Report of the 25th meeting of the JCTLM Executive Committee
7-8 December 2023
Venue: BIPM Hybrid Meeting

List of participants:
Dr G. Miller (JCTLM Chairman, IFCC)
Dr R. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr G. Myers (IFCC)
Dr S. Maniguet (JCTLM Secretariat, BIPM)
Dr W. Low (CIPM)
Dr G. Jones (ILAC)
Mr Erik Oehlenschlaeger (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)
Dr A. Kessler (IFCC)
Dr Sang-Ryoul Park (CIPM)
Dr S. Westwood (Blood cell Counting team Leader, BIPM)
Prof. E. Theodorsson (JCTLM TEP WG Chair)
Prof. C. Cobbaert (IFCC SD)

Excused
Mr T. Fawcett (ICSH)

Dr Miller opened the meeting and welcomed the participants and Mr Erik Oehlenschlaeger who would be representative of ILAC at the meeting.

1 Approval of the agenda [JCTLM-EXEC/23-01]

The agenda was approved with no modification.

2 Report of 24th JCTLM Executive Committee Meeting

2.1 Review of action points arising from the 24th meeting [JCTLM-EXEC/23-02]

2.2 Review of action points arising from mid-year meeting [JCTLM-EXEC/23-03]

The Committee reviewed the action items from the previous meeting and acknowledged that significant progress had been made during last year. The outstanding actions were noted and would be completed after the meeting:

Dr Myers (A22-27) to develop a first draft of the nomination and review procedures for harmonization protocols and associated reference materials for circulation to the Committee.

Prof. Panteghini (A22-29) confirmed the CCLM editor agreed to publish modified methods and suggested that JCTLM should send a formal request to the CCLM editor before announcing this on the JCTLM website. The Committee agreed with the suggested approach for formalization of the process.

The Committee noted the important output from the discussion at the JCTLM Members and Stakeholders Meeting about the need to strengthen the link between WG 1 and WG 2 of ISO/TC 212 so that standards developed by WG2 on traceability were properly referenced in standards developed by WG1. Executive Committee Member organizations that are in liaison with ISO/TC 212 should progress discussions on this in the ISO Technical Committee meetings and when revision of standards is being considered.

3 JCTLM Governance

3.1 Representation on the Executive

Dr Miller reminded the Committee that his second 2 year-term as the JCTLM President would end at the next Executive meeting in December 2024 and a replacement would need to be made for 2025-2026. Dr Wielgosz commented that the procedure to elect a new President of the Committee would be initiated in June 2024, which would require the Secretariat to inform the JCTLM sponsoring organizations of the need to nominate candidates for the post of JCTLM President.

He added that the JCTLM Secretariat host organization would need to be re-elected at the same time.

Mr Erik Oehlenschlaeger informed the Committee that a new representative from ILAC to the JCTLM Executive would be appointed for 2024.

Dr Miller said that he would approach the IFCC Executive Board for getting confirmation of the appointed representatives from the IFCC to the JCTLM Executive, noting the Dr Myers's term had ended.

A/23-01: JCTLM Secretariat to contact IFCC, BIPM, ILAC and ICSH by 1 June 2024 for nominations of JCTLM Chair and Secretariat.

3.2 JCTLM WG TEP appointment

Prof. Theodorsson informed the Committee he would be stepping down from his position as the Chair of the TEP WG after the meeting. The members of the Committee thanked him for his important contribution to the TEP WG over the last years.

The Committee discussed the replacement for the Chair position and recognized the need to revise the Terms of Reference of the TEP WG to include the promotional activities that the Task Group on Strategy had developed. It was agreed to refocus the terms of reference to emphasize promotion of the value of JCTLM to the profession and regulators.

A23-02: Dr Miller to revise the Terms of Reference of the TEP WG (See draft in Annex 2).

3.3 JCTLM Review Team Membership

The Committee also reviewed the recommendations of the DBWG from its last meeting and supported the recruitment of new experts to serve as members of the review teams for Blood Cell Counting and typing (Haemostasis expert), Drugs, Electrolytes and Blood gases (Methodology experts), and Vitamins & Micronutrients.

Dr Miller reminded the members that Dr Henrion was stepping down from the post of Drugs review team leader at the end of the year and his replacement would need to be appointed for next year review cycle. The Committee agreed to investigate the interest of current team members for taking over the leader position and from the experts of the IFCC WG on Immunosuppressive Drugs, considering a necessary transition period for training on JCTLM would necessary.

A23-03: JCTLM Secretariat to send a call for new experts in consultation with review teams leaders for Blood Cell Counting and typing, Drugs, Electrolytes and Blood gases and Vitamins & Micronutrients.
A23-04: JCTLM Secretariat to send a call of interest for the leader position of the Drugs review team.

