

**Report of the 20th meeting of the JCTLM Executive Committee
6-7 December 2018, BIPM, Sèvres, France**

List of participants:

Dr G. Myers (JCTLM Chairman, IFCC)
Dr G. Beastall (IFCC, JCTLM WG-TEP Chair)
Dr A. Kessler (IFCC)
Prof I. Young (IFCC)
Dr R. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr S. Maniguet (JCTLM Secretariat, BIPM)
Dr J. McLaren (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)

Apologies received:

Dr. M. Milton (BIPM)
Dr. W.E. May (CIPM)

Dr Myers opened the meeting and welcomed the participants.

1. Approval of the agenda [JCTLM-EXEC/18-01]

Prof Panteghini asked for an additional discussion point on a new task group on reference measurement system implementation, and Dr Jones asked for a change of agenda point 9 to discuss traceability from the perspective of routine laboratories in place of an update on gap analysis. The changes to the agenda were approved and new discussion item would be discussed under agenda point 8.5.

2. Report of 19th JCTLM Executive Committee Meeting [JCTLM-EXEC/18-02]

There were no comments on the report of the 19th Executive Committee meeting, which had been finalized in April 2018, and published on the [BIPM JCTLM website](#).

2.1 Review of action points arising from the 19th meeting

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

Action (A/17-19): Dr Myers to draft responses to the questions raised by JCTLM Member Organizations in the biennial activity report.

Dr Myers reported that the drafting of the responses to the questions raised by JCTLM Members was underway and that the completion of this action was pending the discussion under agenda point 6.2 on the conclusion of the comparison study between the CIPM MRA and JCTLM review process for the assessment of CRMs.

Action (A/17-22): ILAC to provide an updated version of the list of ILAC full members providers of accreditation services against ISO 15195 and extended to ISO 17034 for publication on the JCTLM website.

Ms Bednarova reported that a questionnaire had been sent out to ILAC full members that were identified as providers of accreditation services against ISO 15195 and to ISO 17034, and that the list of respondents had been provided to the Secretariat. Dr Wielgosz commented that this list needed to be reviewed against the list presently published on the JCTLM website in order to confirm all national accreditation bodies providing the accreditation services for calibration laboratories listed by JCTLM were included.

Action (A/17-23): BIPM to conduct a comparison study for the CIPM MRA review process against the JCTLM review acceptance criteria for certified reference materials and if appropriate to draft a proposal for a fast track review process for discussion at the next DB WG meeting.

Dr Wielgosz said that this action was completed and the conclusions of the study would be discussed under agenda point 6.2.

Action (A/17-27): Dr Jones to coordinate a pilot study for EQAS and to report back to the Executive Committee.

This action was not completed and would be taken over by the TEP WG as part of its action plan on developing guidance on traceability for EQAS participants. Dr Beastall reported that he attended the EQALM Meeting in October 2018 and that discussions with EQAS representatives showed that there was a growing interest to engage further discussion among providers worldwide for sharing key information available in existing EQAS programmes and working towards defining communal key requirements/criteria. He added that an informal discussion group had already started at this venue and was being coordinated by a member of the TEP WG. Further information would be communicated in due time onto the JCTLM web portal and that representatives of EQAS Scheme providers could contact TEP WG for participation in the discussion group.

Action (A/17-28): Dr Myers to draft an action plan for a comparison of ISO 17511 and the IVD regulation with regards to metrological traceability requirements, and analyze the coverage of the JCTLM Database with regards to the biomarkers in the four classes of risk defined in the Regulation.

Dr Myers said that he would follow up on this action after the meeting.

Action (A/17-29): Dr Wielgosz and Dr Beastall to work on the possibility of liaison with WHO and draft a discussion paper.

Dr Wielgosz said that he would follow up on this action after the meeting and along with the next year's review of the MoU between BIPM and WHO.

New Actions

Action (A/18-01): ILAC to review the provided list of accreditation services providers against ISO 15195 and to ISO 17034, and confirm the NABs having provided accreditation services to calibration laboratories against ISO 15195 and reference material producer accredited against ISO 17034 listed by JCTLM.

3. Progress with identifying potential JCTLM Executive Committee Organizations

3.1 JCTLM - ICSH workshop outcome/way forward [JCTLM-EXEC/18-03]

Dr Myers reminded the members of the Committee that a meeting between representatives of the JCTLM and the International Council for Standardization in Haematology (ICSH) was held at the BIPM in May 2018. The meeting discussion focused on the technical aspects and current developments for reference measurement systems for blood cell counting and total haemoglobin in blood samples. The participants also looked at possible options for further involvement of ICSH in JCTLM activities. A discussion paper [JCTLM-EXEC/18-03] which anticipated the possibility of ICSH submitting methods and materials for review by JCTLM and various options for applying for JCTLM membership, was drafted for presentation at the ICSH General Assembly in October 2018. As a result of this discussion ICSH submitted an application for JCTLM Membership at Executive level, which would be considered by the Committee during this meeting.

The Committee acknowledged the successful approach for identifying and encouraging JCTLM - ICSH partnership and agreed to pursue its efforts to engage dialogue and possibly organize a joint Workshop with international organizations representing other fields in laboratory medicine including EQAS and the Molecular Diagnostics area.

The Committee recognized also the need to define a strategy on appropriate guidance when a new organization becomes a member of the Executive Committee. In this regard it was agreed to form a task group to look at the induction of a member engaging in the Executive.

Action (A/18-02): Task-group (Drs Myers, Young, Jones, Beastall, Wielgosz) on the induction process for new Executive member to develop a draft guidance document for the induction process, for discussion at the Executive Meeting in December 2019.

4. JCTLM membership [JCTLM-EXEC/18-12]

Dr Myers presented the document JCTLM-EXEC/18-12 which included the application for JCTLM Membership from the ICSH which applied for an Executive member status. The Committee reviewed this application and approved ICSH as a new member of the JCTLM Executive committee.

The Committee discussed also the rules for interaction between three sponsoring Executive organizations and newly engaged Executive bodies, and, subject to preliminary legal consultation, agreed on that the decision letter sent to new Executive Committee Member Organizations should also explain processes of termination of Membership.

