

**Report of the 14th meeting of the JCTLM  
Executive Committee 25 - 26 June 2015, BIPM,  
Sèvres, France**

List of participants:

Dr G. Myers (JCTLM Chairman, IFCC)

Dr G. Beastall (IFCC)

Dr G. Jones (ILAC)

Dr R. I. Wielgosz (JCTLM Executive Secretary, BIPM) Dr R. Kaarls (CIPM)

Dr H. Schimmel (JCTLM WG 1 Chair)

Prof. L. Siekmann (IFCC, JCTLM WG 2 Chair) Dr S. Maniguet (JCTLM Secretariat,  
BIPM)

Apologies received:

Mrs R. Robertson (ILAC)

Dr K. Phinney (JCTLM WG1 Chair) Dr. M. Milton (BIPM)

Dr. W.E. May (CIPM)

**1. Approval of the agenda [JCTLM-EXEC/15-01]**

The agenda was approved with no changes.

**2. Report of 13<sup>th</sup> JCTLM Executive Committee Meeting**

There were no comments on the report of the 13<sup>th</sup> Executive Committee meeting, which had been finalized in February 2015, and published on the [BIPM JCTLM website](#).

**2.1 Review of action points arising from the 13<sup>th</sup> meeting [JCTLM-EXEC/15-02]**

Dr Wielgosz summarized the action items that were still outstanding:

**Action (A/14-01): WG1/WG2 Chairs in consultation with the technical experts of the WGs to draft a guidance document on the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values, and circulate it for review and approval at the next Executive Committee meeting.**

Dr Wielgosz reported that this action was discussed at the Executive conference call held on 28 May 2015, and that Dr Phinney agreed to produce examples documenting the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values. These examples would be circulated among WG Chairs for review and approval at the next Executive Committee meeting.

**Action (A/14-02): Dr Schimmel to circulate the final version of the document for the Terms of Reference for approval by the members of the Executive, and publication on the JCTLM website.**

Dr Schimmel reported that the final draft of the document for the terms of reference of the JCTLM review teams (JCTLM-EXEC/15-12) was agreed among the leaders of the review teams, and circulated for approval among the members of the Executive prior to this meeting. The Executive Committee approved the document for the review teams' terms of reference, and requested its publication on the BIPM JCTLM website.

**Action (A/14-05): Dr Myers/IFCC to verify the status of the new IFCC WG on clinical total protein measurements, and if IFCC would be willing to put forward a method nomination for biuret titration for total protein measurement.**

Dr Myers informed the members of the committee that the IFCC Scientific Division (SD) formed a sub Working Group on total Protein measurement as part of the IFCC SD Committee for Traceability in Laboratory Medicine (C-TLM), to investigate the method with the view to develop a method-dependent measurement system for total protein.

**Action (A/14-07): Secretariat to contact the leader of the review team for Coagulation factors to verify if it would be possible to contact the ISTH for potential candidates for review team membership.**

This action was not completed yet.

**Action (A/14-08): Secretariat to contact NIBSC and verify if they would be willing to participate in the JCTLM team for “Infectious diseases”.**

Dr Wielgosz reported that he contacted NIBSC and had received no feedback yet from them on this issue.

**Action (A/14-09): Dr Jones to finalize the submission of the paper on history and activities of the JCTLM to *Clinica Chemica Acta*.**

Dr Jones explained that he expected to finalize the drafting of the paper by December 2015 for submission to *Clinica Chemica Acta*.

**Action (A/14-10): Secretariat to contact the NMI not having participated sufficiently regularly in RELA scheme from 2010-2012, and to remind them of the current JCTLM criteria for regular participation of listed laboratories in RELA Scheme to underpin their services listed, and to verify if they wish to withdraw their services or remain listed after 1<sup>st</sup> January 2015.**

This action was not completed yet, and Dr Wielgosz agreed to contact the NMI after the meeting.

