

**Draft Report of the 18th meeting of the JCTLM Executive Committee
11 June 2017, Athens, Greece**

List of participants:

Dr G. Myers (JCTLM Chairman, IFCC)
Dr R. I. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr G. Beastall (JCTLM WG-TEP Chair, IFCC)
Dr H. Schimmel (JCTLM DB WG vice-Chair)
Dr G. Jones (ILAC)
Dr S. Maniguet (JCTLM Secretariat, BIPM)

Apologies received:

Dr. M. Milton (BIPM)
Dr. W.E. May (CIPM)
Dr J. McLaren (CIPM)
Ms R. Robertson (ILAC)
Dr. A. Kessler (IFCC)
Dr K. Phinney (JCTLM DB WG vice-Chair)

1. Approval of the agenda [JCTLM-EXEC/17-01]

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 17th JCTLM Executive Committee Meeting [JCTLM-EXEC/17-02]

The report of the 17th Executive Committee meeting was finalized in February 2017, and published on the [BIPM JCTLM website](#). Prof. Siekmann sent a letter [JCTLM-EXEC/17-03] to request a revision of the statement in point 7.3.3, and suggested not removing temporarily a listed reference measurement method (RMP) from the database when a second RMP was proposed for listing showing discrepant results, noting that the situation should be clarified between the two RMP providers. The Committee agreed with his proposal and requested that the process should be modified to add a note to the listed method to inform the users of existing discrepancy between two methods until discrepancy was resolved.

It was also agreed that this JCTLM process should apply when a newly developed reference measurement procedure might lead to a shift of routine method results.

2.1 Review of action points arising from the 17th meeting

Dr Wielgosz summarized the action items from previous meeting that were still in progress:

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

Dr Wielgosz reported that this action was not completed, and took the opportunity of this meeting to invite suggestions from members of the Committee. In the discussion that followed it was agreed that there were four key points that JCTLM Members and Stakeholders organizations should report on in their biennial activity report. Those were the following:

- Description of the standardization activity that had been carried out by the organization during the last two years, and information on their planned activity for the two next years with regards to the production of certified

reference materials, the development of reference measurement methods and the establishment of reference calibration measurement services.

- Report on their activity involving the promotion of traceability in laboratory medicine including presentations of their work at international conferences and other national meetings for clinical laboratory medicine.
- Report on their collaboration and participation in networks aiming at the implementation of standardized /harmonized reference measurement systems.
- Report of any issues related to traceability that the organization would wish to see considered by JCTLM.

A written statement would also be requested from the organization to confirm whether part of full set of their activity report could be used for publication in the traceability website/ JCTLM website.

Action (A/16-05): Dr Wielgosz to consult the CCQM and in particular the NMIs providing Reference Materials to canvas opinion on the requirement for the CRM certificate and certification report to be available in English as an acceptance criteria for a higher order CRM.

Dr Wielgosz reported that the outcome of the consultation with the NMIs at the CCQM meeting in April 2017 was inconclusive and commented that they should be given further detailed information to clarify why JCTLM was requesting the certification documents of a higher order CRM in a full English version. The Committee agreed that the step forward to ensure a better understanding from all parties involved in CRM activity of the benefit of this proposed new JCTLM requirement would be to draft a white paper for describing the benefit for CRM producers and users, and also for recalling the difference of the review criteria that were employed in the CIPM MRA review process for CMCs evaluation compared to those employed by JCTLM in its review process for assessing CRMs of a higher metrological order. Drs Myer and Wielgosz agreed to draft the discussion paper for presentation at the next Members' and Stakeholders' Meeting.

Action (A/16-09): BIPM to draft a response to NIM's request for a fast track review process of their materials already listed in the BIPM KCDB and invite them to provide the relevant document for consideration of their materials by JCTLM review team.

