

**Report of the 22nd meeting of the JCTLM Executive Committee
3-4 December 2020**

**Venue: Webex Video Conferences
Time: 12:00-14:00 (UTC +1, Paris time)**

List of participants:

Prof I. Young (JCTLM Chairman, IFCC)

Dr R. Wielgosz (JCTLM Executive Secretary, BIPM)

Dr G. Myers (IFCC)

Dr S. Maniguet (JCTLM Secretariat, BIPM)

Dr T. Liew (CIPM)

Dr G. Jones (ILAC)

Ms M. Bednarova (ILAC)

Dr Q. Liu (JCTLM DB WG vice-Chair, AG1)

Prof. M. Panteghini (JCTLM DB WG vice-chair, AG2)

Dr K. Phinney (JCTLM DB WG vice-Chair, AG3)

Mr T. Fawcett (ICSH)

Dr A. Kessler (IFCC)

Dr Sang-Ryoul Park (CIPM)

Dr S. Westwood (Blood cell Counting team Leader, BIPM)

Dr G. Miller (IFCC)

Prof. E. Theodorsson (JCTLM TEP WG Chair)

Apologies received:

Dr M. Milton (BIPM)

1. Approval of the agenda [JCTLM-EXEC/20-01]

The agenda was approved with no change.

2. Report of 21st JCTLM Executive Committee Meeting

2.1 Review of action points arising from the 21st meeting [JCTLM-EXEC/19-02, 03]

The Committee reviewed the action items from the previous meeting that were still outstanding and would be completed after the meeting:

Action(A/19-02): Dr Wielgosz to develop a plan and scope for a training project on ISO Standards.

It was noted that the Secretariat currently lacked the resources to initiate the project, which was on hold.

Action (A/19-05): BIPM to draft a procedure for an induction process for new EC members of JCTLM Executive Member Status for discussion at the Executive Meeting in December 2020.

Progress on the induction of ICSH was discussed under agenda point 3.1.

Action (A/19-12): JCTLM EC members (G. Myers lead) to review new standard ISO 21151 to highlight what information would be suitable for publication in the JCTLM Database, for discussion during a conference call.

2.2 JCTLM pamphlet for regulatory bodies [JCTLM-EXEC20-10]

Dr Myers presented the first version of the JCTLM pamphlet the purpose of which was to introduce JCTLM and its activities and services to the regulatory and Notified Bodies, and any groups that were involved in making decisions about metrological traceability and are meeting regularly with IVD manufacturers. He commented that this first draft was related to the requirement laid down in the new EU IVD Regulation, and another generic version could also be anticipated for electronic distribution to the US and/or Chinese regulatory audience. The Chairman thanked him for his work and invited the members of the Committee to send their comments within the two weeks following the meeting.

Action(A/20-01): The Executive Committee members to send their comments to Dr Myers (cc Secretariat) on the JCTLM Pamphlet for regulatory bodies by the end of December 2020.

3. JCTLM membership

3.1 Developing an induction process for new EC members

Dr Wielgosz reported that Dr Westwood had been active in communicating with ICSH after their accession as a new organization member of the JCTLM Executive Committee. Dr Westwood further presented the induction process which was undertaken with the ICSH representatives, firstly as part of the follow up actions for resolution of review observations of their platelet method, and secondly along with the review of another nomination that was being dealt with by the JCTLM review team of Blood Cell Counting and Typing. Training sessions were conducted during virtual meetings with all members of the review team and the main focus has been on outlining the content of ISO Standards and reaffirming to the members of the team the JCTLM requirement to have access to Standards.

The Committee noted that the access to the standards was still an issue for some of the members of the review team for Blood Cell Counting and Typing. After discussion it was agreed that they should be contacted for reaffirmation of their obligations as members of a JCTLM review team to have access to a copy of the standards, noting JCTLM could not provide copies to the review team members.

Action(A/20-02): JCTLM Secretariat to contact the members of the Blood Cell Counting and Typing review team to reaffirm to them their obligations to have access to the Standards for reviewing nominations in order to remain a member of the team.