Action (A/18-03): JCTLM Secretariat to draft the letter to confirm ICSH as new Executive member organization for comment and approval by three Executive sponsoring organizations.

5. JCTLM Governance

5.1 Appointment of JCTLM Chair and Secretariat

Dr Wielgosz informed the Committee that the procedure for the selection of the JCTLM Chairman and Secretariat was followed. The Secretariat contacted the sponsoring organizations, the IFCC, the ILAC and the BIPM for nominations. The IFCC submitted a

nomination of Prof Ian Young for JCTLM Chair, and there were no alternative nominations received for the Secretariat.

The JCTLM Executive approved the Chairmanship of Prof Ian Young and the BIPM's continued role as Secretariat for the JCTLM.

Action (A/18-04): JCTLM Secretariat to contact the sponsoring organizations and inform them of the appointment of the new Chairman, and update the JCTLM website.

5.2 Representation on the Executive

Dr Wielgosz informed the Committee of the IFCC nominations of Dr Kessler to enter her second term as one representative and Dr Gary Myers to enter his first term as a representative of the IFCC at the Executive Committee meeting in replacement of Dr Beastall. The Committee welcomed these nominations.

5.3 JCTLM WG Chairs

Dr Wielgosz reminded the committee of the need to follow the procedure for the selection and appointment of the Working Group Chairs for renewable two year periods, as the term of the Chairs had come to an end in December 2018.

Dr Liu, Prof Panteghini and Dr Phinney confirmed their willingness to continue to act as Chairs of the Database WG Analyte Group 1, 2 and 3, respectively, and the Committee re-appointed them for a renewable two year term.

Dr Beastall informed the Committee of his proposal to continue to act as the chair of the TEP WG for another year until after 2019 JCTLM Members' & Stakeholders' meeting. The Committee welcomed his proposal and reappointed him as chair for 2019.

5.4 Funding of the JCTLM Secretariat

As reported at the previous meeting the running cost for 2019 was estimated as the same as for 2018, corrected for inflation. It was agreed that BIPM and IFCC would again share the JCTLM Secretariat costs on a 50:50 basis for 2019.

5.5 JCTLM Database

Dr Maniguet presented the status of the database as of December 2018 as well as the updates of the data content and web system that had been carried out in 2018.

In February 2018, four entries for certified reference materials, eight reference measurement methods, and 15 reference measurement services were published in the JCTLM Database following the approval by the Executive of nominations reviewed during DB WG cycle 14 for materials and methods and cycle 12 for services. In addition, the certified reference material for six electrolytes in frozen human serum (NIST SRM 956c) was delisted from the JCTLM Database and placed in the PDF file for no longer available materials. The Committee commented on the need to raise awareness with the material producer of the importance of a submission for the renewed batch of CRM.

The current status of the database as of December 2018 was as follows:

- 290 certified reference materials (CRMs) from 13 producers including 12 NMIs/DIs,
- 194 reference measurement methods covering 90 analytes, and
- 176 reference measurement services covering 45 analytes. These services were delivered by 18 reference laboratories accredited for compliance against ISO 15195 and IEC/ISO 17025 as

Calibration laboratories, and by two National Metrology Institutes (NMIs).

In addition, the Secretariat undertook routine maintenance of the database system in consultation with the external company to ensure continuity of the web service during the year 2018.

The Committee discussed the possibility of modifying the analyte keyword search facility to offer the possibility to search for reference measurement systems for an analyte. This would require the development for a multi-criteria selection including materials, methods, and services for an analyte. It further requested that a list of specific developments should be drafted for submission of a global estimate request to the external contractor.

Some members of the Committee raised the issue of the implementation of existing nomenclatures for the description of measurands in the JCTLM Database. It was agreed that a preliminary review of the measurands in the JCTLM database should be carried out by experts of the Committee to look at the adequacy of using existing IFCC C-NPU nomenclature.

As a conclusion, an analysis of the numbers of visits using google analytics was conducted for 2018 which showed that the average number of visits reached 800 visits per month.

Action (A/18-05): JCTLM Secretariat to draft technical specifications and request a cost estimate for development and changes requested for JCTLM Database website.

6. Revision of JCTLM quality manuals

6.1 Nomination process for replacement materials [JCTLM-EXEC/18-04]

Dr Wielgosz recalled that the JCTLM Secretariat had conducted a study to identify critical criteria for renewing batches of the certified reference materials that were produced in compliance with ISO 17034/ISO 15194 using the same production process. The outcomes of the work were included in the document JCTLM-EXEC/18-04 and discussed at the DB WG meeting. It was observed that when ISO 17034 would be introduced as a normative reference in ISO 15194, the repeat batch development of reference materials was to be specifically dealt with, and that this could reduce the technical activities that needed to be performed by the CRM producer, potentially for stability or homogeneity assessment study. It was agreed that the JCTLM nomination process would remain unchanged in the near future and the risk-based assessment approach for repeated batch unit as described in ISO 17034 would be considered under the next revision of ISO 15194. The Committee concurred with the expected change towards a risk-based approach where the CRM producer would be able to refer to documentation from the original process of CRM production as per ISO 17034 requirements.

6.2 Equivalence between JCTLM and CIPM MRA processes for listing of CRMs [JCTLM-EXEC/18-05]

Dr Wielgosz said that the JCTLM Secretariat had conducted a comparison study for the CIPM MRA review process against the JCTLM review acceptance criteria for certified reference materials as per decision [A/17-23](#), and the outcomes of this work were included in the document JCTLM-EXEC/18-05. He added that this document had been presented for discussion at the DB WG meeting and circulated for comments to the Chairs of the CCQM Key Comparison WG on the review of CMCs within the CIPM MRA framework and of the

CCQM Organic Analysis WG that was a technical group organizing interlaboratory key comparisons to support CMCs from NMIs, including for services to the IVD sector.

