

**Report of the 17th meeting of the JCTLM Executive Committee
6-7 December 2016, BIPM, Sèvres, France**

List of participants:

Dr G. Myers (JCTLM Chairman, IFCC)
Ms R. Robertson (ILAC)
Dr G. Beastall (IFCC, JCTLM WG-TEP Chair)
Prof L. Siekmann (IFCC, JCTLM DB WG vice-Chair)
Dr R. I. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr S. Maniguet (JCTLM Secretariat, BIPM)
Dr K. Phinney (JCTLM DB WG vice-Chair)
Dr J. McLaren (CIPM)
Dr G. Jones (ILAC)

Apologies received:

Dr. M. Milton (BIPM)
Dr. W.E. May (CIPM)
Dr H. Schimmel (JCTLM DB WG vice-chair)

Dr Myers opened the meeting and welcomed all participants and Dr Liu who was a representative from the Health Science Authority (HSA), Singapore and would present the CCQM NMIs' activity regarding HbA1c reference measurement system.

1. Approval of the agenda [JCTLM-EXEC/16-08]

Dr Myers asked the Committee whether any additional points should be considered for the agenda. Dr Jones asked for a discussion of the requirements/standard for publication of reference methods for IVD assays to be added under agenda point 8.1. Prof Siekmann requested that agenda point 9.2 be extended to address the distribution of EQAS RELA samples in China. The changes to the agenda were approved.

2. Liaison with CCQM

2.1 C-Peptide reference measurement system implementation

Dr Wielgosz presented the example of C-Peptide reference measurement system where progress in measurements science have led to two calibration hierarchies for C-Peptide measurements existing, where one relies on a conventional International Standard (IS) lyophilised pure material and the other a certified commutable matrix reference material in serum for calibration of IVD kits. It had been demonstrated that the serum based CRM resolved commutability issues and could reduce between kit variability. Two JCTLM reference methods existed for the value assignment of such materials, but recent comparisons had shown that the methods did not currently agree within their stated uncertainties and work was underway to resolve this issue. This collaborative work was progressing well and there were still on-going issues to be looked at by the group such as the commutability of the conventional IS and the use of either Total C-Peptide or C-Peptide to define the measurand within the reference measurements system.

He drew the Committee's attention to the fact that there would be a need for possible corrective actions for either one or both methods published in the JCTLM Database depending on whether the difference between the two listed methods could be resolved. The issue to be discussed was also a general one, notably, what procedures the JCTLM should adopt before publishing methods whose performance had not yet been demonstrated within external quality assurance schemes?

2.2 Proposed CCQM PAWG Pilot Study on HbA1c

Dr Liu presented the example of the approach proposed by the NMIs for HbA1c reference measurement system which was used a IDMS reference measurement procedure for which the mole fraction of two hexapeptides was measured, with calibration using pure synthetic hexapeptides rather than glycosylated and non-glycosylated forms of the protein. The Committee commented that calibration hierarchy differed from those used in the IFCC reference measurement system which was implemented for HbA1c, and that a similar published IDMS procedure which had been presented at a previous JCTLM Workshop in 2012, which at that point had shown a bias in comparison to the accepted calibration hierarchy of the IFCC method. Dr Liu replied that in recent RELA comparisons his laboratory had demonstrated that any such bias was much reduced, and potentially to levels that would not be significant.

Dr Liu stressed that his institute HSA as well as other NMIs were already using pure hexapeptide calibrator route to provide values for EQA scheme. The benefits of the hexapeptide based calibration hierarchy, was that these materials could be produced by any one of a number of NMIs with capabilities in the field, and would then make the reference measurement much more accessible. What needed to be avoided was the development of two calibration hierarchies that gave different results, and for that reason a CCQM comparison both on the calibrator material and matrix materials was being planned, and comparison with IFCC network laboratories would be sought.

In the discussion that followed, the Committee concluded that it would be vital for the IFCC HbA1c Network Laboratories to be involved in the study. Whilst a more accessible reference measurement system was a commendable goal, every care should be taken to ensure that no significant biases arose from the implementation of two different calibration hierarchies for this very important and well established measurand.

3. Report of 16th JCTLM Executive Committee Meeting [JCTLM-EXEC/16-09]

There were no comments on the report of the 16th Executive Committee meeting, which had been finalized in September 2016, and published on the [BIPM JCTLM website](#).