Dr Wielgosz said that NIM's representatives attended the CCQM meeting in April 2017 during which the proposed new JCTLM acceptance criteria for CRM was discussed (see discussion point above). He suggested that a follow up of this discussion would be to create a fast track for JCTLM review process when a NMI having a CMC listed in the BIPM KCDB submits a CRM for evaluation by JCTLM. It was pointed out that key acceptance criteria that would apply in a fast track process would include the verification of the listing of the CMC declared by the NMI in the BIPM KCDB having this CRM listed as a mechanism to deliver services to disseminate traceability, noting that ISO 17034 may have been applicable for that particular case and the competence for CRM production should have been looked at. The fast track process of JCTLM would require the checking of the intended use and commutability statement of the nominated CRM, noting that JCTLM was listing CRMs that were reviewed in compliance against ISO 15194 requirements.

Action (A/16-12): Dr Phinney / Dr K. Lipka (NIST) to draft a proposal which would highlight the key acceptance criteria with respect to ISO 15194 requirements for submission of renewed batches of the certified reference materials.

This action was not completed yet and BIPM/Secretariat would follow up on this action and provide input for drafting JCTLM criteria concerning the submission of a renewed batch of a CRM for discussion at the next December JCTLM Meetings.

Action (A/16-13): Dr Myers to liaise with ICSH to verify if they would be willing to collaborate in organizing a satellite meeting on traceability and hematology at an international IVD/Manufacturer congress.

Dr Myers reported that he received a positive response from a representative of the ICSH Executive Board for working towards a collaboration between JCTLM and ICSH. In the discussion that followed the members of the Committee agreed to convene a half-day workshop after the December's JCTLM Members' and Stakeholders' meeting on the morning of the 7th December. The targeted audience would be representatives from the JCTLM, ICSH, and representative of IVD Manufacturers being involved in traceability and hematology as well as members of JCTLM review team for Blood cell counting and typing. Drs Beastall and Jones agreed to coordinate the organization for this technical Workshop.

Action (A/16-17): Dr Phinney to contact Dr Long (NIST) to verify if he would be willing to take the lead of the Electrolytes and blood gases review team, and further recruit additional members for the team.

Dr Phinney reported prior to the meeting that Dr Long was not available to undertake the role of leader for the Electrolyte and Blood gases team. The Executive committee requested that D. Ducroq who recently joined the review team should be contacted for the position of leader. A call for experts would also to be launched to recruit more members for the team and also develop the team's expertise in the blood gases area.

Action (A/16-20): Secretariat to contact the leaders of the review teams and ask them to nominate a member of their team who could contribute in the review of the JCTLM Quality System with the view to initiate updates and reflect on technical aspects they experienced in reviewing nominations.

Dr Maniguet reported that two nominations were received for participants in the review of Quality system procedures, notably Dr. Stosch (PTB) who was a member of the Non Electrolyte Metals review team, and Dr Yu (Beckman) who was a member from Proteins review team. The Committee approved these nominations.

Action (A/16-23): Dr Jones to draft a guidance document for authors and journal editors for accurate descriptions of assay performance in journal articles (especially traceability) for publication on the traceability website.

Dr Jones presented the draft for a guidance document [JCTLM-EXEC/17-11] which took the form of a letter to the editors of journals and described key requirements for publication of assay description in journals. He commented that the list was not exhaustive as distinction had to be made between a method purchased from a diagnostic company and another developed in-house. Consequently, specific references would be required for kit methods and more detailed information would be needed for in-house in-vitro diagnostic devices. The Committee thanked Dr Jones for his work and commented that similarities could be observed with key components described in the international standard ISO 17511 (being currently under revision) and requested that a screening of key concepts should be made to avoid omitting concepts described within the ISO document. In addition, it was agreed that IVD companies via their representatives in ISO TC/ 212 WG2 could be consulted for reviewing the draft as they were those directly involved in the development of the method assays. Dr

Jones would contact an editor of a journal in Clinical Chemistry prior to finalizing the guidance document to verify that there were no opened questions.