He reported that the consultation showed that JCTLM and CCQM feedbacks converged in common findings and summarized key outcomes as follows:

- a. Currently, the CIPM MRA and JCTLM review processes for listing of CRMs could not be considered as equivalent, and the CRMs submitted by NMIs needed to go through both processes given they were seen as different in nature. CIPM MRA review process focused primarily on the demonstration of an institute's measurement capability (in Key Comparisons) whereas JCTLM review process focused on the assessment of the compliance of reference materials and their properties and supporting documentation with documented standards. In this regard, it was observed that commutability was not explicitly addressed in the review process of the CIPM MRA for matrix reference materials and the CIPM process would need to be more rigorous with regards to looking at the actual certificates of CRMs for a process of acceptance of the CIPM review to work in equivalence with the JCTLM process.
- b. It appeared also that detailed information on the CRM compliance against ISO 17034 requirement was not reviewed in a material by material fashion in the RMO Quality System review process as undertaken within the JCTLM process. As such a review against ISO 15194 requirements was not carried out in the CIPM MRA review process.
- c. Looking at possible ways forward, it was pointed out that more education within the CCQM community on ISO 15194 would be helpful, and further consideration among NMIs undertaken on how wider scope services related to CRMs recognised under the CIPM MRA would affect support for listing of CRMs in the JCTLM Database.

The Committee acknowledged the outcomes of the study and discussed further the possible way forward. It was agreed that further consultation with NMIs at the next meeting of the CCQM was needed to understand NMIs' intention of having CRMs listed in the different Databases and the expected impact of wider scope CMCs. It was requested also to test their views on using JCTLM listing as a requirement for listing CMCs containing information on CRMs intended for the IVD sector.

The discussion expanded and it was recognized that input from experts in clinical chemistry and laboratory medicine would be helpful for prioritization of measurands of interest within the CCQM key comparison programme related to the IVD sector. This would avoid duplication of efforts in developments of standardization programmes and would raise awareness of IFCC standardization projects, and reference measurement system implementation in laboratory medicine among the NMIs. The representatives of the IFCC at the meeting welcomed the invitation to attend the CCQM plenary meeting in April 2019 and would confirm the names of the attendees in due time.

Action (A/18-06): BIPM to present at the CCQM the results of the comparison study between JCTLM and CIPM MRA processes for listing of CRMs and possible way forward.

Action (A/18-07): BIPM to send an invitation to IFCC representative to attend the CCQM plenary meeting in April 2019.

6.3 JCTLM Survey – language options for certification documentation for reference materials

Dr Maniguet presented the results from the survey evaluation which was conducted among the producers of materials having CRMs listed in the JCTLM Database to test their views and concerns on the possibility of producing the certification documentation partly or fully in English as per decision [A/17-24](#). There were 8 of the 13 producers contacted that responded in full to the survey and of these 4 were from non-English speaking countries. The main outcome from this survey was that the majority of the respondents from non-English speaking countries declared they were prepared to systematically provide free of charge the English version of their certificates. As a result of this, the Executive agreed that a statement would be required from producers for publication in the JCTLM Database on the availability of their certificates in different languages.

Action (A/18-08): Secretariat to update the JCTLM material nomination form to include a comment on the certificate language options available from the producer.

7. Report from the JCTLM WG on Traceability Education and Promotion [JCTLM-EXEC/18-14]

Dr Beastall presented the document JCTLM EXEC/18-14 which included the annual report of the TEP WG for the JCTLM Executive Committee. He first said that after a hectic year of activity in 2017 the WG-TEP settled to a year of steady progress in 2018. There was no formal meeting of WG-TEP during the year.

He went on to say that the website continued to be updated on a regular basis with news items and additional freely available resources. The website was well used with an excellent global profile and feedback was positive. During the year discussions took place on modernising the home page and the revised version would be introduced at the start of 2019. JCTLM was grateful to Paola Bramati in the IFCC Office, who was maintaining the website.

He highlighted other TEP WG work items completed in 2018 and published on www.jctlm.org, and those are summarized below :

- Ten short webinars on traceability in laboratory medicine were produced on the IFCC eAcademy;
- Presentations on traceability in laboratory medicine and JCTLM were made in eight international conferences;
- Five meetings were held under the auspices of the JCTLM worldwide;
- Many publications relating to traceability in laboratory medicine during 2018 were added to the publications library, including notably:
 - Three papers and an editorial on commutability in the March 2018 issue of Clinical Chemistry .
 - The October 2018 issue of Clinical Chemistry & Laboratory Medicine was dedicated to Harmonization.
 - A short paper on the work of JCTLM by Graham Beastall in the e-Journal of IFCC
 - A review entitled ‘Traceability in laboratory medicine: practical application of metrology to healthcare’ by Graham Beastall and Robert Wielgosz for publication in Metrologia
- The annual Newsletter was published in April together with a special report on commutability by Neil Greenberg and Greg Miller
- A survey of JCTLM Members was conducted to assess the level of satisfaction with JCTLM services. There was a modest return (20 Members). Overall, the responses

indicated that Members gave ‘very valuable’ or ‘valuable’ ratings to the JCTLM database; the resources on www.jctlm.org; and the JCTLM channels of communication.

Following on from the discussions at the DBWG meeting, the Committee recognized that there was a need for induction training and support on ISO standards and JCTLM acceptance/review criteria for new members joining the review teams and for laboratory staff submitting nominations for the first time. It was recommended to develop a series of short webinars on case studies for materials, methods and services nominations for pointing out critical issues that would need to be considered. Dr Wielgosz commented also that he would look at the possibility to organize a training course on this issue for new members of the review teams within the framework of the CBKT programme.

The Committee agreed with the proposal for induction training/guidance and requested that this should be discussed and developed further within the TEP WG.

In addition, Dr Beastall presented two new workstreams on the implementation of the traceability in laboratory medicine regarding laboratory accreditation (first workstream), and harmonization of laboratory results (second workstream) at local, national, and international level. The subjects of these workstreams would be to collate references to support materials or prepare guidance as necessary. He added that this proposal would be developed further for discussion with the TEP WG. Prof. Panteghini informed the Committee of the published paper *Documenting metrological traceability as intended by ISO 15189:2012: A consensus statement about the practice of the implementation and auditing of this norm element* by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN standards (WG-A/ISO) that appeared to already cover the first workstream project. The reference Clin Chem Lab Med 2019 Mar 26;57(4):459-464 was being circulated among the Executive Committee members and it was agreed that it would need to be taken into account by TEP WG in featuring future work plan.

The Committee supported these two new work items.

The Committee confirmed Dr Beastall as Chair of the TEP WG for 2019 and approved his recommendation to review the membership of the WG when a new chair will be elected in December 2019.