3.4 JCTLM Membership and Members' activity reports [EXEC23-12]

The Committee reviewed the current JCTLM membership including four Executive Committee Member Organizations, 22 National and Regional Members and 51 Stakeholder members covering 22 different countries worldwide and noted a strong representation of members organizations from Asia.

30 JCTLM member organizations have already sent their biennial activity reports for the period 2022-2023 for consideration by the Executive Committee, and all of these were included in the document EXEC23-12. The Committee acknowledged the reports' quality and requested their publication on the JCTLM website.

A23-05: Secretariat to post JCTLM Member organizations' activity reports on the BIPM JCTLM Members dedicated webpage.

3.5 JCTLM and JCTLM Secretariat operating costs for 2023 and budget for 2024 [EXEC23-14]

Dr Wielgosz presented the document 23-14, which included the details of the operating costs of the JCTLM Secretariat for 2023 and the expected operating costs in 2024. The operating costs for the JCTLM Secretariat were 113 328 Euro in 2023 and are expected to be 138 138 Euro in 2024. He pointed out that overall costs for 2023 were less than the predicted budget which anticipated an increase of activity related to development of a web platform for submissions and review of JCTLM nominations, and development of a new set of procedures on the operation and update of the new database application by the JCTLM Secretariat as well as the ongoing revision of the JCTLM Quality manual. As the database development project was now foreseen for 2024, the budget had been shifted to that year.

The IFCC had confirmed that its annual contribution in 2023 would be limited to a maximum of 50 000 euro and the remaining cost would be covered by the BIPM. The IFCC and BIPM are currently discussing JCTLM Secretariat funding for 2024 and future years.

4 Outputs from the Task Group on Strategy [EXEC23-13, 19]

4.1 Outcome of the survey

Dr Wielgosz presented the document EXEC23-19 including the results of the questionnaire on information and services provided, and processes used, by the JCTLM which was conducted amongst the members and stakeholders of the JCTLM from July to October 2023. He reported that about 220 responses were received from a broad range of organizations and a fair representation of JCTLM Stakeholders: Accreditation bodies, IVD Manufacturers, Metrology Institutes, EQAS Providers and Medical laboratories or Reference Laboratories. He further summarized the main outcomes of the questionnaire as follows:

- Feedback supports the usefulness of JCTLM in ensuring the Quality of Laboratory Medicine Results
- The JCTLM process requires appropriate support and resources
- Lack of recognition by regulators is a weakness that needs to be overcome
- Promotional activities of JCTLM outputs are needed
- A key promotional point is that analytes covered in the JCTLM Database represent something like 95% of the total volume of tests made (although covering just over 200 analytes)
-No consensus that JCTLM activities should be broadened to cover all available reference materials

The Committee recognized the feedback was encouraging for continuing the JCTLM database of internationally recognized measurement system components that undergo a comprehensive and independent review by teams of experts for compliance with relevant ISO standards, notably considering that:

- about 50% of respondents have not yet submitted nominations but were willing to do so,
- about 90% of respondents described the JCTLM database as essential, highly useful or useful,
- about 80% of respondents described the current JCTLM independent expert review as an essential or useful process.

The Committee discussed the question about the potential modification of the JCTLM Database processes to allow the inclusion of entries based on self-declared compliance with ISO standards, for which feedback showed no consensus that this should be done by JCTLM. Some members commented that self-declaration of compliance from contributors for listing available materials in a second list, would not require any peer-review. The Committee noted the potential utility of a more general list of available materials to the IVD community, but that was beyond the role of the JCTLM.
The Committee agreed that the JCTLM brand that was based on an independent third-party peer-reviewed items for compliance with ISO Standards should remain independent from a self-declared catalogue of materials.

The Committee discussed the question about the potential modification of the JCTLM Database processes to allow the inclusion of entries in the JCTLM Database that were potentially useful, but not fully compliant with ISO standards, noting that would result in publishing non-compliances classified as minor according to JCTLM review procedures. It rejected this modification, considering this would cause confusion and not provide the user with additional benefits.

The Committee agreed that JCTLM should work with CCQM to ensure processes for NMIs/DIs to list entries in the JCTLM DB and for having CMCs listed in the BIPM KCDB were aligned as much as possible.

4.2 JCTLM Membership and update of Declaration of Cooperation

4.3 Promoting JCTLM

4.4 Engagement of regulators

Dr Wielgosz presented the document EXEC23-13, which included the report activity from the JCTLM Strategy Task Group which met 7 times during 2023. The membership included representatives from the four Executive Committee Organizations as well as NMIs, IVD Industry and accreditation bodies. He gave an update on the JCTLM marketing plan including a SWOT analysis and 3 planned initiatives, notably:

1) Positioning and awareness of JCTLM
The aim would be to increase the visibility of the JCTLM Database and visibility for those applying Metrological Traceability in conformity with International Standards, with the support of the TEP WG.