Action (A/16-27): R. Wielgosz to contact the Enzymes RT Leader to verify if he would be willing to chair a half-day technical workshop on how to implement the IFCC reference measurement procedures for Enzymes and how accredited laboratories should be declaring their services for inclusion in the JCTLM Database

Dr Wielgosz said that he contacted the Enzymes RT leader who suggested him to postpone the workshop until the PPTD in Chengdu in October 2018 as to ensure a greater involvement/availability of the members of the Enzymes review team in the organization of the technical workshop as well as to reach the right audience, noting that the reference laboratories from Asia had been the major contributors to the nominated calibration reference measurement services in enzymes area in the latest review cycle.

The Committee agreed with the proposal.

Action (A/16-35): Secretariat to contact leaders of the review teams that have not yet provided their environment scan information to submit their presentation for consideration by the Database WG chairs and Executive Committee by end of March 2017.

Dr Maniguet reported that the leaders of the review teams for which the environment scan was not provided at December's JCTLM Database WG meeting were contacted, and there had been no additional scans returned. Dr Schimmel confirmed to the Committee that the scan for the Non-peptide hormones team was being finalised and would be communicated to the Secretariat shortly after the meeting.

The actions listed below were not completed yet, and would be followed up at the next Executive meeting.

Action (A/16-10): Dr Wielgosz to send a request to the IFCC Scientific Division to review the IFCC reference measurement procedures for pH, Blood Gases, and Electrolytes and consider nominating these for listing in the JCTLM database.

Action (A/16-26): R. Robertson to contact the Enzymes RT leader to draft the main issues to be raised to the accreditation bodies in regard to their assessment for enzyme reference measurement laboratory services for compliance with ISO according to ISO 17025 and ISO 15195.

New Actions

Action (A/17-01): Secretariat to revise the text of the relevant JCTLM procedure to modify the process for allowing a note to be added on a listed method when a second method was proposed for listing method showing discrepant results or when evidence was given that a method results might lead to a shift compare to a routine method.

Action (A/17-02): G.Myers/R. Wielgosz to draft a discussion paper concerning the implementation of the proposed JCTLM requirement for submission of full English version of the certification documents of CRM for presentation at the next JCTLM Members' and Stakeholders' meeting.

Action (A/17-03): Secretariat to draft the fast track process when a NMI submits a CRM listed as a mechanism for service delivery for a CMC published in the database of the CIPM MRA and to circulate it for comment to the JCTLM DB WG and final approval at the next December's JCTLM Executive Committee meeting.

Action (A/17-04): Drs Beastall and Jones to set up a proposal for a half-day workshop on 7 December 2017 to consider traceability in hematology area in consultation with ICSH representative, and Review team on blood cell counting and typing.

Action (A/17-05): Secretariat to contact Mr Ducroq (WEQAS) to verify if he would be willing to take the lead of the Electrolytes and Blood Gases review team, and to launch a call for new experts for participating in the review team.

Action (A/17-06): G. Jones to finalize the guidance document for publication of method assay after review against concepts described in ISO 17511 standard and consultation with the editor of Clinical Chemistry journal that there were no remaining opened questions

3. Progress with identifying potential JCTLM Executive Committee Organizations

As reported at the previous meeting contact with International Council for Standardization in Hematology (ICSH) was progressing. Dr Beastall said that he would not be able to attend their General Assembly in October 2017 due to another meeting commitment. The organization of a half- day workshop was discussed earlier as a follow up of action point A/16-13 under agenda point 2.1.

4. JCTLM membership applications [JCTLM-EXEC/17-10, 12]

Dr Maniguet presented the document [JCTLM EXEC/17-10] which included an application for JCTLM Stakeholder Membership. This was submitted by Shanghai Center for Clinical Laboratory (SCCL) from China which was an EQAS provider. The Committee reviewed and accepted SCCL as a Stakeholder Member of the JCTLM.

In addition there had been three new organizations that became Stakeholder members of the JCTLM since the last December's Executive meeting. Those were the following:

- Roche Diagnostics from the United States which was an in-vitro diagnostic instrument and reagent manufacturer,
- R B Diagnostic Private Limited from India which was a private laboratory organization,
- MedicalSystem Biotechnology Co., Ltd. from China which was an in-vitro diagnostic instrument and reagent manufacturer.