Action (A/18-09): Dr Beastall to draft a paper for discussion with the TEP WG on new workstreams.

Action (A/18-10): Dr Wielgosz to look at the feasibility of organizing an induction course for new members of the review teams.

7.1 Plan for JCTLM 2019 Members’ and Stakeholders’ Meeting [JCTLM-EXEC/18-15]

Dr Beastall presented the document JCTLM EXEC/18-15 which included the first version of the programme for Members’ and Stakeholders’ meeting on 2 and 3 December 2019. He further added that a survey was conducted among the JCTLM members and interesting suggestions for topics and presentations were submitted and included in the programme. The Committee supported this first version of the programme with the proposed presentations from JCTLM Members. It was agreed that JCTLM members should be invited to present additional topics during the poster session.

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 review teams' recommendations which had been submitted for review as part of cycle 15 for materials and methods and cycle 13 for services.

There were 98 nominations for reference materials for five groups of analytes, 13 nominations for reference measurement methods for five groups of analytes which had been submitted for CRM/RMP review cycle 15, as well as 24 nominations for services for five groups of analytes which had been submitted for RMS review cycle 13.

Dr Myers said that the Database WG met on 5 December and successfully completed the review of all review teams' recommendations concerning these 96 nominations. All of these are summarized in the following sub-sections for each group of analytes including final Database WG recommendations.

8.1 Approval of Cycle 15 RM and RMP and Cycle 13 RMS

8.1.1 Blood cell counting and typing [JCTLM-EXEC/18-06]

There was one nomination submitted for a platelet counting reference measurement method which was still being under review. The Database WG Chairs reported on the need to clarify inconsistencies with regard to the nature and classification of non-compliances of the method against the ISO 15193:2009 requirements. The Database WG recommended to assign a group of experts from the WG to review the nominated method for blood cell counting and typing. The Committee supported the Database WG's recommendation to provide support to the review team and resolve any inconsistencies.

Action (A/18-11): M. Panteghini to contact the team leader for Blood cell counting in order to finalize the review for nominated platelet counting reference measurement method and circulate the recommendation for comment and approval by the end of February 2019.

8.1.2 Drugs [JCTLM-EXEC/18-07]

There were 13 nominations for certified reference materials that have been reviewed by the review team for Drugs and that were not being recommended for listing in the JCTLM Database.

The first nomination was a certified reference material for Sirolimus in human blood for which the recommendation for listing in the database was pending the resolution of a non-compliance regarding the hierarchical position statement in the certificate. The DBWG advised for defining the material as a secondary calibrator and recommended the resolution of a critical non-compliance concerning the inconsistency of the commutability statement and the intended use statement of the material.

The remaining nominations were for 12 nominations for pure drugs of abuse certified reference materials, and all of these were not being recommended for listing until the producer addresses the major non-compliances with regard to paragraph 6.1 (supporting documentation) of ISO 15194.

The DB WG noted that 6 of the 12 materials were submitted to replace listed material units and requested that the producer should be informed of the JCTLM requirement for demonstration of the extent-of-equivalence of materials as by JCTLM procedure DB-P04A.

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

8.1.3 Electrolytes [JCTLM-EXEC/18-08]

There were 23 nominations for certified reference materials, five nominations for reference measurement methods and six nominations for reference measurement services that were reviewed by the review team for Electrolytes, and 29 out of these 34 nominations were being recommended for inclusion in the JCTLM Database.

There were 18 nominations covering three multi-element materials in serum for which the producer submitted data/information that adequately addressed all the non-compliances observed during last year's review cycle, and all of these were being recommended for inclusion in the JCTLM database.

There were five more electrolytes nominations related to a multi-analyte conventional reference material in serum, and all of these were not being recommended for inclusion in the JCTLM database. The review team observed notably a critical non-compliance with regard to the traceability statement and concluded that the material was more representative of an QC material when the field methods (not higher order methods) are used to certify values. It was noted that other nominations for Proteins and Metabolites measurands related to this multi-analyte conventional reference material in serum had also been rejected during this review cycle.

There were also five nominations for ICP OES based reference measurement methods for the measurement of Lithium, Sodium, Potassium, Magnesium, and Calcium in human serum, plasma, and urine, and five nominations for reference measurement services from the calibration laboratory having developed these methods, and all of these were being recommended for listing in the JCTLM Database

Finally, there was an IC-based reference measurement service for Sodium in human serum which was submitted by a calibration laboratory from China, and was being accepted for inclusion in the JCTLM database

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

8.1.4 Enzymes [JCTLM-EXEC/18-09]

There were 14 nominations for reference measurement services from two calibration laboratories that have been reviewed by the review team for Enzymes, and of these seven nominations for reference measurement services from a calibration laboratory were being accepted for listing in the JCTLM Database.

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

8.1.5 Metabolites and Substrates [JCTLM-EXEC/18-10]

There were 15 nominations for certified reference materials, three nominations for reference measurement methods and two nominations for reference measurement services that were reviewed by the review team for Metabolites and Substrates, and of these one glucose method and one urea service were being recommended for inclusion in the JCTLM Database.

Materials

There were two nominations for certified reference materials for creatinine in frozen human serum (covering two concentration levels) for which the producer submitted data/information to respond to non-compliances observed during last year's review cycle, and two major non-compliances would still need to be resolved prior to recommending the listing of the materials in the database. These included the need for clarification in the certificate of the intended use statement with respect to the hierarchical position of the material and the addition of the sampling size for homogeneity assessment prior to recommending the listing of the materials in the database.

There were eight more nominations for two materials for glucose, creatinine, uric acid and urea in frozen human serum (covering two concentration levels) for which the producer submitted EQA/commutability data and its revised certificate that addressed adequately the non-compliances observed during last year's review cycle. It was however noted that EQA results were not suitable data to fulfill the JCTLM acceptance criteria for demonstrating material equivalence, and the material was not being recommended unless the producer addressed this requirement and provide suitable comparison data for material equivalence demonstration.

Finally, there were five nominations related to a multi-analyte conventional reference material in serum, and all of these were not being recommended for inclusion in the JCTLM database. It was noted that the review outcomes for this multi analyte material for metabolites measurands were consistent with the findings from Electrolytes and Proteins groups.