4. JCTLM Governance

4.1 JCTLM Review Team Membership

Dr Wielgosz reported that the Secretariat completed the five years review process for JCTLM Review teams membership which resulted in the reappointment of 75% of the review teams' members who were contacted. There were currently 60 experts contributing to the twelve JCTLM review teams, amongst which ten were new members appointed during the year. Mr Fawcett informed the Committee that the ICSH would submit a nomination for a member of the Coagulation Factors review team.

4.2 Representation on the Executive

Prof. Young informed the Committee that he would not renew his mandate for an additional two years and was willing to act as the Chair of the JCTLM until a new Chair would be elected by the end of January 2021. The Committee thanked him for his support and

leadership of JCTLM. It further requested that the procedure for selection of a new President should be followed, which would require the Secretariat to inform the JCTLM Executive Committee members organizations of the need to nominate candidates for the post of JCTLM President. It was also reminded that the JCTLM Secretariat host organization would need to be re-elected at the same time.

Dr Myers informed the Committee that his term as IFCC representative in the JCTLM Executive Committee was renewed for an additional two years by the IFCC Executive Board.

Action(A/20-03): JCTLM Secretariat to contact IFCC, BIPM, ILAC and ICSH by 15 December 2020 for nominations of JCTLM President and Secretariat, for review and approval of applications during an extraordinary session of the JCTLM EC which would be held remotely by the end of January 2021.

4.3 JCTLM WG Chairs

Dr Wielgosz said that the term of the Chair and three vice Chairs of the JCTLM Database WG would come to an end at the end of 2020, noting that in accordance with JCTLM rules the responsibilities of the JCTLM DB WG Chairman would be taken over by the new JCTLM president who would be elected in January 2021.

Dr Phinney, Prof. Panteghini and Dr Liu confirmed their willingness to continue to chair the WG Analyte Group 3, 2 and 1, respectively.

The Committee reappointed them for a renewable two-year term mandate.

4.4 Funding of the JCTLM Secretariat

As reported at the previous meeting the running cost for 2021 would be similar to 2020, without the annual cost of the routine maintenance of the web system application for which new developments would be made an additional requirement for funding was anticipated. It was agreed that BIPM and IFCC would again share the JCTLM Secretariat costs on a 50:50 basis for 2021.

4.5 JCTLM Database

Following the previous meeting the first version of the document covering technical specifications for updating the web database application and inclusion of new generation functionalities was drafted. Dr Maniguet presented the mandatory requirements for the implementation of a new software platform and database management system including a new web designed user interface with a contextual search facility and machine-readability. The request for the development for a new web user platform that would support the operational processes of the JCTLM nomination and review process would also be included as an option.

Dr Wielgosz also informed the Committee that following its last meeting in October the CIPM had agreed to participate in the funding of the developments for the JCTLM Database update within the limits of the defined mandatory requirements.

After discussion, the Committee agreed with the presented approach for the development of a new version of the JCTLM Database. A web-based platform seemed desirable, and the cost of the option would need to be reviewed. At the same time, the process for requesting complementary third parties funding would need to be clarified as additional resources for financing the optional development may be needed.

Action (A/20-04): JCTLM Secretariat to launch a call for tender for the new JCTLM Database and clarify the CIPM rules on soliciting and accepting third party funding.

5. Revision of JCTLM quality manuals

5.1 Procedure for accession and termination of JCTLM Executive Member Status which is referred to in the DoC

Prof Young drafted a list of the key elements for accession and termination of JCTLM Executive Member Status, and this would be formalized in a procedure document.

Action (A/20-05): JCTLM Secretariat to finalize the procedure for an induction process for new EC members of JCTLM Executive Member Status for circulation and EC comments by end of June 2021.

5.2 Revision of JCTLM rules for regular participation in EQAS Scheme

Prof. Young said that further discussion on the JCTLM rules for regular participation in EQAS Schemes was still needed among the review group as no consensus was reached yet following on from a suggestion made for tightening the rules and requesting laboratories to participate each year for each measurand listed. Other Committee Members considered the current situation sufficient. After discussion, the Committee agreed that EQAS participation provided a spotlight on laboratory performance, and input into laboratory accreditation which was also required by JCTLM, and the accreditation process was therefore the foundation for JCTLM acceptance of the service.