Dr Beastall reported that a letter to IFCC corporate member organizations with a copy of the 2017 Newsletter and the leaflet about Stakeholder membership for diagnostics companies was sent to 50 companies. In order to increase the number of responses from the IVD industry, Drs Myers and Beastall added that there was a need to identify within IVD companies those relevant contact persons that could be reached for raising awareness of JCTLM activity and possibility for them to apply for a JCTLM Stakeholder Membership. A first list of contact persons was already produced [JCTLM EXEC/17-12] and they would report on the progress at the next Executive meeting.

Action (A/17-07): Secretariat to confirm SCCL as JCTLM Stakeholder Member.

5. JCTLM Governance

5.1 Representation on the Executive [JCTLM/EXEC17-05]

Dr Wielgosz presented the document JCTLM-EXEC/17-05, which included the nomination of Dr Anya Kessler as new representative of the IFCC at the JCTLM Executive Committee meeting in replacement of Prof Siekmann. The Committee welcomed her nomination.

5.2 JCTLM WG Chair

Dr Schimmel informed the Committee that he would step down in September as vice-Chair of the Database WG (covering Blood Cell Counting and Typing, Coagulation Factors, Enzymes, Infectious Diseases, Nucleic Acids, Proteins), leader of the JCTLM Review Team for Non-Peptide Hormones, and member of the JCTLM Review Team for Nucleic acid. The Committee thanked Dr Schimmel for his important contribution as one of the founding members of the JCTLM WG, and for his continued participation as a leader and member of the JCTLM Review Teams.

The Committee reviewed two nominations for JCTLM review team membership that were submitted for approval in document JCTLM/EXEC-17-04a,-b, and accepted the application of Dr Steven Westwood (BIPM) as new member of the JCTLM Review Team for Drugs, and Dr Carolyn Burdette (NIST) as new member of the JCTLM Review Team for Vitamins and micronutrients, and for Metabolites and Substrates.

Action (A/17-08): Secretariat to confirm Dr Steven Westwood (BIPM) as new member of the JCTLM Review Team for Drugs, and Dr Carolyn Burdette (NIST) as new member of the JCTLM Review Team for Vitamins and micronutrients, and for Metabolites and Substrates.

5.3 JCTLM Database

Dr Maniguet reported that the publication of materials, methods and services that have been reviewed by the JCTLM Database WG during 2016 review cycle, and approved for JCTLM listing at last Executive Committee meeting was done in February 2017. She added that the new items published as well as the updated status of the JCTLM Database were included in the latest issue of the JCTLM Newsletter. This fourth issue of the Newsletter was released in March 2017 and can be downloaded from the following link:

<http://www.bipm.org/utis/common/pdf/JCTLM/JCTLM-Newsletter-2017.pdf>

6. Report from the JCTLM WG on Traceability Education and Promotion [JCTLM-EXEC/17-06]

Dr Beastall presented the document JCTLM EXEC/17-06 which included the second activity report of the TEP WG for the JCTLM Executive Committee, and progress report for each Work Stream. He updated each Work stream's activity and pointed out the following points:

Work Stream 1: Definitions

The project was complete and the [Glossary of terms used in traceability in laboratory medicine](#) was posted on the TEP WG website in May 2017.

Work Stream 2: Mini-presentations to explain scientific concepts regarding traceability

This project was progressing and seven out of the ten mini-presentations were published on the traceability website (jctlm.org) covering the following topics:

- The pillars of standardization,
- Basic traceability chains,
- Basics of traceability applied to laboratory medicine,
- Standardization and harmonization,
- Traceable and commutable calibrators,
- Examples of reference materials,
- Examples of reference measurement procedures.

The remaining presentations were expected to be completed in September.

Work Stream 3: Why traceability matters to manufacturers?

This project had been carried out successfully under the leadership of Dave Armbruster who retired from Abbott. The Committee recognized the important contribution from Dave Armbruster for raising awareness of traceability within IVD industry, and recommended that a new IVD representative should be identified for leading the activity of the group.

Work Stream 4: Why traceability matters to patients and the public?

The status of the project was ongoing.