The Committee agreed with the suggested approach that the TEP WG should provide support for promoting JCTLM activities and metrological traceability.

2) Acknowledgement by regulators
The aim would be to increase awareness of the JCTLM database amongst regulators and promote its usefulness in supporting regulatory frameworks, including meeting requirements for metrological traceability with the support of a dedicated Task Group within the TEP WG.

The Committee agreed that the TEP WG should establish such a Task Group.

3) Increasing resources, membership, and funding
The aim would be to provide JCTLM with resources for database services to 2040+ and provide schemes for organizations wishing to support JCTLM financially, mechanisms to do so. The financial goal is to raise 40000 euro per annum for the database maintenance and development. The Task Group on Strategy suggested the implementation of a tiered membership model including Members with paying fee and benefits and Associate Members with no paying-fee. A two- step approach for implementing the modification of membership was proposed with first the revision of the text of the Declaration of Cooperation (DoC) by the Sponsoring Organizations to permit a tiered membership model. Details of the tiered model would then be developed by the Executive., avoiding the need to revise and resign the Declaration of Cooperation each time a change in membership details was needed.

The Committee agreed the tiered membership model and its two-steps approach for its implementation in 2025.

A23-06: Dr Miller to include a Task Group for regulators in the updated terms of reference of the TEP WG engagement.

A23-07: Dr Miller/Dr Wielgosz to draft revised text for the DoC and subsequent document on membership categories for consideration of the Executive Member Organizations and Committee.

5 Outputs of Task Group on Knowledge Transfer [EXEC23-20]

Dr Miller presented the report of activity of the Task Group on Knowledge Transfer (TG KT) formed in January 2023 to improve the rate of acceptance for first submissions to JCTLM.

5.1 JCTLM submission Checklist and actions to achieve harmonized reviews across RTs

The TG KT examined all review team reports for non-approved submissions for 4 years, identified all critical and major non-conformances and examined non-conformances for what was deficient in the submission. It developed guidance looking at what was the ISO requirement and what documentation was required to fulfil the requirement.
Dr Miller said the checklist was circulated for comment to DB WG review teams and IFCC Scientific Division and for approval to the Executive before its meeting.
Submission checklist would be posted to JCTLM Procedures for use in the 2024 submissions cycle.

A23-08: JCTLM Secretariat to post the DB WG Instruction Checklist in the JCTLM procedures webpage.

5.2 Plans for e-learning module development

Dr Miller reported that the second task regarding the development of e-learning modules on the submission and review processes for CRM and RMP would start in 2024 and the recruitment of new volunteers with experience in the JCTLM processes would be needed to be cover this work items.

He also informed the Committee that the DB WG had recommended that the TG KT develop a checklist for submissions of reference measurement services based on common deficiencies. In addition, he suggested to develop a generic template presentation for reporting review teams' findings.
The Committee agreed with the two work items.

A23-09: Dr Miller to proceed with recruitment of additional volunteers for TG KT.

6 New JCTLM Database Development

6.1 Current status of funding

Dr Wielgosz said that the funds required to proceed with the web-based nomination and review version of the JCTLM database were now available following contributions from 7 NMIs, 4 IFCC Corporate Members and the ICSH as well as the outcome from the Workshop.

As new versions of ISO 15193 and 15194 are nearing completion (Publication foreseen October 2024), the most cost-effective solution would be to base the web-based nomination/review process on the new versions of the standards.

He added that the quotation obtained in 2021 for the development of web-based nomination and review process from the service provider were made according to the currently established JCTLM process and most probably would need to be adapted to capture the workflow of a web-based system.

6.2 ISO 15194 – expected changes in the revised standard [EXEC23-21]

Dr Westwood gave an update on the activity regarding the revision of the ISO 15194 over the last year:

- ISO 15194 CD2 circulated February 2023, comments closed 28th April 2023
- 100 Comments (27 pages) received - 78 from ISO TC 334
- Comments reviewed May/June 2023
- ISO 15194 Draft DIS – harmonized with ISO 15193, forwarded to ISO
- Draft DIS and Normative References approved by CEN (for Annexe Z, IVD regulations)
- ISO 15194 DIS submitted for review October 2023 to March 2024

He further presented the expected changes in the revised standard:

- Requirements, concepts and definitions consistent with ISO 17511:2020;
- Harmonized with ISO 15193 DIS;
- Removed or reduced redundant or limited relevance text;
- Section 4 in the 2nd edition - Systematic designation of CRM properties - deleted;
- Expanded and clarified Scope statement to specify requirements for higher-order CRMs that underpin routine measurements in laboratory medicine;
- Added requirements regarding intended use and commutability;
- Specified documentation requirements for certificate and report accompanying a CRM.