**Action (A/14-11): Prof Siekmann to liaise with the Enzymes team to verify if the technical issues that they had raised in their recommendation could not be anticipated with the current template.**

This action was still ongoing, and Prof Siekmann reported that a number of issues were still under discussion, such as the veracity of the lower limit of the uncertainty declared by some reference laboratories in the field of Enzymes measurement.

**Action (A/14-13): Dr Beastall, Kaarls and Wielgosz to update the draft for the document on the role and criteria for ordinary membership to include two categories for ordinary members, and circulate the final document for comment to the members of the Executive.**

**Action (A/14-14): Dr Beastall to update the draft of the document on JCTLM Executive Committee Membership, and circulate the draft for comment to the members of the Executive.**

These two actions were completed and will be discussed under agenda points 3 and 4.

**Action (A/14-18): Secretariat to contact IFCC Scientific Division in order to confirm which method (i.e. combination of modifications and original procedure) is used within the network and include appropriate reference in the JCTLM Database.**

Dr Wielgosz reported that the Secretariat contacted the IFCC SD, and updated the JCTLM Database to include the reference: Clinical Chemistry, 2008, 54, 1018, which was accepted by the IFCC network and used by the IFCC network Laboratories. The IFCC representatives confirmed that the JCTLM database provided the correct information to the users for the IFCC method for HbA1c (HPLC/ MS-ESI).

**Action (A/14-19): Executive Committee/Dr Jones to review the nominations for reference measurement methods for Electrolytes and draft the comment to be addressed to the review team leader for further consideration.**

Dr Wielgosz reported that the Electrolyte review team undertook a second review of the nominations for the reference measurement methods and services for six electrolytes submitted during 2014 review cycle, in order to take into account the issue raised by the Executive Committee regarding the possible effects of protein concentrations on the method measurement results.

Further to the Executive comments, the review team had recommended to list five of the six electrolytes methods and services, and had not recommended the listing of the method and service for the measurement of sodium in serum until additional evidence was provided by the nominator to clarify the use of the method with different concentrations of lipids or protein.

The Executive approved the review team's recommendations, and requested that this traceability issue should be raised with the method developers having a sodium measurement method currently listed in the database, and that a response be sought with the aim of clear advice to users of the methods and services.

**Action (A/14-21): Ad-hoc WG (Dr Myers, Dr Wielgosz, Dr Kaarls, Mrs Robertson, and Prof Siekmann) on WG governance, Chaired by Dr Myers, to draft a proposal on the most appropriate structure and assignment of duties to the JCTLM Executive, WG Chairs and the Secretariat, by March 2015, and circulate it for comment to the members of the Executive for discussion in June 2015.**

This action was completed and will be discussed under agenda point 3 and 7.

#### **New Actions:**

**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.

**Action (A/15-02):** Secretariat to post the approved document for the JCTLM Review Teams' Terms of Reference on the BIPM JCTLM Website.

### **3. Report back from ad-hoc group on JCTLM Future Structure [JCTLM-EXEC/15-03, 08, 09]**

Dr Myers reported on the activities of the ad-hoc Working Group on JCTLM Future Structure, and presented the documents JCTLM-EXEC/15-03, 08 and 09 that included a revised JCTLM organizational structure, as well as the WG proposal for changing the membership categories to include a National and Regional member category and a Stakeholder member category, and for reorganizing the JCTLM WG1 and 2 as one WG. He further added that during the meeting which was held at NIST on 10 April, Dr May supported the proposed Expert/Stakeholder Member category and the revised governance structure, and that a meeting would be scheduled with NIST staff in July to discuss the role of JCTLM and the forthcoming changes to get technical people involved in JCTLM activity.

The Executive reviewed the WG recommendations for changes in the structure and governance, and agreed on the following points:

-JCTLM WG1 (materials and methods) and WG2 (services) would be reorganized as one WG for Database with a Chair and three vice Chairs. It was agreed that the role of the JCTLM Executive Committee Chair would be extended to the role of JCTLM Database WG Chair, and that each of the vice-chairs would have the responsibility for an Analyte Group comprising three to four Review Teams. (The Analyte Tasked Working Groups will be determined under agenda point 7.4)

-JCTLM WG new structure would be trialed during this review cycle, and the vice Chairs of the WG Database and the leaders of the review teams would have to report at the WG meeting in December on the review teams' recommendations proposed for each of the submitted nominations reviewed.