3.1 Review of action points arising from the 16th meeting

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

Action (A/15-32) : Secretariat to draft a template (pro forma) for the written activity reports to be submitted on a biennial basis by the JCTLM member organizations

This action was not completed yet and would be followed up in the first quarter of 2017.

Action (A/15-33) : Dr Myers to draft responses to the questions that CNAS (China) submitted in its activity report for comment by the EC

Dr Myers reported that the draft of the responses to the questions raised by CNAS in its activity report was currently being discussed with Prof Siekmann, and the final version would be circulated for EC comment and communicated to CNAS in early 2017.

Action (A/15-40): Dr Wielgosz in consultation with Leader of the Coagulation factor review team to identify the appropriate contact person within the ISTH organization who could provide guidance on the ISTH involvement in the Coagulation factor review team activity

Dr Wielgosz reported that he had not been in contact recently with the Review Team Leader for Coagulation Factors, and would take the opportunity of the planned liaison meeting between the BIPM and the NIBSC which would be held at the BIPM mid-January 2017 to follow up this action. However, the ISTH had not nominated their renewed batch of Coagulation Factor standards for JCTLM review.

Action (A/15-45): Dr Jones to draft a paper which would address gap and the needed development of reference system components to establish traceability for patients' measurement results.

Dr Jones said that he failed to draft a paper to address gap analysis and the needed development for reference measurement system components, and stressed that paper/publication may not be the appropriate format to communicate this information considering that the content of the Database would have already been updated at the time of the publication. This would be discussed further under agenda point 10.

Action (A/15-46): WG-TEP to develop a presentation for introducing JCTLM which would be available for speakers attending meetings organized under JCTLM auspices, and a template for JCTLM presentations which would include the JCTLM Logo and tag line

Dr Beastall said that JCTLM branded supports had been developed including a template for JCTLM presentations and a generic introduction of the JCTLM which would be available from the traceability website for speakers attending meetings organized under JCTLM auspices, and this, as soon as the portal dedicated to traceability in laboratory medicine would be published.

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

Dr Wielgosz said that this action would be taken at the next CCQM meeting in April 2017 as the proposed JCTLM requirement for requesting the certification documents in a full English version would affect the issuing of the certificates at a national level. He reminded the Committee that the CIPM MRA worked on mutual recognition, and there were no requirements within this arrangement or the ISO harmonized standards to produce the documentation in English.

He added that the issue was discussed during the week at the JCTLM Database WG meeting and the proposal was made that from the perspective of the users originating from the country where the material was produced, the JCTLM Database should give them the option to access the documentation in their national language, and at least to inform them on the languages in which the certificate was available.

The Committee agreed with the Database WG's proposal for including in the JCTLM Database either links to the documentation on material certification in both the national version and a full English version or information on which language the certificate was available.

Action (A/16-08): Database WG vice-chairs to draft a proposal for the nomination and review process that will apply for the replacement of materials.

Dr Wielgosz said that this action was not yet completed, and during its meeting held on 5 December the Database WG had welcomed the proposal from Dr Phinney (vice-Chair of the Database WG) in collaboration with K. Lippa (NIST) to draft a proposal which would highlight the key acceptance criteria with respect to ISO 15194 requirements for submission of renewed batches of the certified reference materials, considering that a number of the requirements would have been already met and verified for the previous lot and this would be applicable to the new materials if the producer had maintained its production procedures.

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

Dr Wielgosz said that this action would be taken at the next CCQM meeting in April 2017 where he would raise the difference in the review and acceptance criteria for the two databases noting that the BIPM KCDB was listing the NMIs' measurement capabilities (where CRMs were listed as a mechanism to deliver services to disseminate traceability) whereas the database of the JCTLM was listing CRMs that were reviewed in compliance against ISO 15194 requirements.

Action(A/16-11): Prof Siekmann to review the requirements for EQAS providers for Reference Measurement Services and to draft a revised document for the procedure WG2-P-02.

Prof Siekmann said that he reviewed the procedure document WG2-P-02 and confirmed that the procedure document was addressing appropriately the requirements for suitable proficiency testing provider at the international level, and had no further comment on the corresponding revised DB WG procedure.