A23-10: Executive members to review the version DIS of ISO 15194 due for comment in March 2024 to ensure compliance requirements are clearly stated**.**

6.3 ISO 15193- expected changes in the revised standard [EXEC23-22]

Dr Kessler gave an update on the activity regarding the revision of the ISO 15193 over the last year:

She further presented the expected changes in the revised standard:

- title and chapter headings have been changed to better reflect the objective of the document
- requirements, concepts and definitions have been incorporated for consistency with ISO 17511:2020, ISO 15194:XXX, and ISO 15195: 2018;
- content has been adapted to make the document applicable to all types of measurands;
- The subchapters of Chapter 4 ‘Requirements for a reference measurement procedure’ have been revised and specified in order to present the requirements more transparently;
- subclause 4.1 has been added to emphasize quality requirements for a reference measurement procedure;
- aspects of validation have been updated and summarized in Chapter 4.15.

A23-11: Executive members to review the version DIS of ISO 15193 due for comment in March 2024 to ensure compliance requirements are clearly stated.

6.4 Expected changes required to the database due to ISO standard revisions and timeline

Dr Maniguet said that changes in the database as well as in the Quality manual procedures would need to be anticipated to accommodate changes in the ISO standards.
She added that experts from the DBWG should advise on the modifications to workflow of the nomination/review process that would be useful to adopt in the new web-based system.

The Committee agreed to establish a Task Group on Database expansion to advise the Secretariat when drawing up the specifications for the new web-based system.

A23-12: Dr Miller to invite JCTLM experts to form an advisory group for the Secretariat for the workflow to be used in the new web-based system.

7 Report from the JCTLM WG on Traceability Education and Promotion

7.1 Activity update of JCTLM TEP WG [EXEC23-23]

Prof. Theodorsson gave an update on the activity of the TEP WG during the last year and highlighted the information in the new version of the website jctlm.org.

7.2 Identifiers for JCTLM Database measurands [EXEC23-24]

Prof. Theodorsson presented the work activity which was conducted during last year by the JCTLM WG-TEP/Naming & Coding team related to measurands of the JCTLM database. NPU was identified as a primary choice of names and codes for developing the JCTLM database. The main advantages of the NPU are that it embodies metrology principles and avoids the plethora of codes used by the LOINC and SNOMED systems. However, its possible disadvantages are that it has a minimal number of users globally and focuses on measurement results in “systems” present in living humans and not in reference materials.

The Committee welcomed the work of JCTLM WG-TEP/Naming & Coding team and foresaw the issue would be further discussed at the CCQM Workshop on Digital and FAIR Chemical and Biological Reference Data and Certificates: Challenges and Opportunities from 9 to 12 September 2024.

7.3 Report of the outcome of 2023 JCTLM Members and Stakeholders meeting with workshop

Prof. Theodorsson reported the JCTLM Members and Stakeholders meeting held as a hybrid meeting at the BIPM on 4-5 December 2023 attracted more than 250 attendees from 30 countries worldwide.
The Committee thanked Dr Tony Badrik for his involvement in the organization of the Workshop which would result in a manuscript and submitted for publication in a clinical laboratory journal.

7.4 JCTLM Members and Stakeholders meeting 2025

Prof. Theodorsson informed the Committee that the TEP WG discussed the topic for next JCTLM Members and Stakeholders meeting for 2025 and a suggested topic was the clinical and economical value of metrological traceability. Comments from the Committee included the need to choose topics that would ensure a broad participation from all communities represented in JCTLM.

8 Development of JCTLM promotional material

Dr Wielgosz said that as part of the marketing plan developed by the TG on Strategy was to foresee that promotional materials would be available for distribution at laboratory medicine conferences.

9 Report from Task Force on Reference Measurement System Implementation [EXEC23-25]

Prof. Panteghini gave a presentation the activity of the JCTLM TF RMSI during last year and reported on the review of the second set of measurands listed in the JCTLM database with regards to the uncertainty achievable with traceability to the highest metrological for 17 measurands. This task would be completed, and a paper publication be drafted by end of 2024.

He pointed out to the Executive Committee the following outcomes:
-options for reducing u_{ref}. For instance, using a pure human albumin reference preparation at the top of the traceability chain, together with an improved RMP used to assign values to the secondary CRM could work as a better alternative.
-the need to establish a RELA EQAS service for HDL_C to understand the uncertainty at the highest level of the calibration hierarchy with reference to high purity crystalline cholesterol.

