the Newsletter, and would extend the scope of the newsletter to external contributions to promote measurement result traceability in laboratory medicine.

10. JCTLM DB WG: Approval of Recommendations

Dr Myers presented the summary of the nominations for reference materials, reference measurement methods and reference measurement services with the final review teams' recommendations which had been submitted for review as part of WG1 review cycle 12 and WG2 review cycle 10.

There were nineteen nominations for reference materials for five groups of analytes, six nominations for reference measurement methods for four groups of analytes which had been submitted for WG1 review cycle 12, as well as 27 nominations for services for four groups of analytes which had been submitted for WG2 review cycle 10.

10.1 Approval of Cycle 12 RM and RMP and Cycle 10 RMS nominations and outstanding issues from previous Cycles

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

10.1.1 Drugs [JCTLM-EXEC/15-28,28.1]

There was one nomination for reference material for Drugs. This had been reviewed, and was being recommended for approval and publication in the JCTLM database.

10.1.2 Non-peptide hormones [JCTLM-EXEC/15-31]

There was one nomination for a reference measurement method for Non-peptide hormones for which the review had been deferred to a next review cycle after the peer review publication for describing the method would be available.

There were two nominations for reference materials for Non-peptide hormones. Both of these had been reviewed, and were not recommended for publication in the JCTLM Database. A major non-compliance which was related to the commutability assessment was observed for these nominations, and had been discussed at the Database WG meeting. It was agreed that the organization would be given a deadline of two months to provide JCTLM with supplemental information for further review by the review team.

The Executive approved the recommendations from the Database WG.

There was one nomination for reference measurement services for Non-peptide hormones, which had been reviewed, and was being recommended for listing in the JCTLM Database.

10.1.3 Metabolites and substrates [JCTLM-EXEC/15-32]

There were eight nominations for reference materials for Metabolites and Substrates. All of these had been reviewed, and of these, six pure materials were being recommended for approval and publication in the JCTLM database. For the two remaining serum materials, a major non-compliance related to the commutability assessment was observed and had been discussed at the Database WG meeting. It was agreed that the organization would be given a deadline of two months to provide JCTLM with supplemental information for further review by the review team.

The Executive approved the recommendations from the Database WG.

There were two nominations for reference measurement methods for Metabolites and Substrates. Both of these had been reviewed, and one was being recommended for approval and publication in the JCTLM database.

There were eight nominations for reference measurement services for Metabolites and Substrates. All had been reviewed, and of these seven were being recommended for approval and publication in the JCTLM database.

10.1.4 Enzymes [JCTLM-EXEC/15-29,30]

There were seventeen nominations for reference measurement services for Enzymes. All had been reviewed and of these nine were being recommended for approval and publication in the JCTLM database.

10.1.5 Proteins [JCTLM-EXEC/15-33]

There were six nominations for reference materials, one nomination for a reference measurement method and one nomination for a reference measurement service for Proteins. All were still under review at the time of the meeting, and final review teams' recommendations were expected by mid-January 2016.

10.1.6 Vitamins [JCTLM-EXEC/15-34,35]

There were two nominations for reference materials for Vitamins. All had been reviewed, and were not being recommended for approval and publication in the JCTLM database.

A major non-compliance related to the commutability statement was observed and had been discussed at the Database WG meeting. It was agreed that the organization would be given a

deadline of two months to provide JCTLM with supplemental information for further review by the review team.

The Executive approved the recommendation from the Database WG.

In addition, there were two nominations for reference measurement methods for Vitamins. All had been reviewed, and were being recommended for approval and publication in the JCTLM database.

The Executive approved the the review teams' recommendations for publishing materials, method and services in the JCTLM Database.

The Executive noted that the assessment of commutability was an issue, notably for the producers of CRMs newly involved in the field of health markers. It was agreed that this issue should be part of the action plan of the WG-TEP for developing examples/template and educational materials on how the commutability statement should be stated to be in line with the correct intended use of the material.