Methods

There was a first nomination for an ID LC-MS/MS reference measurement procedure for glucose in serum/calibration solution which was being recommended for listing in the JCTLM Database. It was noted that appropriate corrective actions had been made by the institute to address the non-compliance regarding the limit of detection observed at last year's review cycle.

There was a second nomination for a reference measurement procedure for total bilirubin in lyophilized, fresh, or frozen blood serum, or blood plasma which was not being recommended for inclusion in the JCTLM Database. Major non-compliances regarding the lack of information on the method traceability to the SI, and the absence of the expected uncertainty contribution arising from the calibration of molar absorption coefficient of the method using the measurement from NIST SRM916a needed to be addressed and resolved prior resubmission to JCTLM.

In addition, the WG requested that suitable information should be provided for demonstrating the compatibility of the method with other two listed measurement procedures.

There was a third nomination for an ID/LC/MS/MS reference measurement procedure for urea in human serum which was not being recommended for inclusion in the JCTLM Database. Major non-compliances related to the lack of an interference study and related information as well as minor non-compliances related to the lack of limit of detection and material standard assessment needed to be addressed and resolved prior resubmission to JCTLM.

Services

There was a first nomination for reference measurement service for bilirubin in lyophilized, fresh, or frozen blood serum, or blood plasma which was not recommended for listing in the JCTLM database. The service was based on a newly developed reference measurement method which was not being accepted during this review cycle.

The remaining nomination was submitted by a reference laboratory for a reference measurement service for Urea in fresh, frozen or lyophilized human serum, and was recommended for inclusion in the database.

The Committee approved the DB WG's recommendation for Metabolites and Substrates nominations for materials, methods and services.

8.1.6 Non-Peptide Hormones [JCTLM-EXEC/18-11]

There were 30 nominations for high purity certified reference materials of steroid hormones and their derivatives (15 in a neat form and 15 ampouled material) that were submitted from the same producer. All nominations have been reviewed and were not being recommended for inclusion in the JCTLM database. Major non-compliances regarding the lack of information provided in the supporting documentation for nominated materials needed to be addressed and resolved prior resubmission to JCTLM. The Database WG recommended the revision of the material documentation/provision of complementary information to adequately address the non-compliances related to the following ISO 15194:2009 requirements: statement of the hierarchical position and the scope of application of the materials; instructions on opening of the immediate container and disposal of any remaining material after use; statement about how the transferable mass of the material is assigned for fifteen ampouled materials; statement on metrological traceability statement for sixteen materials, and homogeneity statement.

The WG recommended also that the producer should be informed of the JCTLM requirement for demonstration of the extent-of-equivalence of nominated materials with already published material for the same measurand and batch replacement.

The Database WG noted that the producer had also submitted nominations of neat pure materials for Drugs and recommended the harmonization of the review reports with the Drugs team when the same issues arose for nominations of (neat) pure materials.

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

8.1.7 Nucleic acid [JCTLM-EXEC/18-16]

There were two nominations for reference measurement methods that have been reviewed by the review team for Nucleic acid and of these the nomination for a reference method for KRAS G12D/WT in solution by digital PCR was recommended for inclusion in the JCTLM database.

There was a second nomination for a reference method for Human cytomegalovirus quantification by dPCR which was not recommended for listing in the JCTLM database. A critical element concerning the reformatting of reference method procedure within a single

document, and two major elements on clarification of the scope of the method and measurand needed to be addressed and resolved before resubmission to JCTLM.

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

8.1.8 Proteins [JCTLM-EXEC/18-13]

There were 17 nominations for certified reference materials, two nominations for reference measurement methods and one nomination for reference measurement services for Proteins that had been reviewed and of these three A β 42 materials, six HbA1c materials and one HbA1c service were being recommended for approval and publication in the JCTLM Database.

Materials

There were three nominations for certified reference materials containing mass concentration of amyloid Beta1-42 peptide (A β 42) in three CSF (cerebrospinal fluid) materials, and all of these were being recommended for listing in the JCTLM Database.

The DB WG supported the recommendation of the review team including the minor observation that additional details on the purity assessment would add value to the certification report.

There was a nomination for a reference material with a certified value for insulin in human serum solution, for which the producer submitted data/information to respond to non-compliances observed during last year's review cycle. However, a critical non-compliance concerning the intended use statement of the material still needed to be clarified and documented prior to recommending the listing of the material as of higher order in the database.

There was a nomination for a reference material with a certified value for C-reactive protein (CRP) in human serum solution, which replaced the previous unit delisted from the JCTLM database in September 2017. A critical non-compliance concerning the intended use statement of the material needed to be specified and documented prior to recommending the material for listing in the database.

There were three nominations for Glycated Hemoglobin in Human Hemolysate buffer reference materials (three concentration levels) for which the Chinese producer submitted data/information that adequately addressed all the non-compliances observed during last year review cycle. However, the Database WG discussed the lack of report on the extent-of-equivalence and referred the final recommendation to the Executive Committee.

There were three more nominations for Glycated Hemoglobin in lyophilized human blood hemolysates reference materials (three concentration levels) submitted by a French producer that have been produced and characterized in compliance with ISO 15194 requirements. However, the Database WG discussed the lack of report on the extent-of-equivalence and referred the final recommendation to the Executive Committee.

Following the discussion at the Executive Committee meeting, it was agreed that the information provided by the Chinese and French producer for HbA1c in whole blood materials were sufficient for listing of the HbA1c materials on the data base.

There was a final nomination for a reference material for Glycated Hemoglobin in frozen human blood which was not being accepted for inclusion in the JCTLM database. Critical non-compliances concerning the purity determination of the peptides utilized to value assign the material and demonstration of extent of equivalence with other materials listed in the JCTLM Database needed to be addressed and resolved prior resubmission to JCTLM. The DB WG recommended that the material certification method (based on the IDMS measurement principle) should be submitted for JCTLM review, after demonstration of its compatibility with the IFCC HPLC method using native samples.