Action (A20-06): IY/AK/MB/MP to finalize the draft of the proposal of the revised JCTLM rules for regular participation in EQAS Schemes and circulate it for comment to the EC and implementation at the next review cycle in February 2022.

5.3 Revision of the document procedure DB WG P-04a [JCTLM-EXEC/20-12]

Dr Wielgosz presented the latest version of the revised procedure P04-a which included an additional paragraph concerning the possibility of NMIs and DIs participating in the CIPM MRA to use the results of key comparisons to demonstrate the extent of equivalence of their CRMs with others in the comparison exercise.

After discussion, the Committee supported the DBWG recommendation that the revision of the model should also anticipate the level of comparability which could be demonstrated with respect to the type of analyte (well defined/complex), number of materials used in a comparison study, and level of uncertainty expected/targeted in the comparison study.

Action (A20-07): RW/QL/MP/KP to finalize the draft of the revised procedure document P04-a and P04-b and circulate for EC comment and implementation at the next review cycle in February 2022.

5.4 Proposal for review process modification [EXEC20-13]

Prof. Young presented the document EXEC20-13 which included a request for modification of the JCTLM nomination and review process that has been submitted by an organization developing methods with the view to streamline the process. After discussion, the Committee agreed that the request for implementing a second review session during the year was not acceptable. However, the submission of a separate publication summarizing how compliance was met with reference in the nomination spreadsheet was acceptable, as this was a minor

change in the process. It further requested that the text of the relevant procedure be reviewed accordingly.

Action (A20-08): JCTLM Secretariat to revise the text of the relevant procedure documents to include the possibility for the nominator to provide their method compliance description as a separate supporting document.

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

Prof. Theodorsson gave a presentation on the activity of the TEP WG having been appointed as Chair in June. He reported on the edition of the Special Issue of the Newsletter on COVID-19 which was released in July, the drafting of an illustrated version for the ISO 17511 scheme for metrological traceability (noting the targeted audience was the routine laboratories).

He further highlighted the recent TEP WG meeting held by Video Conference on 30 November 2020 and the main recommendations arising from the meeting discussions.

The TEP WG agreed on a major activity for development of a guidance document on metrological traceability in laboratory medicine (similar to the EURACHEM guidance on Uncertainty) for publication on the JCTLM website. The aim of this work stream would be to provide some background and sufficient information on ISO standards for use by working laboratories.

The Executive supported this new work stream for the TEP WG.

The TEP-WG also agreed on a proposal for organizing the 2023 JCTLM workshop on EQAS. The Committee noted this initiative and agreed that the discussion on the organization of the 2023 JCTLM Members and Stakeholders meeting would be postponed to the next EC Meeting.

The TEP WG discussed the next Issue of the JCTLM Newsletter which is to be released in March and agreed on the publication of a Special Report on the revision ISO 17511.

The Committee agreed with the suggested article item for the Newsletter. Following discussion at the previous meeting, it requested that a work item on the use of the JCTLM logo would also need to be considered by the TEP WG.

6.1 JCTLM Members and Stakeholders meeting 2021

The Committee agreed that the discussion on the venue of the meeting would be postponed at a later time, noting the difficult situation of the COVID-19, and the additional cost involved if another venue outside the BIPM was selected.

7. Report from the Task Force Group of Reference Measurement System Implementation [EXEC20-09]

Prof. Panteghini presented the document EXEC20-09 which included the annual activity report of the Task Force Group on Reference Measurement System Implementation. He first highlighted that five additional members were appointed to the TF-RMSI. Following the discussion at the previous meeting, twelve common analytes were selected and a major achievement has been the realization of a synopsis of higher-order matrixed RMs and RMPs listed in the JCTLM Database for these measurands, including their main characteristics for implementing traceability and fulfilling specifications for suitable uncertainty, noting that the evaluation criteria were derived from the analytical performance specification (APS)

described in CCLM, 2017, 55(2)189. The study demonstrated that traceability to the SI could be established by IVD manufacturer within the defined goal of APS for a majority of measurands, noting however that this was possible by using the JCTLM listed methods rather than the materials. This is also because for some measurands suitable reference materials are lacking. Another work item has been to identify missing materials and methods for the measurands, noting that this led also to the delisting of materials which were no longer available. The next suggested work item would be to consolidate the data in a scientific publication, which was approved by the Committee.