Action (A/15-43): Secretariat to publish the nominations recommended for publication in the JCTLM Database by end of January 2016, and send out the report on the outcome of the review to the nominating organizations.

10.2 Update on IFCC EQAS results

Prof. Siekmann reported that the number of laboratories participating in the IFCC EQAS RELA Scheme had continued to increase over the last years, and that there were about fifty-five laboratories participating in the RELA. He explained that a number of laboratories intended to first participate in the RELA exercises prior to becoming accredited, and this could explain why there were only fourteen laboratories currently listed in the JCTLM database. He commented that there would be an increasing and large contribution in the JCTLM activity in the next years from laboratories in Asian. He pointed out that problems had occurred when distributing the RELA samples in China, and they expected that this would be overcome with a new RELA EQAS distributing company in this region.

He further added that the laboratories having reference measurement services listed in the JCTLM database would be re-reviewed with respect to their results in the 2015 IFCC EQAS. He pointed out that a new sample for HDL and LDL Cholesterol had been offered as a service as part of the EQAS RELA2015 but this service could not be successfully completed and would be postponed until after a commutability study would be undertaken.

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

Action (A/15-44): Prof Siekmann to contact the CCQM OAWG Chair / PTB to see if they would be interested in coordinating a CCQM studies with a RELA samples.

10.3 Progress / plans for Cycle 13/Cycle 11 call for RMs,RMPs and RMSs

It was agreed that the new call for nominations for Reference Materials, Methods, and Services would be launched on the 1st of February 2016 with a deadline for submissions in May 2016.

11. Update on Gap Analysis Studies

Dr Jones said that an update on the gap analysis was presented at the JCTLM Members' and Stakeholders' on 1 December 2015, based on a comparison of what was in the JCTLM database and what analytes were routinely measured in his laboratory and other hospital laboratories.

He said that a follow up for this analysis could be to develop an approach and criteria for prioritizing the health markers for which standardization activities were needed. This would identify the reference system components most required for a selection of analytes routinely measured at a national and global level. Dr Myers commented that the Harmonization consortium had been working on developing a similar process and that a key issue appeared to be how to prioritize clinical importance when deciding on health markers.

In the discussion that followed, it was agreed that a discussion paper should be drafted to highlight the missing items to inform the NMIs/DIs as well as other material producers and the method developers what gaps existed.

Action (A/15-45): Dr Jones to draft a paper which would address gap and the needed development of reference system components to establish traceability for patients' measurement results.

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

See Action (A/15-33) discussed under agenda point 5.

There had been no additional documents submitted to the JCTLM Executive Committee.

13. Liaison with ISO TC 212

Dr Wielgosz reported that the first meeting of the ISO TC 212 WG2 was held in Chicago (US) in March 2015 [JCTLM-EXEC/15-22], and the second meeting was held at the IRMM in Geel (Belgium) [JCTLM-EXEC/15-24] in November 2015.

He presented the documents JCTLM-EXEC/15-21 and -25 that included the revised figures for ISO 17511 and the comments collated on ISO 17511, respectively.

13.1 Revision of ISO 17511:2003

Dr Wielgosz reported that the ISO/TC212/WG2 was continuing the revision of the ISO 17511 and highlighted that the major points of discussion for the revision of the standard were the followings: the extension of scope to cover patient's sample measurement results and not just focus on calibrators; the extension of the scope of the standard to include traceability to harmonization protocols; the incorporation of metrological traceability of values for catalytic concentration of enzymes, which was currently described in the standard EN ISO 18153:2003. The timeline foreseen for the publication of the revised standard was three years.

13.2 Revision of ISO 15195

Dr Wielgosz reported that the revision of ISO 15195 had been drafted with ISO 17025 as a normative reference and was intended to be read as containing only points of clarification on ISO 17025 requirements for Reference Measurement Laboratories, as opposed to being a

completely standalone standard. He added that the current status of the revised text of the ISO 15195 was a CD version, and that additional modifications to the text would be needed to be consistent with the standard ISO 17025 which was currently being revised. As a result the an extension in the timeline for ISO 15195 revision had been requested in order to be able to make the standard consistent with the newly revised ISO 17025 document.