Work Stream 5: Global significance of traceability,

The review article was published in *Clinical Chemistry and Laboratory Medicine*, translated in Spanish and was being translated in Chinese.

Work Stream 6: Tools to promote traceability.

This project was on going and Dr Beastall pointed out that a directory of EQA organizations was accessible from IFCC website since the last Executive meeting.

He added that he would focus in the coming months in developing a strategy for distribution of the two newly-published Webinars for training in laboratory medicine.

The Committee discussed future activities that could be addressed by the TEP-WG and suggestions were made for developing a strategy/process for encouraging linkage of the traceability website to other partners' website. It was also noted that TEP-WG could address traceability from an applicative point of view such as focusing at its impact on Reference interval at national level, or laboratory in house assay.

6.1 JCTLM Members and Stakeholder's meeting [JCTLM-EXEC/17-07]

Dr Beastall presented the draft programme for the 2017 Members' and Stakeholders' meeting [JCTLM EXEC/17-07] which was made available from the BIPM website. He added that the first meeting announcement was sent by email at the end of May to about 600 contact persons by the BIPM. He suggested that a second announcement be sent early July to advertise the possibility for the participants to present a poster.

In the discussion that followed the Committee agreed on the following action points:

- To open up the participation to wider laboratory medicine and IVD industry community the title for the biennial JCTLM Members' meeting would be modify to read:
"Accurate results for patient care Workshop 2017" with the sub-title "A JCTLM Members' and Stakeholders' Meeting"
- The final version of programme for the meeting would be edited with the JCTLM elements of graphic design already used in the leaflet or Newsletter.
- A leaflet for advertising the meeting at the AACC and IFCC booths during the AACC meeting in San Diego in August 2017 would be developed.
- A presentation on the revision of the new European IVD Regulation and its implication for the IVD industry should be included in Session 4 of the meeting.
- A dedicated webpage for publicizing the JCTLM Members' and Stakeholder's meeting would be developed with its own url.

Action (A/17-09): Secretariat to finalize the programme for the JCTLM 2017 Workshop to include the new title and edit it with the recognizable JCTLM elements of design.

Action (A/17-10): Secretariat to produce a dedicated webpage and leaflet for the JCTLM 2017 Workshop for distribution at the 2017 AACC conference in San Diego.

7. JCTLM DB WG: Current Nomination Call

7.1 Status

Dr Maniguet presented a summary of the number of nominations that have been submitted for review cycle 14 for materials and methods, and for review cycle 12 for services. There were 79 nominations submitted by 30 May 2017 in the following groups of analyte:

Drugs: there was one nomination for a certified reference material, and one nomination for a reference measurement method;

Electrolytes: there were 18 nominations for certified reference materials, five nominations for reference measurement methods, and three nominations for reference measurement services;

Enzymes: there were seven nominations for a certified reference material, and 14 nominations for reference measurement services;

Metabolites and Substrates: there were 10 nominations for certified reference materials, two nominations for reference measurement methods, and four nominations for reference measurement services;

Non-peptide hormones: there was one nomination for a certified reference material;

Non-electrolytes metals: there was one nomination for a reference measurement method;

Proteins: there were seven nominations for certified reference materials, two nominations for reference measurement methods, and one nomination for reference measurement service;

Vitamins: there were two nominations for a certified reference material.

Action (A/17-11): Secretariat to distribute complete nominations to Database WG Chairs by end of June, and JCTLM review teams by 15 July 2017.

7.2 Update on IFCC EQAS results [JCTLM-EXEC/17-09]

Dr Maniguet presented the document JCTLM-EXEC/17-09 which included the outcome of the review completed by Prof Siekmann and Dr Kessler on how often the reference laboratories listed as service providers in the JCTLM database regularly participated in the RELA collaborative surveys for the last three years 2013, 2014 and 2015 according to the rules of JCTLM procedure manual. They reported that most of the reference/calibration laboratories fulfilled the requirements and participated for each of their listed measurands at least once in a time period of three years (2013 - 2015) and in every year at least for one measurand in the relevant group.

There were three service providers from China and Japan showing a lack of participation for one measurand in the Enzymes or Metabolites and Substrates Group.