There were five nominations related to a multi-analyte conventional reference material in serum, and all of these were not being accepted for inclusion in the JCTLM database. Major concerns were about how this material can fit within the scope of the database where values were assigned using not well described methods or routine methods (not higher order methods), and certificate included a statement that the material was not a certified material. Additional critical requirements on the homogeneity, stability, measurement procedures and details on the calculation of the uncertainty needed to be addressed and resolved prior resubmission to JCTLM.

Methods

There was a first nomination for an HPLC reference measurement method for CDT biomarker for which the nominating organization provided sufficient evidence to address most of the non-compliances observed during last year's review cycle. However, critical elements concerning the calculation of the uncertainty (with uncertainty contributions associated to the individual steps of the method that needed to be considered for GUM compliance) still needed to be specified and addressed prior resubmission to JCTLM.

There was a second nomination for a IDMS based procedure for quantification of B-type natriuretic peptide in plasma, which was not being recommended for inclusion in the JCTLM Database. Critical elements concerning the definition of the measurand and method compatibility with immunoassays needed to be specified and addressed prior resubmission to JCTLM. The DB WG discussed the review of this nomination where representative of the nominating organization was involved to some extent in the review process. It was recommended that DB WG Vice Chair would review separately the report related to the BNP method in order to avoid a potential conflict of interest and prevent possible complaints by other nominating bodies.

Services

The DBWG recommended the publication of a HbA1c reference measurement service from a Japanese calibration laboratory after minor corrections would be made for consistency of the measurement and uncertainties ranges with those in the certificate, and redefinition of analyte/quantity as HbA1c /amount of substance fraction.

The Committee approved the DB WG's recommendation for Proteins nominations for materials, methods and services.

8.1.9 Vitamins [JCTLM-EXEC/17-23]

There were two nominations submitted by a reference laboratory from China for reference measurement services for 25-hydroxy vitamin D2 and D3 in serum that were still being under review. The DB WG agreed to deferred the nomination until recommendation is finalized.

Action (A/18-12): Dr Phinney to contact the team leader for Vitamins to clarify the outcomes of the review for two nominated 25-hydroxy vitamin D2 and D3 in serum reference measurement services and circulate the recommendation for comment and approval.

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

Action (A/18-13): 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.

The Executive further discussed some issues that arose at the previous Database WG meeting. The first discussion point was on the improvement of process for review and reporting the recommendations when nominations were being submitted by an institute to which a member of the review team was affiliated. It was agreed that the Database WG chair being responsible for the review team should have a leading role in this process. The Committee requested that the Quality Manual should be revised to avoid conflicts of interest during the review and reporting at the annual Database WG meeting.

Also, it was agreed that the revision should cover the request for guidance from the team leaders on how to conduct and share the review of nominations within his/her team.

Another issue regarding the quality of the review conducted by the review team was discussed among the members of the Committee. This related to the possible lack of access to the international standards by the members of the review teams when these documents laid down the requirements used to perform the review of nominations. It was agreed that a survey would be conducted among the review team members to look at what ISO standards they have access to.

Action (A/18-14): JCTLM (I. Young, G. Myers, R. Wielgosz, S. Maniguet) to review the relevant Executive procedure and draft a proposal for a process to avoid conflict of interest during the review and reporting process and for providing guidance to the team leaders for conducting the review of nominations.

Action (A/18-15): Secretariat to conduct a survey among the review team members to look at what ISO standards they have access to.

8.2 Demonstration of comparability of nominated CRMs with listed materials

It was recalled that the Database WG agreed that further guidance was needed for demonstrating and evaluating the equivalence of CRMs as per the procedure document (DBWG P 04A). The working group recommended that the text of the procedure document should be revised to anticipate the number of samples that would be required for assessing the materials comparability. Over the years, it appeared that comparison data submitted for assessment by the reviewer was not always publicly available or published in dedicated reports as foreseen in JCTLM procedure. The DB WG noted that the user of a material should have the possibility to access information on the extent of equivalence study among listed materials when such a reference or JCTLM report had been published in the JCTLM database. However, to date there were only very few reports available in the JCTLM database.

The Committee discussed further the issue and agreed that the Database WG Chairs would review the procedure document to anticipate the process employed by NMIs for material comparability studies as part of their material certification process (and noting this was not always publicly available).

Action (A/18-16): Database WG chairs together with the Quality Team Chair to review the text of the document procedure DB WG P-04a and draft a proposal for revising the guidance for demonstrating material equivalent in considering materials compatibility process undertaken by NMIs.

8.3 Update on IFCC EQAS results

Dr Kessler gave an update on the IFCC EQAS Scheme and the RELA exercise completed in 2017. She said that the number for RELA results disclosed on the website had continued to increase to reach 420 results for 2017 RELA and that the number of laboratories participating in RELA EQAS Scheme remained the same at 50, with the percentage of services listed by JCTLM staying constant at 35%. She also pointed out an increase of the requests for trial measurements for two groups of analytes during the last two years (metabolites in 2016 or hormones in 2017) with a notable contribution of Chinese laboratories which seemed consistent with the focus areas of for their national standardization projects. Finally, she announced the launch of a new service starting in 2019 for Hemoglobin for which nine laboratories had already signed up.

Dr Kessler also reported on the outcomes of the ongoing review of JCTLM listed reference measurement services and how regularly they participated in EQAS RELA scheme as per JCTLM rules. It was observed that three service providers from France, Italy, and Japan were showing a lack of RELA results for one measurand in the Enzymes or Metabolites and Substrates Group in the last time period of three years (2015-2017). In the discussion that followed the Committee agreed that the service providers should be contacted to confirm with them the status of their respective services listed in the database with regards to their participation in EQAS Scheme and remind them they would need to participate in next EQAS scheme to remain listed in the database.

The Committee further discussed the stringency of the frequency of three years applied by JCTLM rules for an EQAS participation of a laboratory for each measurand listed and its limit of applicability when a group of measurand comprises one measurand. It was agreed that an expert group would need to review the criteria for assessment of laboratory performance according to regular participation in EQAS, noting that accredited laboratories were required to participate regularly in ring trials at a periodicity varying from 1 to 3 year-period accordingly to their own National Accreditation Body's procedures.

Action (A/18-17): Secretariat to contact the three service providers not fulfilling one of the JCTLM requirements for regular participation in EQAS Scheme and confirm with them their service status and inform them they would need to participate in an EQAS in order to address the non-compliance.