New Actions

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

4. Progress with identifying potential JCTLM Executive Committee Organizations

Dr Beastall reported that he attended the General Assembly of the International Council for Standardization in Hematology (ICSH) on 26 October 2016 where he was invited to give a presentation introducing the JCTLM and traceability in laboratory medicine and gave examples of on-going standardization projects/ network for HbA1c, HBA2, and proteins containing metals. He added that his presentation had been well received by the participants who were representatives from EQAS providers, and Diagnostic industry, and noted a large attendance from Asia.

In the discussion that followed, the Committee concluded that further dialogue should be engaged in with ICSH and recommended to look at the possibility to organize a satellite meeting in conjunction of an international IVD/ Manufacturers congress on traceability and hematology to cover topics such as blood cell counting, white/red blood cell, hemostasis.

Dr Myers brought the Committee's attention to the document [EXEC/16-25] which identified International Societies and their relevant technical sub-committees that were involved in hematology, immunology, or infectious diseases, and could be approach by

JCTLM. He commented that he would continue updating this contact list for identifying potential JCTLM EC Organizations.

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

5. JCTLM membership applications [JCTLM-EXEC/16-10, 16-10.1]

Dr Wielgosz reported that the Secretariat produced a leaflet for introducing JCTLM to potential JCTLM Member Organizations which was published on the BIPM [JCTLM website](#) and had been distributed by email to BIPM's JCTLM contact list. As a result, eight organizations applied for JCTLM Membership with seven seeking JCTLM Stakeholder membership, and one JCTLM Regional and National membership. The Committee reviewed these applications [JCTLM EXEC/16-10, 10.1] and accepted the application of the Korean Society of Clinical Chemistry (KSCC) from South Korea for JCTLM Regional and National Membership and the seven remaining applications for JCTLM Stakeholder Membership, notably:

- Quik S.A.S. "Quality is the Key" (QUIK) from Colombia which was a private laboratory organization;
- ECAT Foundation from The Netherlands which was a EQAS provider;
- Korean Association of External Quality Assessment Service (KEQAS) from South Korea which was a EQAS provider,
- Wales External Quality Assessment Scheme (WEQAS) from United Kingdom which was a EQAS provider;
- Laboratory of Toxicology, Faculty of Pharmaceutical Sciences, Ghent University (Ref4U), Belgium which was a Reference Laboratory having service listed by JCTLM;
- Guangdong Provincial Hospital of Chinese Medicine (GPHCM) from China which was a Reference Laboratory having service listed by JCTLM;
- Beijing Aerospace General Hospital from China which was a Reference Laboratory having service listed by JCTLM;

Dr Beastall pointed out that there were no applications from the IVD companies although the leaflet had been circulated among the IFCC Corporate Members. He added that the text of the leaflet could be revised in a way so that it would "speak" to the IVD audience, and suggested to draft a second version of the text of the leaflet in consultation with IVD /Manufacturers. The Committee agreed with the proposal.

Action (A/16-14): Secretariat to contact the organizations having sent an application for JCTLM Membership to confirm acceptance by the Executive Committee of their request to become a JCTLM Stakeholder or National and Regional Member.

Action (A/16-15): Dr Beastall to draft a second version of the text of the JCTLM Membership that would be more targeted to the IVD /Manufacturers.

6. JCTLM Governance

6.1 Representation on the Executive

Dr Wielgosz informed the Committee that the Secretariat had contacted the sponsoring organizations, the IFCC, the ILAC and the BIPM for nominations of JCTLM Chairman and

Secretariat. The nomination of Dr Myers from the IFCC was received for JCTLM President, and no nominations for the Secretariat were received

The JCTLM Executive approved the re-appointment for the next two years of Dr Myers as Chairperson, and the BIPM's continued role as Secretariat for the JCTLM.

6.2 JCTLM WG Chairs

Prof. Siekmann informed the Committee of his resignation as vice-Chair of the Database WG, and as member of the JCTLM Review Team for Drugs, Metabolites and Substrates and Non Peptide Hormones.

The Committee thanked Prof. Siekmann for his important contribution in the establishment of the JCTLM and great work in support of the JCTLM from the start, and thanked him for his continued participation as a member in the JCTLM Review Teams.