He also noted that there needed to be agreement on the measurand definition for 'serum triglycerides' in the JCTLM Database, which currently listed three types of triglyceride-related RMPs with selectivity for different measurands. He proposed that these should be reviewed and modified to be consistent with the TF RMSI recommendation. In particular, the TF RMSI believes that 'total glycerol', meaning the sum of triglycerides, diglycerides, monoglycerides, and free glycerol in serum was the measurand definition that mirrors the analytical selectivity of the majority, if not all, of marketed IVD-MDs. RMPs that measure 'total glycerol' are the appropriate ones to be used to ensure SI traceability of IVD-MDs.

He pointed out the need to further raise awareness on the results and recommendation as well as gap analysis for identifying missing CRMs conducted by the TF RMSI amongst the parties involved in the production of reference materials.

A23-13: JCTLM Secretariat to promote TF RMSI paper via publication on the JCTLM newsletter, jctlm.org, and within the CCQM community.
A23-13a: JCTLM Secretariat to modify the database information on the RMPs for 'triglyceride' regarding the measurand definition.

10 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 20 for materials and methods and cycle 18 for services.
There were 128 nominations consisting of 14 material, 36 method and 80 service nominations that were distributed to ten JCTLM review teams in 2023.

Dr Miller said that the Database WG held a hybrid meeting on 6 December and successfully completed the review of all review teams' recommendations concerning these 124

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.

10.1 Approval of Cycle 20 RM and RMP and Cycle 18 RMS

10.1.1 Analyte Group 1

10.1.1.1 Non-Peptide Hormones [EXEC23-04]

There were four nominations for reference measurement methods and 33 nominations for reference measurement services that were reviewed by the review team for Non-Peptide Hormones, and of these, two resubmitted ID LC-MS/MS reference measurement procedures for determination of free thyroxine and cortisol in human serum as well as seven reference measurement services for 17α-hydroxyprogesterone, cortisol, testosterone, total thyroxine and 17β-estradiol in blood serum/plasma from four Chinese reference laboratories were being recommended for listing in the database.

There was a new LC- based reference measurement method for Aldosterone which was not recommended for listing until the major non-compliance regarding comparison with the ID-GC/MS method listed in the JCTLM database was resolved. It was noted that the ID-GC/MS method was not currently available for a comparison study as it was no longer used by RfB. However, as the ID-GC/MS method was currently listed in the JCTLM database, results/data showing the equivalence between the ID-GC/MS and the newly nominated ID-LC/MS/MS methods should be reviewed. The JCTLM DBWG recommended RfB to submit their results showing the equivalence between the two methods for review.

The Committee approved the DB WG's recommendation for Non-peptide hormones nominations. It further requested that in the next year RfB update their listed reference measurement service for aldosterone to the ID-LC/MS/MS method for which they are now accredited.

A23-14: Dr Miller to contact RfB to provide the comparison/validation data for aldosterone LC versus GC methods for DB WG review.

10.1.1.2 Metabolites and Substrates [EXEC23-05]

There were four nominations for certified reference materials and 11 nominations for reference measurement services that were reviewed. Two of these were resubmitted nominations regarding a multi component matrix material for creatinine and urea in human serum as well as five reference measurement services for serum/plasma creatinine, urea and glucose from three reference laboratories. These were being recommended for inclusion in the JCTLM Database.

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

10.1.1.3 Drugs [EXEC23-06]

There were 10 nominations for reference measurement methods and four nominations for reference measurement services that were reviewed, and of these, seven LC-MS/MS-based

reference measurement procedures for the quantification of lamotrigine, levetiracetam, gabapentin, topiramate, methotrexate, zonisamide and carbamazepine in human serum /plasma were being recommended for inclusion in the JCTLM Database.
There were three methods that were not accepted for listing due to the lack of a peer-reviewed publication.

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

10.1.2 Analyte Group 2

10.1.2.1 Proteins [EXEC23-07]

There were three nominations for certified reference materials, a nomination for reference measurement method, and three nominations for reference measurement services that were reviewed, and of these, a matrix material certified for the concentration of anti-β2 glycoprotein I immunoglobulin G antibodies in human serum, CDT reference method for measurement of the alcohol consumption biomarker, and two reference measurement services for HbA1c and total hemoglobin were being recommended for inclusion in the JCTLM database.

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

10.1.2.2 Enzymes [EXEC23-08]

There were 22 nominations for reference measurement services that were reviewed by the review team for Enzymes, and of these 15 nominations for CK, LDH, ALT, AST, GGT, AMY, ALP; blood serum/plasma/calibration solution from three new reference laboratories were being recommended for approval and publication in the JCTLM Database.