8. JCTLM DB WG: Approval of Recommendations

Dr Maniguet presented the summary of the nominations for reference materials, reference measurement methods and reference measurement services with the final DB WG's recommendations that had been submitted for review as part of cycle 17 for materials and methods and cycle 15 for services.

There were 70 new nominations including 41 materials, 13 methods and 16 services, as well as six outstanding nominations from the previous year that had been distributed for consideration to seven JCTLM review teams in 2020.

Prof. Young said that the Database WG held two conference meetings on 1/2 December and successfully completed the review of all review teams' recommendations concerning these 70 nominations. All of these are summarized in the following sub-sections for each group of analytes including final Database WG recommendations.

He further indicated that in the interest of time, only specific outstanding nominations and general issues that were raised during the DBWG meeting would be discussed by the committee, considering that other reported issues were resolved during the DBWG Meeting sessions.

8.1 Approval of Cycle 17 RM and RMP and Cycle 15 RMS

8.1.1 Blood cell counting and typing

There were two nominations for reference measurement procedures for the enumeration of erythrocytes and leukocytes that have been withdrawn by the methods' contact person during the review process.

There was a 2019 nomination for a reference measurement method submitted for the determination of erythrocyte concentration in blood which was being recommended for listing in the JCTLM Database, providing the method developer makes correction for non-compliances.

The Committee approved the DB WG's recommendation for Blood Cell Counting nominations.

8.1.2 Enzymes [JCTLM-EXEC/20-04]

There were 11 nominations related to certified reference materials, and seven nominations for reference measurement services that were reviewed by the review team for Enzymes, and of these a material for Pancreatic alpha-amylase in buffer and seven Enzymes services were being recommended for approval and publication in the JCTLM Database.

The Committee approved the DB WG's recommendation for Enzymes nominations.

8.1.3 Metabolites and Substrates [JCTLM-EXEC/19-07]

There were 13 nominations for certified reference materials, two nominations for reference measurement methods and four nominations for reference measurement services that were reviewed by the review team for Metabolites and Substrates, and of these three reference measurement services for serum urea, creatinine and glucose were being recommended for inclusion in the JCTLM Database. In addition, five pure amino acids materials were being recommended for listing with the provision that minor non compliances would be resolved by the material producer.

The Committee discussed the 2019 outstanding recommendation for the total bilirubin Service and the general issue of the traceability to the SI that arose for this reference measurement system due the lack of primary calibrator. It was agreed that the service providers would need to describe how they maintained traceability to the SI over the last years and whether this process had an impact on their measurement uncertainty value. In addition, the recommendation of the outstanding total bilirubin service would remain deferred until after the laboratory provided additional information. At the same time failure to provide this additional information would results in the delisting of the listed service from the JCTLM Database.

The Committee approved the DB WG's recommendation for Metabolites and Substrates nominations.

Action (A20-09): JCTLM Secretariat to request the service providers for total bilirubin measurement to clarify what procedure they employed to ensure traceability to the SI and what was the impact on their measurement uncertainty value.

8.1.4 Non-Peptide Hormones [JCTLM-EXEC/20-06]

There were five nominations for certified reference materials, five nominations for reference measurement methods and three nominations for reference measurement services that have been reviewed by the review team for Non-Peptide Hormones, and of these two methods for serum 17 β -estradiol and estriol and a service for 17 β -estradiol were being recommended for listing in the database.

The Committee approved the DB WG's recommendation for Non-Peptide hormones nominations.

8.1.5 Proteins [JCTLM-EXEC/20-08, 08a]

There were seven nominations for certified reference materials, three nominations for reference measurement methods and two nominations for reference measurement services that were reviewed by the Proteins team, and of these a material for Standard Solutions for Measurement for Glycated Albumin was being recommended for approval and publication in the JCTLM Database. In addition, the nominated biuret method for total protein as implemented by a listed laboratory was not being recommended for listing until the corrective action related to the uncertainty value calculation was corrected.