-The new JCTLM policy for the review of the review teams' recommendations for listing nominations in the database, and the approval by the Executive Committee would be based on the report made by each of the three Analyte tasked WG Chairs at the annual meeting.

-The members of the Executive Committee recognized the heavy reliance of the JCTLM reference measurement services (RMS) review process on participation of calibration laboratories in the RELA scheme, and that timely information from the RELA scheme was needed for the review of RMS nominations. It was agreed that a RELA advisor should participate in the JCTLM RMS review process and give an update on the participation of the calibration laboratories in the RELA Scheme at the annual JCTLM WG meeting. It was also requested that the JCTLM quality procedures should be modified to adapt the JCTLM deadlines for the review the calibration laboratories' listed services with the RELA deadlines for reporting results.

-The Executive Committee agreed with the change in membership categories to include the two following categories:

- A JCTLM Stakeholder Members category for 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;
- A National and Regional Members category that contribute to the activities of the International Organizations that are members of the JCTLM Executive Committee

**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 August.

**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.

#### **4. Revision of JCTLM Declaration of Cooperation Document [JCTLM-EXEC/15-04]**

##### **4.1 Mission Statement and Structure and Operation Statements [JCTLM-EXEC/15-05]**

Dr Myers presented the document JCTLM-EXEC/15-05 which included the proposed revision for the Mission Statement for JCTLM. The members of the Executive Committee reviewed the proposed document, and agreed with the proposed changes.

**Action (A/15-05):** Dr Myers to finalize the document JCTLM –EXEC/15-05, and circulate it by end of August 2015 for comment by the members of the Executive.

##### **4.2 Appendix IV: Participation of organizations in the JCTLM [JCTLM-EXEC/15-06]**

##### **4.3 Appendix I and II: List of JCTLM Members and WGs [JCTLM-EXEC/15-07]**

##### **4.4 Appendix III: JCTLM Framework and database [JCTLM-EXEC/15-10]**

Dr Wielgosz presented the documents JCTLM-EXEC/15-06, -07 and -10 which included the proposed revision of the Appendices I, III and IV of the document for the Declaration of Cooperation with respect to the new JCTLM organization structure, and membership discussed earlier. The Executive committee reviewed these documents, and requested that additional corrections be made to the Appendices.

The Executive Committee agreed to withdraw the Appendix II of the Declaration of Cooperation presently listing JCTLM WG1 and WG2 with respective WG Chairs.

**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 August 2015 for comment by the members of the Executive.

**Action (A/15-07):** Secretariat to send a letter 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.

**Action (A/15-08):** Secretariat to contact the JCTLM Members organizations and ask them to submit a two pages reports in order for the Executive to do a presentation and to verify if they wish to participate in doing a presentation at the JCTLM Members and Stakeholders meeting in December.

#### **5. Progress with identifying potential JCTLM Executive Committee Organizations**

Drs Myers and Wielgosz informed the Committee that they met on 22 June 2015 with two representatives from the International Council for Standardization in Haematology (ICSH) for presenting the activity of the JCTLM, and the IFCC SD HbA2 standardisation. ICSH representatives explained their activity in the field of HbA1C and HbA2 together with the material and method used in this field. They indicated their interest in possibly nominating reference material and reference method in use, and in participating in the JCTLM Executive meeting. They made the proposal that JCTLM representative could attend their meeting in Milan and in Glasgow.

#### **6. Terms of Reference and activities of the JCTLM WG on Traceability Education and Promotion**

Dr Beastall presented the document JCTLM-EXEC/15-13 (to be posted on the website) which included the Terms of Reference of the JCTLM WG on Traceability Education and Promotion. The Executive reviewed and commented this document.

**Action (A/15-09):** Dr Beastall to finalize the document for the ToRs of the WG on Traceability Education and Promotion (JCTLM-EXEC/15-13), and to distribute it for comment at the next Executive meeting in December.