The procedure for the selection and appointment of the Working Group Chairs for renewable two year periods was followed. The Executive re-appointed Dr Phinney as vice-Chair of the Database WG as Chair of the Vitamins, Non Electrolytes Metals, and Electrolytes and blood gases Review Teams. It was further agreed that the re-election of Dr Schimmel as vice-Chair of Database WG would be dealt with by email after he had confirmed he was still willing to be candidate for WG chairmanship as well as Leader of Non-peptide Hormones review team.

The Executive re-appointed Dr Beastall as Chair the TEP WG.

The Committee reviewed the JCTLM review team memberships and Database WG recommendations, and agreed on the following points.

The Committee requested that Dr Liu should be contacted to verify if he would be willing to be candidate to take over as Vice-Chair of the Database WG (covering the Drugs, Metabolites and Substrates, and Non-Peptide Hormones Review Teams) in replacement of Prof Siekmann.

Dr Phinney reported that Dr B. Toussaint (Leader of the Electrolytes and blood gases review team) informed the JCTLM before the Database WG meeting that she would step down as leader of the review team after completion of this year review cycle.

The Committee thanked her for her active contribution as leader of the team, and concurred with the Database WG recommendation to contact S. Long from NIST who was a member of the team, and invite him to take the lead of the team and to recruit additional members for the team.

The Committee approved the Database WG recommendation to appoint Dr. Enea Pagliano (NRC Canada) and Dr. Rainer Stosch (PTB) as member of the Non Electrolyte Metals review teams noting that both candidates had expertise in measurands of emerging Non Electrolyte Metals concerns: anions and small molecules containing metal elements.

Dr Wielgosz reminded the Committee that Dr Schimmel had acted as the interim leader for the Proteins review team for the past two years with the view that a new leader would be appointed in 2017. The Committee concurred with the Database WG recommendation to contact Dr Quaglia (LGC), who was a member of the Protein team, and invite her to take the lead the review team for Proteins.

Dr Wielgosz informed the Committee that he was stepping down as leader of the review team for Quality System development. The Committee concurred with the Database WG recommendation to accept Dr Maniguet as new leader of the Quality System Team and to contact the leaders of the review teams and ask them to nominate a member of their team who could contribute in the review of the JCTLM Quality System with the view to initiate updates and reflect on technical aspects they experienced in reviewing nominations.

Action (A/16-16): Secretariat to contact Dr Liu to verify if he would be willing to be Vice-Chair of the Database WG (covering the Drugs, Metabolites and Substrates, and Non-Peptide Hormones Review Teams).

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

Action (A/16-18): Secretariat to contact Dr Quaglia (LGC) to verify if she would be willing to take the lead of the Proteins review team.

Action (A/16-19): Secretariat to confirm Dr. Enea Pagliano (NRC Canada) and Dr. Rainer Stosch (PTB) as member of the Non Electrolyte Metals review teams

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

6.3 Funding of the JCTLM Secretariat

As reported at the previous meeting the running cost for 2017 was estimated as the same as for 2016, corrected for inflation. It was agreed that BIPM and IFCC would again share the JCTLM Secretariat costs on a 50:50 basis for 2017.

6.4 JCTLM Database

Dr Maniguet presented the status of the database as of December 2016 as well as the updates of the data content and web system that have been carried out in 2016. The report of the updates carried out the first half of 2016 can be found in the report of the 16th Executive Committee meeting.

In the second half of 2016, the Japanese multi enzymes certified reference material, JC ERM 20327 Lot 003, was delisted from the JCTLM Database and placed in the PDF file for no longer available certified reference materials. The producer had already indicated that a new lot had been released and the nomination for the new batch would be submitted for next year's review cycle.

The current status of the database as of December 2016 was as follows:

- 293 certified reference materials (CRMs) amongst which 33 are in List II (i.e. Reference Materials value assigned using an internationally agreed protocol), and 3 are in List III (i.e. Reference Materials for nominal properties),
- 180 reference measurement methods covering 80 analytes, and
- 146 reference measurement services covering 39 analytes. These services were delivered by 15 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 database web system was updated to add an auto-completion function in the analyte key word search form which provided a better guidance on the analyte present in the JCTLM Database.

7. Revision of JCTLM quality manuals

7.1 Executive Procedures [JCTLM-EXEC/16-11]

7.2 Database WG Procedures [JCTLM-EXEC/16-12]

7.2.1 Nomination process for replacement materials

This point was dealt with under agenda point 2.1.