The Committee noted the general issue of the total protein traceability chain and the definition of the measurand which was raised during the review of the method and is also discussed below. It further approved the DB WG's recommendation for Proteins nominations.

The Committee discussed the 2019 outstanding recommendation for the human serum total protein Service and the general issue of the traceability to the SI for this reference measurement system with regards to the nature of the primary calibrator used. Prof.

Panteghini commented that the primary calibrator used at the time of the development of the CLSI method was a bovine albumin material when a human serum albumin calibrator is currently available and listed in the JCTLM Database. It was agreed that this issue would need to be addressed by the IFCC Scientific Division, and in the meantime that the outstanding service nomination would be listed in the database with an explanatory note on the nature of the measurand for the service which would also be added to other listed services in the JCTLM Database.

The Committee discussed another outstanding recommendation for a nomination for a new Total Hb Method for which the DBWG main concern was about the lack of a direct comparison of the new method with the already listed CLSI method, and whether to consider this as a major non-compliance for listing the new method, noting that, indirectly, method comparison results were provided via RELA results. The Committee agreed that sufficient comparison evidence was provided and approved the listing of the new method in the JCTLM database.

The Committee discussed the outstanding recommendation for a nominated HbA1c service for which the DBWG main concern was that the laboratory's EQAS Results were not publicly available. It was agreed to defer the recommendation for listing of the service in the JCTLM Database until after results of the laboratory are published (e.g. RELA2020/IFCC HBA1c network results) and to address to the IFCC Scientific Division the related observation of the presence of two clusters of results in the RELA scheme 2020 for HbA1c.

Action (A20-10): JCTLM Secretariat to publish an explanatory note on the nature of the measurand for the service for total protein measurement to clarify to the users the traceability issue.

8.1.6 Vitamins [JCTLM-EXEC/20-16]

There were five nominations for a multi-component certified reference material and a nomination for a reference measurement method that were reviewed by the review team for Vitamins, and of these the 5 nomination for the multi components materials were being recommended for inclusion in the database.

The Committee discussed the issue raised about the possibility of adding the information in the Certificate about the commercial assays tested during the commutability study and agreed that the recommendation for listing the materials would be deferred until clarification that the information on the commercial methods tested can be made available to users.

Action (A/20-11): Dr Phinney to clarify whether the information on the commercial methods tested in the commutability study can be made available to users and report to the EC by the end of January 2021.

Action (A/20-12): JCTLM Secretariat to publish the nominations recommended for publication in the JCTLM Database and send out the report on the outcome of the review to the nominating organizations.

8.1.7 Drugs [JCTLM-EXEC/20-15]

There were four nominations for an isotope dilution LC-MS/MS based candidate reference method for the quantification of cyclosporine A, tacrolimus, sirolimus and everolimus in

human whole blood, which were being recommended for listing, considering the developer of the method responded adequately to the non-compliances observed during last year review cycle.

The Committee approved the DB WG's recommendation for the Drugs methods.

8.2 Follow-up on IFCC CDT method review and decision [JCTLM-EXEC/20-14]

Dr Wielgosz presented the document EXEC/20-14 which included a letter from the IFCC-SD Chair following the rejection of the appeal of the IFCC-WG-CDT by the JCTLM. The Committee discussed the first request of the IFCC for more detailed guidance on what additional steps would be required to make the IFCC WG-CDT method compliant with JCTLM criteria and agreed with the proposal that Dr Westwood would act as a mediator for following up on the action of providing an alternative format of the response for required data.

The Committee discussed also a second request for consideration of the revision of the IFCC WGs method development processes to ensure JCTLM criteria were integrated from the start of a project, and agreed that this was a more global issue which would need to be addressed within the IFCC SD.

Action (A/20-13): Dr Westwood to liaise with the IFCC-WG-CDT and JCTLM Review Team and clarify the corrective actions required for the IFCC-CDT method to be compliant with relevant ISO standards used by the JCTLM.