## **7. JCTLM Reference Measurement Systems Database WG Structure**

### **7.1 Composition and meetings of WG**

As discussed under agenda point 3, the Executive Committee agreed to merge the activity of JCTLM WG1 (materials and methods) and WG2 (services) in a new JCTLM Database WG under the Chairmanship of JCTLM president. The supervision of the technical review of the JCTLM nominations would be undertaken by three vice Chairs of the WG Database that would have to report at the annual WG Database meeting on the review teams' recommendations.

### **7.2 Review and proposals for changes to Review Teams**

The Executive reviewed the membership of the thirteen JCTLM Review Teams and requested the following actions to be undertaken:

**Action (A/15-10):** Secretariat to contact the Leader of the Blood Grouping review team to verify if she would agree to rename the team as Blood Grouping and Cell typing review team given that the methods used were the similar, and this with the view to get nominations in Cell typing.

**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

**Action (A/15-12):** Secretariat to contact C. Seger to verify if he was willing to remain a member of the review team for Drugs.

**Action (A/15-13):** Secretariat to contact the leader of the Electrolytes and Blood gases team to have feedback on the participation of the members and to verify if a call for nominations should be launched to complete the review team.

**Action (A/15-14):** Secretariat to contact H. Andres to verify if he was willing to remain a member of the review team for Metabolites and Substrates.

The Executive decided to rename the review team for Microbial Serology as Infectious diseases, and requested that representatives of the Infect-met project and the group for Standardisation of Genome Amplification Techniques (SoGAT) be invited at the forthcoming meeting in December.

**Action (A/15-15):** Secretariat to update the list JCTLM Review Teams to rename Microbial Serology under Infectious diseases

**Action (A/15-16):** Secretariat to contact K. Phinney to verify if M. Holden was still an active NIST staff member.

Dr Wielgosz informed the Committee that he had discussed the issue of outstanding reviews with the Leader of the Proteins review team at Euromedlab, who had committed to complete the review and assignments for the two method nominations that were submitted under last year WG1 review cycle 11 before end of July

Dr Schimmel agreed to undertake the review of three outstanding membership applications submitted last year.

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

### **7.3 Role and responsibilities of JCTLM WG Chair and Vice Chairs**

This item was discussed under agenda point 7.1.

### **7.4 Assignment of Review Teams to Analyte groups**

The Executive Committee appointed the Chairs of the three Analyte groups, and assigned Review teams to each Analyte Group as follows:

Prof. Dr. L. Siekmann agreed to chair the Drugs, Metabolites and Substrates, and Non-Peptide Hormones Review Teams;

Dr H. Schimmel agreed to chair the Coagulation Factors, Enzymes, Proteins, Nucleic Acid, Pathogens, Blood cell counting, Blood Grouping and cell typing Review Teams;

Dr K. Phinney was appointed as Chair of the Vitamins, Non Electrolytes Metals, and Electrolytes and blood gases Review Teams.

### **7.5 Revision of the JCTLM WG Quality Manuals (marked up versions to be distributed)**

## **8. Timetable for finalization and approval of documents**

### **8.1 Declaration of cooperation document**

See Action (A/15-03, -05, and 06).

### **8.2 WG quality manuals**

See Action (A/15-04).

## **9. Summary of nominations received in current cycle for CRMs, RMMs and RMSs**

There were 52 nominations that have been submitted for review to JCTLM WG1 review cycle 12 and to WG2 review cycle 10 in the following analyte groups:

Drugs: there was one nomination for a certified reference material;

Enzymes: there were 17 submissions for reference measurement services;

Metabolites & Substrates: there were eight submissions for certified reference materials, two nominations for reference measurement methods, and 8 nominations for reference measurement services;

Non-Peptide hormones: there were two submissions for certified reference materials, one nomination for a reference measurement method, and one nomination for a reference measurement service;

Proteins: there were six submissions for certified reference materials, one nomination for a reference measurement method, and one nomination for a reference measurement service;

Vitamins: there were two submissions for certified reference materials, and two

nominations for reference measurement methods

**Action (A/15-18):** Secretariat to distribute these new nominations to JCTLM review teams by 15 July 2015

## **10. Update on Gap Analysis Studies**

Dr G. Jones reported on the variability and the veracity of the information on the traceability statements that could be provided by IVD industry in the insert package for their assay for creatinine measurements (understood as a well-established reference measurement system) and for Blood gases (for which no items were currently listed in the JCTLM database).