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

10.1.2.3 Nucleic acids [EXEC23-09]

There were 7 resubmitted nominations for certified reference materials and 14 nominations for reference measurement methods that were reviewed by the review team for Nucleic acids. Of these, 7 material nominations regarding a reference material of genomic DNA containing BRAF V600E Mutation and two levels of in vitro transcribed SARS-CoV-2 RNA as well as 7 reference measurement procedures for determination of SARS-CoV-2 RNA and BRAF V600E / EGFR mutation by digital PCR were being recommended for listing.

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

10.1.2.4 Blood cell counting and typing [EXEC23-10]

There were two resubmitted nominations for reference measurement procedures for leukocytes and erythrocytes in whole blood that were not being recommended for approval as technical review observations reported by the review team last year were only partially addressed by the laboratory.

The Committee approved the DB WG's recommendation for Blood cell counting review team.

10.1.3 Analyte Group 3

10.1.3.1 Electrolytes and blood gases [JCTLM-EXEC/23-12]

There were two nominations for reference measurement methods and five nominations for reference measurement services that were reviewed by the review team for Electrolytes and blood gases, and of these, four reference measurement services for serum calcium, potassium, or sodium from two Chinese reference laboratories were being recommended for listing in the JCTLM database.

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

10.1.3.2 Vitamins [JCTLM-EXEC/22-11]

There were two nominations for ID LC MS-based reference measurement services for 25-hydroxyvitamin D3 in serum that were reviewed by the review team for Vitamins and were not being recommended for listing in the JCTLM Database, considering the methods implemented by the laboratories were deviating from the JCTLM listed RMPs used.

The Committee approved the DB WG's recommendations for Vitamins nominations.

(A/23-14a): JCTLM Secretariat to publish the nominations recommended for publication in the JCTLM Database and send out the report on the outcomes of the review to the nominating organizations.

10.1.4 Issues arising from the DBWG review meeting

Dr Miller presented DB WG recommendations from issues reported by review teams in the last review cycles.

1) The DBWG recommended requiring RMS submitters to provide the SOP used, in English, for review of deviations from the listed RMP. Currently, submitters self-identify and explain deviations. The purpose would be to confirm the listed RMP was being used without modifications, otherwise this would make it a different RMP. Deficiencies found should be reported by JCTLM to the accreditation body since, in principle, the accreditation should identify such situations.
   The Executive approved the recommendation and requested the relevant DB WG procedure was revised for clarifying the SOP was required for assessment of deviations from the listed RMP.

A23-15: JCTLM Secretariat to revise the text of the procedure DBWG P-02B, section 6.4.4.5 on the requirement for provision of SOP document by the service provider.

2) DB WG noted that Chinese service providers were using EQARL from NCCL in China as participation in EQA and the website was not accessible outside of China. It was recommended that NCCL China be contacted to confirm whether the EQAS was open for laboratories outside of China and if it was meeting JCTLM requirements in Section 7 of the DBWG P-02B.

A23-16: JCTLM Secretariat to contact NCCL China to clarify if the EQAS was open for laboratories outside China, if the results could be made available outside China, and if it was meeting JCTLM requirements in Section 7 of the DBWG P-02B.

3) Dr Miller opened the discussion on whether unsuitable RMPs and CRMs should be delisted when identified for the following reasons:
    a. RMPs with poor performance e.g. uncertainty,
    b. CRMs with excessive uncertainty,
    c. Secondary CRMs used as calibrator without commutability assessment,

The Committee believed that a first task was for the Task Force on Reference Measurement System Implementation to raise awareness on Analytical Performance Specification APS amongst CRM producers when planning production of new CRMs. Unsuitable RMPs and CRMs would be addressed ad hoc when they would be identified.

4) Dr Miller informed the Committee that the IFCC WG on neonatal bilirubin contacted the JCTLM about deficiencies regarding two RMPs for total bilirubin listed in the JCTLM Database, namely C3RMMP28 (AACC RMP) and NRMeth 29 (Doumas RMP). They noted that the two listed RMPs that are based on the same published methodology have very different applicable ranges that don't overlap. In addition, the AACC RMP does not have any uncertainty listed.

The DBWG recommended that the missing measurement uncertainty needed to be included and the measuring interval should be based on data from the more recent publication and reference to the older publication removed. There were three RMSs listed for total bilirubin and of these two services used the Doumas RMP which was the older entry.

In the discussion that followed, the Committee agreed that the two methods and service listed in the JCTLM Database should be reviewed, and the service provider notified of the deficiencies, which they should address.