Action (A/18-18): Expert group (A . Kessler, I. Young, M. Panteghini, and M. Bednarova) to review the JCTLM rules for regular participation in EQAS Scheme to address the case where there was only one analyte per measurand group and to draft a proposal for guidance for discussion at the Executive Meeting in December 2019.

8.4 Progress/ plans for Cycle 16 for RMs and RMPs and Cycle 14 for RMSs

In accordance with the generic time schedule of the JCTLM review cycle, it was agreed that the next call for nominations for Reference Materials, Methods, and Services would be launched on the 1st of February 2019 with a deadline for submissions in May 2019.

8.5 Discussion on new concept for establishing group on reference measurement system

Prof Panteghini presented to the Committee his proposal for a new JCTLM activity which would focus on providing guidance on the implementation of reference measurement systems to the IVD community. This work would consist of two parts: the definition and approval of reference measurement systems, in their entirety and not just in their main components (reference materials and methods); and the promotion of the implementation by IVD industry of traceability to such reference systems in a scientifically sound and transparent way (for instance the inclusion of the defined reference measurement system in their assay or calibrator package insert).

The Executive supported the proposal for the new work stream based and recognized that case studies for measurands listed by JCTLM would give appropriate guidance to the IVD community on the effect of defined schemes of calibration hierarchy on the uncertainty of measurement results. It was also noted that this activity would be timely, with the publication of the revised standard ISO 17511 that laid down the requirements for establishing reference measurement systems expected in the near future. The formation of a Task Group on reference measurement systems implementation was agreed, and Prof Panteghini appointed as the Chair of the Task Group.

Action (A/18-19): Prof Panteghini to draft the Terms of Reference for the Task Group on reference measurement systems implementation for EC comment and approval and identify experts to participate in the group, and report outputs at the next Executive meeting.

9. Update on traceability from routine laboratories perspective

Dr Jones gave an informative presentation on the traceability of laboratory results from the perspective of routine laboratories. He raised practical issues (report formats, validation of documentation for SOPs, method comparisons, review of reference intervals, information to clinicians) that his laboratory encountered in implementing change of supplier and needed to resolve to avoid/understand any impact on the traceability or discontinuity in the interpretation of laboratory measurement results. He pointed out similar practical considerations would be necessary at national level in view of e-health patient records when reporting differences between laboratories would be more visible. He also observed that there was some information on metrological traceability provided in the supplier documentation that referred to JCTLM, but that this could be much improved. He reminded the Executive, that JCTLM had produced a paper to provide advice to manufacturers and others on the appropriate manner to make reference to JCTLM (listing of reference materials, methods and services in any documentation in which information on metrological traceability was included) and this should be advertised further.

The Committee thanked him for this contribution.

10. Liaison with ISO TC 212

Dr Wielgosz reported that the previous meeting of the ISO TC 212 WG2 has been held in Republic of Korea in October 2018, and that all documents under development by ISO-TC212/WG2 were expected to be published in 2019. He also informed the Committee that Dr Neil Greenberg would resign as convenor of the WG2 after 4 years of mandate. The Committee took this opportunity to acknowledge his great work in collaboration with JCTLM over these years.

10.1 Update of revision of ISO 17511:2003

The document DIS of the revised text of the ISO 17511 on the requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples was being registered and the publication of the IS was anticipated in October 2019. Similar time line was expected for the publication of the new international standard ISO/DIS 21151 on the requirements for international harmonization protocols establishing metrological traceability of values assigned to calibrators and human samples.

The Committee noted that further investigation on the implementation of ISO standard on harmonization would be needed in view of a possible inclusion of harmonized reference systems in the JCTLM database. It was agreed that this would be a JCTLM task in the future strategic plan.

10.2 Other work items in ISO TC 212

The revised text of ISO 15195 on the requirements for the competence of calibration laboratories using reference measurement procedures was published in December 2018. The document FDIS for the practical guide for the estimation of measurement uncertainty was being registered and the publication expected in 2019.

The Committee discussed further possible work items at the occasion of the systematic revision of ISO 15193:2009 and 15194:2009, and recommended commutability and implementation of the IFCC recommendation on commutability recently published should be brought forward and submitted in due time for revision.

11. Liaison with the EC

11.1 Update on comparison study of impact of IVD Regulation and JCTLM DB coverage

Dr Myers recalled that he would follow up on the action for drafting an action plan for a comparison review of ISO 17511 and the IVD regulation with regards to metrological traceability requirement, and an analysis of the coverage of the JCTLM Database with regards to the biomarkers in the four classes of risk defined in the Regulation.

12. Liaison with the WHO

Dr Wielgosz recalled that the BIPM would conduct a revision of the Memorandum of Understanding signed between the BIPM and the WHO in 2002, and it was appropriate to engage dialogue at this occasion with regards to the idea of a JCTLM/WHO common portal for reference measurement systems in laboratory medicine and the coverage with regards to the biomarkers in the four classes of risk defined in the Regulation.

13. Reports related from related activities/meetings

13.1 Report for the IFCC SD meeting

Dr Myers presented the document JCTLM EXEC/18-17 which included the report from 62nd IFCC Scientific Division Meeting held in Budapest, Hungary on 8-9 November, 2018 with highlights on new projects.

He informed the Committee that beginning in 2019 the WG on Standardization of Bone Marker Assays, WG on Parathyroid Hormone, and WG on Vitamin D Standardization Program would be merged creating a new SD Committee on Bone Metabolism chaired by Dr. Etienne Cavalier

He added that a new proposal titled, “Development of a Reference Measurement System for Sustainable PT/INR Standardization” was approved by the SD. The proposed objectives of this project were:

- a. To develop a harmonized reference measurement procedure based on the WHO manual tilt tube (MTT) technique as well as the complete reference measurement system for global standardization of the PT/INR test.
- b. To review the agreed WHO procedure for calculating ISI of new international standards as the procedure should not lead to deterioration of the traceability of PT/INR test results.
- c. To evaluate the necessity of the co-existence respectively continuation of different thromboplastin reference materials for ensuring global PT/INR standardization.
- d. To establish a network of at least three calibration labs running the harmonized MTT technique for certifying the calibration of commercial thromboplastins from IVD-manufacturers.