The Committee agreed with Prof Siekmann's recommendation to contact the two service providers and eventually delist their services for the related measurands from the database.

Action (A/17-12): Secretariat to contact the two service providers not fulfilling one of the JCTLM requirements for regular participation in RELA EQAS Scheme participation, and confirm with them their service status prior to delist their service from the JCTLM Database.

8. Update on Gap Analysis Studies

Dr Jones reported that he had produced an article which was published as a Special Report for the fourth issue of the JCTLM Newsletter which was released in March 2017. This described complete and not complete reference measurement systems based on his gap analysis and can be downloaded from the following link:

http://www.bipm.org/utis/common/pdf/JCTLM/JCTLM_Newsletter_2017_Special_Report.pdf

The Committee acknowledged this contribution and commented that from the feedback they received this would be a useful tool for all parties involved in standardization and planning resources for developing materials, methods, and services for reference measurement systems.

9. Liaison with ISO TC 212

Dr Wielgosz reported that a meeting of the ISO TC 212 WG2 has been held in Minneapolis (USA) on 23-25 May 2017, and the next meeting would be held in Brussels (Belgium) on 1 - 3 December 2017 and the status of the drafting of the documents developed or revised by ISO-TC212/WG2 were progressing as follows: the draft FDIS of the revised text of the ISO 17511 was expected to be ready in December 2017 which would allow for a 6 months period of comment until publication.

As reported in the previous meeting revision of the text of the ISO 15195 which was pending the finalization of the ISO/IEC 17025 document.

10. Future meeting of the JCTLM

10.1 JCTLM Members and Stakeholders meeting 2017

This was discussed under point 6.1.

10.2 JCTLM events in 2017 and 2018

Dr Beasall informed the Committee that the proposal for a JCTLM Symposium was accepted at the COLABIOCLI congress in Uruguay in September 2017, and at the IFCC WorldLab in Durban in October 2017. He said that discussions with EQALM regarding a joint session at EQALM 2018 were still underway.

10.2.1 PPTD-2018 meeting in Chengdu China, 11-13 October 2018

Dr Wielgosz informed the Committee that NIM (China) confirmed the financial funding for organizing the PPTD Workshop in Chengdu China on from 10 to 12 October 2018 in collaboration with JCTLM.

10.3 Joint meeting in 2018 with ICSH on traceability

The organization of a JCTLM-ICSH joint meeting was discussed under point 3 and it was agreed to organize a preliminary workshop on 7 December 2017.

11. Close

The Chairman closed the meeting on 11 June at 12:00.

Annex 1: Summary List of Actions

Outstanding actions from the 17th Executive Meetings:

Action (A/16-10): Dr Wielgosz to send a request to the IFCC Scientific Division to review the IFCC reference measurement procedures for pH, Blood Gases, and Electrolytes and consider nominating these for listing in the JCTLM database.

Action (A/16-12): Dr Phinney / Dr K. Lippa (NIST) to draft a proposal which would highlight the key acceptance criteria with respect to ISO 15194 requirements for submission of renewed batches of the certified reference materials.

Action (A/16-26): R. Robertson to contact the Enzymes RT leader to draft the main issues to be raised to the accreditation bodies in regard to their assessment for enzyme reference measurement laboratory services for compliance with ISO according to ISO 17025 and ISO 15195.

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Action (A/17-07): Secretariat to confirm SCCL as JCTLM Stakeholder Member.

Action (A/17-08): Secretariat to confirm Dr Steven Westwood (BIPM) as new member of the JCTLM Review Team for Drugs, and Dr Carolyn Burdette (NIST) as new member of the JCTLM Review Team for Vitamins and micronutrients, and for Metabolites and Substrates.

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Action (A/17-11): Secretariat to distribute complete nominations to Database WG Chairs by end of June, and JCTLM review teams by 15 July 2017.

Action (A/17-12): Secretariat to contact the two service providers not fulfilling one of the JCTLM requirements for regular participation in RELA EQAS Scheme participation, and confirm with them their service status prior to delist their service from the JCTLM Database.