A23-17: Dr Miller/Prof Panteghini to review the methods and services for total bilirubin in the JCTLM database and develop a list of deficiencies to be addressed.
A23-18: JCTLM Secretariat to contact NIST for submission of their CRM for Bilirubin

10.2 Update on IFCC EQAS results [EXEC23-26]

Dr Kessler gave an update on the IFCC EQAS Scheme and the RELA exercise completed in 2023. She reported the number of participations was 730, an increase from last year, while the number of JCTLM listed laboratory was 24. She reported that the IFCC C-TLM and NMIs had started to coordinate their measurement activities via joint projects to demonstrate traceability between RELA participants and NMI laboratories and Total Hb would be studied in RELA 2024.
The Committee discussed the application of the minimum APS as defined by the TF RMSI, and Dr Kessler agreed to implement the lower APS limit to the RELA results for measurands 2023 showing only JCTLM listed laboratory and accredited laboratories using listed RMPs.

A23-19: Dr Kessler to prepare RELA graphs showing only listed RMS and accredited laboratories using listed RMPs and apply APS from the TF RMSI for review at the mid- year review EC meeting.

10.3 Plan for Cycle 21 for CRMs and RMPs and Cycle 19 for RMSs

Dr Maniguet said the usual schedule for the nomination and review process would be followed with the start of the next call for nominations planned on 1st February 2024.

11 Reports from related activities / meetings

11.1 IFCC SD [EXEC23-27]

Prof. Cobbaert gave a presentation report on strengthening the collaboration with metrologists.

11.2 ICSH GA [EXEC23-15, 16]

The JCTLM report presented at the General Assembly and the report of the ICSH Assembly held in October 2023 are available as JCTLM Working documents EXEC23-15 and 16, respectively.

11.3 ILAC [EXEC23-17]

Mr Oehlenschlaeger presented the ILAC report to JCTLM [EXEC23-17] submitted as a working document and highlighted that the work to extend the ILAC MRA to include the accreditation of biobanks had reached the stage where applications for recognition could be accepted. This followed the publication of the revised supporting documents as outlined in the resolution adopted during the 25th ILAC General Assembly in 2022: ILAC Resolution GA 25.09.

11.4 CCQM [EXEC23-28]

R. Wielgosz presented an overview of the CCQM activities relevant to the JCTLM and highlighted a new joint comparison study for Estradiol-17beta which would be carried out in collaboration with the IFCC RELA.

12 Activities within ISO TC 212

This agenda point was discussed under agenda point 6.

13 Liaison with the WHO

R. Wielgosz reported that a letter from the BIPM Director had been sent to the WHO Secretary General to initiate increased collaboration between the WHO and JCTLM.

14 Future meetings of the JCTLM

The Committee confirmed a Database WG meeting on 2 December, and a JCTLM Executive Committee meeting on 3 and 4 December 2024.

The Committee confirmed that the next JCTLM Members' and Stakeholders' meeting would be held at the BIPM in December 2025.

The Chairman closed the meeting at 13:00.

Annex 1: Summary List of Actions

Outstanding Actions from the previous Executive Meeting:
Dr Myers (A22-27) to develop a first draft of the nomination and review procedures for harmonization protocols and associated reference materials for circulation to the Committee.

Prof. Panteghini (A22-29) confirmed the CCLM editor agreed to publish modified methods and also suggested that JCTLM should send a formal request to the CCLM editor before announcing this on the JCTLM website. The Committee agreed with the suggested approach for formalization of the process.

Actions from the 25th Executive Meeting:
A/23-01: JCTLM Secretariat to contact IFCC, BIPM, ILAC and ICSH by 1 June 2024 for nominations of JCTLM Chair and Secretariat.
A23-02: Dr Miller to revise the Terms of Reference of the TEP WG (See draft in Annex 2).
A23-03: JCTLM Secretariat to send a call for new experts in consultation with review teams leaders for Blood Cell Counting and typing, Drugs, Electrolytes and Blood gases and Vitamins & Micronutrients.
A23-04: JCTLM Secretariat to send a call of interest for the leader position of the Drugs review team.
A23-05: Secretariat to post JCTLM Member organizations' activity reports on the BIPM JCTLM Members dedicated webpage.
A23-06: Dr Miller to include a Task Group for regulators in the updated terms of reference of the TEP WG engagement.
A23-07: Dr Miller/Dr Wielgosz to draft revised text for the DoC and subsequent document on membership categories for consideration of the Executive Member Organizations and Committee.
A23-08: JCTLM Secretariat to post the DB WG Instruction Checklist in the JCTLM procedures webpage.
A23-09: Dr Miller to proceed with recruitment of additional volunteers for TG KT.
A23-10: Executive members to review the version DIS of ISO 15194 due for comment in March 2024 to ensure compliance requirements are clearly stated**.**
A23-11: Executive members to review the version DIS of ISO 15193 due for comment in March 2024 to ensure compliance requirements are clearly stated.
A23-12: Dr Miller to invite JCTLM experts to form an advisory group for the Secretariat for the workflow to be used in the new web-based system.
A23-13: JCTLM Secretariat to promote TF RMSI paper via publication on the JCTLM newsletter, jctlm.org, and within the CCQM community.
A23-13a: JCTLM Secretariat to modify the database information on the RMPs for 'triglyceride' regarding the measurand definition.
A23-14: Dr Miller to contact RfB to provide the comparison/validation data for aldosterone LC versus GC methods for DB WG review.
Action (A/23-14a): JCTLM Secretariat to publish the nominations recommended for publication in the JCTLM Database and send out the report on the outcomes of the review to the nominating organizations.
A23-15: JCTLM Secretariat to revise the text of the procedure DBWG P-02B, section 6.4.4.5 on the requirement for provision of SOP document by the service provider.