8.3 Update on IFCC EQAS results

Dr Kessler gave a presentation on the update of the IFCC EQAS Scheme and RELA results for 2020 for which the publication was delayed in September 2020 due to the pandemic. She highlighted the continuing linear increase of the number of laboratories participants in RELA which was much more than the number of the laboratories listed by JCTLM. She added that results diagrams for key measurands illustrated that a majority of the participants' results were within the limit of equivalence when these were available. She pointed out the trend in the 2020 RELA results for Total Hemoglobin and HbA1c measurands for which further investigations were underway for understanding the presence of two clusters of results.

8.4 Progress/ plans for Cycle 18 for RMs and RMPs and Cycle 16 for RMSs

As in previous review cycles, the same calendar would be applied for the next nomination and review cycle in 2021.

9. Liaison with ISO TC 212

It was noted that the revision of ISO 15193:2009 and 15194:2009 has started as well as the drafting of a new technical specification/document on commutability within the WG2, and the revision of the standard ISO15189 with planned publication in 2022 was underway within WG1.

10. Liaison with the WHO

It was agreed that BIPM would re-establish communication with the new WHO contact person.

11. Reports related from related activities/meetings

11.1 IFCC SD meeting

Prof. Young said that the IFCC SD meeting would be held on Monday 8 December and feedback would be provided at the next EC meeting.

11.2 ICSH General Assembly

Dr Fawcett said that the ICSH General Assembly was held on 3/4 October 2020 during two Video conferences meetings, and Prof Wendy Erber was elected as new Chair of the ICSH in replacement of Prof. Machin.

12. Future meetings of the JCTLM

There were no additional meetings/events discussed.

13. Close

The Chairman closed the meeting on 5 December at 14:00.

Annex 1: Summary List of Actions

Outstanding Actions from the 21st Executive Meeting:

Action (A/19-05): JCTLM Secretariat to draft a procedure for an induction process for new EC members of JCTLM Executive Member Status for discussion at the next Executive Meeting.

Action (A/19-12): JCTLM EC members (G. Myers lead) to review new standard ISO 21151 to highlight what information would be suitable for publication in the JCTLM Database, for discussion during a conference call.

Actions from the 22nd Executive Meeting:

Action(A/20-01): The Executive Committee members to send their comments to Dr Myers (cc Secretariat) on the JCTLM Pamphlet for regulatory bodies by the end of December 2020.

Action(A/20-02): JCTLM Secretariat to contact the members of the Blood Cell Counting and Typing review team to reaffirm to them their obligations to have access to the Standards for reviewing nominations in order to remain a member of the team.

Action(A/20-03): JCTLM Secretariat to contact IFCC, BIPM, ILAC and ICSH by 15 December 2020 for nominations of JCTLM President and Secretariat, for review and approval of applications during an extraordinary session of the JCTLM EC which would be held remotely by the end of January 2021.

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Action (A20-07): RW/QL/MP/KP to finalize the draft of the revised procedure document P04-a and P04-b and circulate for EC comment and implementation at the next review cycle in February 2022.

Action (A20-08): JCTLM Secretariat to revise the text of the relevant procedure documents to include the possibility for the nominator to provide their method compliance description as a separate supporting document.

Action (A20-09): JCTLM Secretariat to request the service providers for total bilirubin measurement to clarify what procedure they employed to ensure traceability to the SI and what was the impact on their measurement uncertainty value.

Action (A20-10): JCTLM Secretariat to publish an explanatory note on the nature of the measurand for the service for total protein measurement to clarify to the user the material traceability issue.

Action (A/20-11): Dr Phinney to clarify whether the information on the commercial methods tested in the commutability study can be made available to users and report to the EC by the end of January 2021.

Action (A/20-12): JCTLM Secretariat to publish the nominations recommended for publication in the JCTLM Database and send out the report on the outcome of the review to the nominating organizations.

Action (A/20-13): Dr Westwood to liaise with the IFCC-WG-CDT and JCTLM Review Team and clarify the corrective actions required for the IFCC-CDT method to be compliant with relevant ISO standards used by the JCTLM.