**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

**Action (A/15-20):** Dr G. Jones to respond to Dr K. Phinney and request that she develops a fast track review process proposals for replacement batches of material that have been already listed in the JCTLM database.

## **11. Future meetings of the JCTLM**

### **11.1 Conference call of JCTLM Executive (September/October 2015)**

The Executive committee decided that at this stage an autumn conference call of JCTLM Executive was not necessary.

### **11.2 JCTLM Symposium and Stakeholder meetings (2015)**

The Executive agreed to hold a two days JCTLM Members' and Stakeholders' meeting to be held at the BIPM on 30 November and 1<sup>st</sup> December 2015.

The two days of meeting will be split into five sessions:

Session 1: Update on JCTLM activities;

Session 2: JCTLM Member activities;

Session 3: Developments in Traceability Requirements around the Globe;

Session 4: Identifying future priorities in Traceability in Laboratory Medicine;

Session 5: New Challenges for Traceability in Laboratory Medicine.

**Action (A/15-21):** Secretariat to announce by 15 July the JCTLM Members' and Stakeholders' meeting to be held on 30 November and 1 December 2015

It was agreed that a session for the JCTLM WG on Traceability Education and Promotion would be held at the WGs meeting on the 2nd December 2015, and that attendance from JCTLM member organizations and IFCC corporate members would be valuable.

**Action (A/15-22):** Secretariat to announce the formation of JCTLM WG on Traceability Education and Promotion to JCTLM members, and a meeting to be held on 2 December 2015.

The organization of a JCTLM Workshop (satellite meeting) at the venue of the IFCC meeting in Athens in June 2017 was discussed and it was agreed to propose an agenda for this meeting.



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

### **11.3 JCTLM Symposium in Beijing 2016**

Dr Wielgosz reported that the National Institute of Metrology (NIM) from China agreed to co-organize a JCTLM Symposium in Beijing in 2016 which would be held in conjunction with workshops that would focused on therapeutic or peptide /proteins measurement issues.

### **12. Close**

The Chairman closed the meeting on 26 June at 12h00.

S. Maniguet 07 July 2015

Finalized 29 October 2015

## Annex 1: Summary List of Actions

### **Actions from the 14<sup>th</sup> Executive Meeting:**

**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.

**Action (A/15-02):** Secretariat to post the approved document for the JCTLM Review Teams' Terms of Reference on the BIPM JCTLM Website.

**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 August.

**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.

**Action (A/15-05):** Dr Myers to finalize the document JCTLM –EXEC/15-05, and circulate it by end of August 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 August 2015 for comment by the members of the Executive.

**Action (A/15-07):** Secretariat to send a letter 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.

**Action (A/15-08):** Secretariat to contact the JCTLM Members organizations and ask them to submit a two pages reports in order for the Executive to do a presentation and to verify if they wish to participate in doing a presentation at the JCTLM Members and Stakeholders meeting in December.

**Action (A/15-09):** Dr Beastall to finalize the document for the ToRs of the WG on Traceability Education and Promotion (JCTLM-EXEC/15-13), and to distribute it for comment at the next Executive meeting in December.

**Action (A/15-10):** Secretariat to contact the Leader of the Blood Grouping review team to verify if she would agree to rename the team as Blood Grouping and Cell typing review team given that the method used were the similar, and this with the view to get nominations in Cell typing.

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**Action (A/15-15):** Secretariat to update the list JCTLM Review Teams to rename Microbial Serology under Infectious diseases.

**Action (A/15-16):** Secretariat to contact K. Phinney to verify if M. Holden was still an active NIST staff member.

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

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