A23-16: JCTLM Secretariat to contact NCCL China to clarify if the EQAS was open for laboratories outside China, if the results could be made available outside China, and if it was meeting JCTLM requirements in Section 7 of the DBWG P-02B.
A23-17: Dr Miller/Prof Panteghini to review the methods and services for total bilirubin in the JCTLM database and develop a list of deficiencies to be addressed.
A23-18: JCTLM Secretariat to contact NIST for submission of their CRM for Bilirubin
A23-19: Dr Kessler to prepare RELA graphs showing only listed RMS and accredited laboratories using listed RMPS, and apply APS from the TF RMSI, for review at the mid-year review EC meeting.

Annex 2:

JCTLM Working Group on Traceability: Education and Promotion (JCTLM-TEP WG) : Updated in January 2024

Mission

JCTLM Working Group on Traceability: Education and Promotion is charged to educate health care providers on metrological traceability in laboratory medicine and to promote the value of JCTLM activities for achieving metrological traceability to improve clinical outcomes and patient safety.

Terms of reference

- **Aims:**

  To promote the importance of metrological traceability in laboratory medicine as a means to reduce between method variability to improve clinical outcomes and patient safety.

  To increase visibility of the JCTLM Database and visibility for those applying Metrological Traceability in conformity with International Standards as a means of reducing between method variability to improving clinical outcomes and patient safety.

  To increase awareness amongst regulators of the JCTLM Database and promote its usefulness in supporting regulatory frameworks, including meeting requirements for metrological traceability.

- **Membership:**
  - Members of WG-TEP are approved by the JCTLM Executive Committee. They serve a two-year term of office, renewable for two-year periods.
  - Membership of WG-TEP comprises:
    - Representatives of each of the organizations on the JCTLM Executive Committee.
    - Additional persons representing the wider JCTLM Membership with skills and experience in educational and promotional strategies.
  - The Chair of WG-TEP will be appointed by the JCTLM Executive Committee and will attend meetings of the Executive Committee.
  - The Secretary of WG-TEP will be chosen by the WG-TEP Members.

- **Specific Goals:**

- Development of campaigns that raise the visibility of the JCTLM Database within key stakeholder groups.
- Coordination of JCTLM representation and promotional activities at meetings, symposia and conferences in laboratory medicine organized by other professional organisations.
    - Development of material for promoting the JCTLM Database at meetings, symposia and conferences in laboratory medicine organized by other professional organisations.
    - Organisation of the two-yearly JCTLM Members Workshop, in collaboration with the JCTLM Secretariat, on topics presented to and approved by the JCTLM Executive Committee.
- Develop a Task Group to increase awareness amongst regulators of the JCTLM database and promote its usefulness in supporting regulatory frameworks related to meeting requirements for metrological traceability.
- Assessment of applications for meetings to be held with JCTLM auspices.
- Production of educational materials to promote the value of implementing traceability in laboratory medicine.
- In conjunction with the JCTLM Secretariat, production of the annual JCTLM eNewsletter.
- Maintenance of the JCTLM.org website, which contains information, resource material and news items about the role of JCTLM in supporting traceability in laboratory medicine. This website links to the JCTLM Database at BIPM and will be available to link to the websites of all JCTLM members.

- **Method of Working:**
    - WG-TEP reports through its Chair to the JCTLM Executive Committee.
    - WG-TEP will meet mainly by electronic communication and will normally hold four meetings each year. WG-TEP will hold a face-to-face meeting at least once every two years in association with the JCTLM Members meeting which shall not conflict with other meetings of the JCTLM.
    - WG-TEP will produce brief notes of each meeting with action points, which will be sent to the JCTLM Secretariat for distribution to Executive Committee members.
    - Any expenses for WG-TEP educational or promotional activities must be approved in advance by the Executive Committee.
    - The travel expenses of WG-TEP members will be covered by their parent organization or employer.