13.3 Other work items in ISO TC 212

Dr Schimmel reported that a Technical Specification for the estimation of measurement uncertainty was being drafted based on examples from laboratory measurement results. The aim was to produce a practical guidance document which would be understood by the laboratory medicine community.

14. Liaison with the EC

14.1 Update on revision to the IVD Directive

Dr Schimmel informed the Committee that the revised text of the EC Directive on IVD medical devices was being considered by the European parliament and that the publication of the revised IVD directive as regulation would probably be voted in the course of 2016.

15. Liaison with the WHO

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

Dr Beastall said that he could only inform the committee that there had been contact with the WHO with the attendance of a representative of the IFCC at the WHO-ECBS meeting.

Dr Wielgosz introduced the document JCTLM EXEC/15-23 which included the guidance for preparation and calibration of secondary standards to WHO standards. He added that this document had been circulated to the ISO TC212/WG2 for comment until 16 November. The Committee agreed that JCTLM should comment although the deadline was passed to request the authors to make the ISO 15194 mandatory in the document.

16. Reports from related activities/meetings

The Committee noted the successful organization of the COLABIOCLI Symposium and Workshop on “Implementation of the Concept of Traceability in Clinical Laboratories in Latin America” held in Quito (Ecuador) on 25 and 26 September 2015. The aim of the workshop was to enhance the cooperation between the Societies of Clinical Laboratories and those active in developing Quality Infrastructure (QI), notably the National Metrology Institutes (NMIs) and the National Accreditation Bodies (NABs). The committee thanked Prof Siekmann for his work in organizing this meeting which was attended by representatives from twelve countries from Latin America.

Dr Wielgosz informed the Committee that a WADA Workshop would be held at the BIPM on 28 and 29 September 2016, and that experts from the clinical chemistry and laboratory medicine field would be invited for presenting case studies for measurands that were also of interest for the WADA community.

17. Publicity for the JCTLM

This issue was dealt with under agenda point 6.

Dr Myers commented on the need to work the branding of JCTLM. He proposed to discuss a tag line which should be attached to the JCTLM logo, and to develop a template layout for JCTLM presentations. The Committee welcomed this proposal and agreed on the following tag line “Accurate results for patient care” and that JCTLM should develop a presentation a template.

Action (A/15-46): WG-TEP to develop a presentation for introducing JCTLM which would be available for speakers attending meetings organized under JCTLM auspices, and a template for JCTLM presentations which would include the JCTLM Logo and tag line.

18. Future meetings of the JCTLM

It was agreed that the next Database WG Meeting would be held on the 5th December 2016, and would be followed by the 16th Executive Committee Meeting which would be held on the 6th and 7th December 2016.

18.1 JCTLM Symposium in 2016

Dr Wielgosz informed the committee that an international Workshop was being co-organized by the BIPM and NIM (China), and would be held in Chengdu Sichuan in China from 1 to 3 June 2016, and would focus on Protein and Peptide Therapeutics and Diagnostics. There would be three parallel sessions dealing with: a) Advanced Methods for Peptide and Protein Drug Characterization and Quality Assurance; b) Standards and Advances in Peptide and Protein Diagnostics; c) Advances and Challenges in IVD Standards and Research. The NIM had asked the Executive whether the meeting could be held under the auspices of the JCTLM, as this would be an excellent opportunity to promote the concept of traceability in the in vitro diagnostics sector within China. The Executive agreed for the meeting to be organized under JCTLM auspices and suggested that and JCTLM Executive meeting be held of 4 June, following the workshop.

18.2 JCTLM Members and Stakeholders meeting 2017

It was agreed that the JCTLM Members’ and Stakeholders’ meeting would be held at the BIPM on 5 and 6 December 2017.

This would be followed by a WGs meeting on 7 December as well as a JCTLM Executive meeting on 8 and 9 December 2017.