He said also that SD and ICHCLR were collaborating to develop a proposal for an international conference to bring together the various groups developing reference materials along with stakeholders (including NMIs, JCTLM, laboratory medicine organizations, IVDs, and regulators) to address barriers to harmonization, to minimize redundancies and to increase standardization internationally. The meeting was proposed as a 2 day satellite meeting held in conjunction with IFCC WorldLab 2020 in Korea.

The Committee recognized that NMI collaboration for organizing this international conference would be beneficial and in line with previous decision to expand further communication and liaison between metrology and clinical chemistry community.

Action (A/18-20): Dr Wielgosz to inform NMIs at the next CCQM meeting of the planned workshop.

13.2 Status update on the following projects: CardioMet, NeuroMet2 and EMN on Traceability in Laboratory Medicine

Dr Beastall said that JCTLM sent a letter in support of three proposals for European EMPIR-project and all were funded and would start in April/May 2019. Presentations would be made at the next JCTLM Members’ and Stakeholders’ meeting in December 2019.

14. Future meetings in 2019 /2020

The Committee confirmed that the next JCTLM Members’ and Stakeholders’ meeting would be held at the BIPM on 2 and 3 December 2019. This would be followed by a TEP-WG meeting on 4 December (morning), and a Database WG meeting on 4 (afternoon) and 5 (morning) December as well as a JCTLM Executive meeting on 5 and 6 December 2019.

It was also agreed to either hold an Executive meeting in conjunction of the EUROMEDLAB in Barcelona in May or alternatively a teleconference meeting of the Executive Committee in April/May 2019 for discussing a preliminary programme for next JCTLM Members’ and Stakeholders’ Meeting and reviewing any action items of this meeting

Dr Wielgosz said that the third edition of the international conference on Protein and Peptide Therapeutics Drugs would be discussed at the next CCQM meeting in April 2019.

The Committee supported this proposal from Ms Bednarova for a session on the difference between ISO 17025:2017 and ISO 15195:2018 at the next ILAC meeting in Mexico in April 2019. It requested whether it would be possible to make the presentation remotely due to conflict of calendar with other meeting, and decision would be made after confirmation of the possibility from the organizers.

15. Close

The Chairman closed the meeting on 7 December at 13:00.

Annex 1: Summary List of Actions

Actions from the 19th Executive Meeting:

Action (A/17-19) : Dr Myers to draft responses to the questions raised by JCTLM Member Organizations in the biennial activity report.

Action (A/17-28): Dr Myers to draft an action plan for a comparison of ISO 17511 and the IVD regulation with regards to metrological traceability requirements, and analyze the coverage of the JCTLM Database with regards to the biomarkers in the four classes of risk defined in the Regulation.

Action (A/17-29): Dr Wielgosz and Dr Beastall to work on the possibility to liaise with WHO and draft a discussion paper.

Actions from the 20th Executive Meeting:

Action (A/18-01): ILAC to review the provided list of accreditation services providers against ISO 15195 and to ISO 17034, and confirm the NABs having provided accreditation services to calibration laboratories against ISO 15195 and reference material producer accredited against ISO 17034 listed by JCTLM.

Action (A/18-02): Task-group (Drs Myers, Young, Jones, Beastall, Wielgosz) on the induction process for new Executive member to develop a draft guidance document for the induction process, for discussion at the Executive Meeting in December 2019.

Action (A/18-03): JCTLM Secretariat to draft the letter to confirm ICSH as new Executive member organization for comment and approval by three Executive sponsoring organizations.

Action (A/18-04): JCTLM Secretariat to contact the sponsoring organizations and inform them of the appointment of the new Chairman, and update the JCTLM website.

Action (A/18-05): JCTLM Secretariat to draft technical specifications and request a cost estimate for development and changes requested for JCTLM Database website.

Action (A/18-06): BIPM to present at the CCQM the results of the comparison study between JCTLM and CIPM MRA processes for listing of CRMs and possible way forward.

Action (A/18-07): BIPM to send an invitation to IFCC representative to attend the CCQM plenary meeting in April 2019.

Action (A/18-08): Secretariat to update the JCTLM material nomination form to include a comment on the certificate language options available from the producer.

Action (A/18-09): Dr Beastall to draft a paper for discussion with the TEP WG on new workstreams.

Action (A/18-10): Dr Wielgosz to look at the feasibility of organizing an induction course for new members of the review teams.

Action (A/18-11) : M. Panteghini to contact the team leader for Blood cell counting in order to finalize the review for nominated platelet counting reference measurement method and circulate the recommendation for comment and approval by the end of February 2019.

Action (A/18-12): Dr Phinney to contact the team leader for Vitamins to clarify the outcomes of the review for two nominated 25-hydroxy vitamin D2 and D3 in serum reference measurement services and circulate the recommendation for comment and approval.

Action (A/18-13): 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/18-14): JCTLM (I. Young, G. Myers, R. Wielgosz, S. Maniguet) to review the relevant Executive procedure and draft a proposal for a process to avoid conflict of interest during the review and reporting process and for providing guidance to the team leaders for conducting the review of nominations.

Action (A/18-15): Secretariat to conduct a survey among the review team members to look at what ISO standards they have access to.

Action (A/18-16): Database WG chairs together with the Quality Team Chair to review the text of the document procedure DB WG P-04a and draft a proposal for revising the guidance for demonstrating material equivalent in considering materials compatibility process undertaken by NMIs.

Action (A/18-17): Secretariat to contact the three service providers not fulfilling one of the JCTLM requirements for regular participation in EQAS Scheme and confirm with them their service status and inform them they would need to participate in an EQAS in order to address the non-compliance.

Action (A/18-18): Expert group (A. Kessler, I. Young, M. Panteghini, and M. Bednarova) to review the JCTLM rules for regular participation in EQAS Scheme to address the case where there was only one analyte per measurand group and to draft a proposal for guidance for discussion at the Executive Meeting in December 2019.

Action (A/18-19): Prof Panteghini to draft the Terms of Reference for the Task Group on reference measurement systems implementation for EC comment and approval and identify experts to participate in the group, and report outputs at the next Executive meeting

Action (A/18-20): Dr Wielgosz to inform NMIs at the next CCQM meeting of the planned workshop.