19. Close

The Chairman closed the meeting on 4 December at 12:00

Annex 1: Summary List of Actions

Actions from the 15th Executive Meeting:

Action (A/15-24) : Secretariat to publish as a Technical document on the JCTLM webpage the examples for NIST SRM certificate of analysis including the mention use of serum densities to convert from mass fraction to concentration values.

Action (A/15-25) : Dr Schimmel to circulate for approval to the EC his recommendations for the appointment of two new members of the review team for Proteins, and Secretariat to update the list of members of the teams accordingly.

Action (A/15-26) : Dr Wielgosz/Dr Jones to draft a presentation for the April 2016 CCQM EAWG meeting regarding the need for reference materials in pH and electrolytes for the clinical community.

Action (A/15-27) : Dr Beastall to draft a proposal for a JCTLM Educational Workshop at the IFCC meeting in Athens in June 2017

Action (A/15-28) : Secretariat to finalize the draft of the revised text of the JCTLM Declaration of Cooperation between the CIPM, IFCC and ILAC, and of its Appendices I to IV for final approval by the members of the sponsoring organizations by January 2016

Action (A/15-29): JCTLM to develop a proposal for initiating meeting with representatives of those international organizations involved in developing measurement standards within laboratory medicine, with a view to developing a closer working relationship with the JCTLM.

Action (A/15-30): Dr Beastall and Dr Jones to draft a working document for discussion at the ICSH General Assembly in October 2016.

Action (A/15-31) : Secretariat to write to the JCTLM Member organizations having provided a written report for their activity related to JCTLM to verify if they wish to render it public

Action (A/15-32) : Secretariat to draft a template (pro forma) for the written activity reports to be submitted on a biennial basis by the JCTLM member organizations

Action (A/15-33) : Dr Myers to draft responses to the questions that CNAS (China) submitted in its activity report for comment by the EC

Action (A/15-34) : Secretariat to send an evaluation form for the 2015 members' and stakeholders' meeting to all participants

Action (A/15-35) : Secretariat to contact the participants in the 2015 Members' and Stakeholders' meeting to invite them to send their suggestions for the next meeting in 2017

Action (A/15-36): Secretariat to contact the leaders of the review teams to request them to present an "environment scan" in regard to the standardization activity covering their team's scope of activity, at the next Database WG meeting.

Action (A/15-37) : Secretariat to contact the members of the Blood grouping team and Blood Cell Counting team to announce the merging of their team, and to verify if they wish to continue to participate in the newly renamed Blood Cell Counting and Typing team.

Action (A/15-38): Secretariat to launch a call for experts in the field of Drugs, Electrolytes and Blood Gases, Metabolites and Substrates and Vitamins.

Action (A/15-39) : Secretariat to contact the leader of the review team for Non Electrolytes Metals to verify the status of the team and whether a call for experts would be needed.

Action (A/15-40): Dr Wielgosz in consultation with Leader of the Coagulation factor review team to identify the appropriate contact person within the ISTH organization who could provide guidance on the ISTH involvement in the Coagulation factor review team activity

Action (A/15-41): Dr Myers to draft of a list of prospective JCTLM Member organizations by February 2016 after consultation with the BIPM, ILAC and IFCC.

Action (A/15-42): BIPM to provide to the IFCC by the end of December 2015 the invoice for 50% of the running costs of the JCTLM Secretariat

Action (A/15-43) : Secretariat to publish the nominations recommended for publication in the JCTLM Database by end of January 2016, and send out the report on the outcome of the review to the nominating organizations.

Action (A/15-44): Prof Siekmann to contact the CCQM OAWG Chair / PTB to see if they would be interested in coordinating a CCQM studies with a RELA samples.

Action (A/15-45): Dr Jones to draft a paper which would address gap and the needed development of reference system components to establish traceability for patients' measurement results.

Action (A/15-46): WG-TEP to develop a presentation for introducing JCTLM which would be available for speakers attending meetings organized under JCTLM auspices, and a template for JCTLM presentations which would include the JCTLM Logo and tag line.