7.3 Secretariat Procedures [JCTLM-EXEC/16-13]

Dr Maniguet reported that the drafting for the revision of the documents for the Executive, Database WG and Secretariat procedures was completed and the three sets of procedures included in the documents JCTLM-EXEC/16-11, 12 and 13 had been circulated for comment in advance of the EC meeting. It was agreed that with no further comments received by 15 January 2017 these documents would be considered as approved and published on the BIPM JCTLM website.

Dr Maniguet pointed out that the revision of the two previous procedures WG1P-04A and P-04B had been left on hold as the question was raised at the last Executive meeting on whether or not those processes should remain as part of the JCTLM activity. These two documents described the processes for comparing certified values of the same measurand in multiple reference materials, and for demonstrating the extent-of-equivalence of multiple reference measurement methods for the same nominal measurand.

It was clear from the discussions held during the Database WG meeting this week that these two procedures would need to be kept and revised to take into account issues and recommendation from the WG. It was agreed that the document P-04A would be revised as a guidance document on how CRM producers would process for addressing the JCTLM requirement for comparability with a CRM already listed for the same measurand as an acceptance criteria for a higher order CRM.

Dr Wielgosz reported that the Database WG Review Teams raised the issue of the level of validation required as well as the evidence requested by JCTLM when a method for a new measurand was submitted when there was no previous method published in the Database to allow for comparison. He added that the DB WG recommended that the JCTLM Quality Manual procedure should be updated to clarify the process to be followed by the owner of a method submitting a nomination for inclusion in the JCTLM Database in order to prevent the listing of two methods for the same measurand that would demonstrate different measurement results. The DB WG's suggested the new three-step process as follows:

1. The method owner would seek for possibilities to get comparability and initiate a comparison study with a published reference measurement method. If there was no other method yet published, comparability would be sought against an existing routine field method used to prove that the method can be used without impacting the routine measurement results.
2. If there was no possibility to carry out a bilateral comparison with a previously published method, the method owner would provide a statement that he would have sought for all possibilities to get comparability, and the reference

measurement method would be listed and subject to further compatibility assessment when another published reference method becomes available.

3. If the comparison study carried out between the two methods demonstrated difference in the measurement results, the listed method would be temporary removed from the JCTLM Database until the discrepancy of the results would be fully resolved.

The Committee approved the Database WG recommendation to update the two previous processes addressing the comparability of two or more CRMs or methods for a same measurand, and requested that relevant procedures should be modified to include the new processes described above.

Action (A/16-21): Secretariat to revise the previous procedure documents WG1-P-04A, and P-04B as part of the Database WG Quality Manual.

Action (A/16-22): Secretariat to publish the revised and approved JCTLM Executive, Database WG and Secretariat procedure on the BIPM website.

8. Report from the JCTLM WG on Traceability Education and Promotion [JCTLM-EXEC/16-14, 15]

Dr Beastall presented the document JCTLM EXEC/16-14 which included the first annual report of the TEP WG for the JCTLM Executive Committee, and a progress report for each Work Stream. He added that the TEP WG had held three meetings since the working group was established in December 2015. He highlighted the expected outputs of each Work stream as follows:

Work Stream 1: Definitions

The output of this work would be made accessible on the TEP WG website via a glossary of the common terms with a link to the formal definitions. The target date for completion was February 2017.

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

The output of this work would be a series of 10 mini-presentations each addressing a specific topic related to a specific scientific concept that was related to traceability in laboratory medicine and which would be available as webinars from the WG-TEP website. The target date for completion was June 2017

Work Stream 3: Why traceability matters to manufacturers?

This project required:

- Collating and presenting a list of relevant scientific publications
- Making presentations on Traceability in Laboratory Medicine in symposia and posters at relevant scientific meetings
- Raising awareness of JCTLM stakeholder membership among IVD manufacturers

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

The output of this work would be based on a story telling the similarity between laboratory medicine and practical case (cooking) with the view to produce a cartoon/video to illustrate the importance of traceability to patients and the public.

Work Stream 5: Global significance of traceability,

The output of this work would be a review article, which would then be translated or adapted into several languages. The target date for completion of the paper was December 2016.

Work Stream 6: Tools to promote traceability.

This work required:

- Producing webinars as tools to introduce traceability into curricula for training in laboratory medicine

- Producing advanced webinar for trainers in laboratory medicine
- Producing a directory of EQA organizations
- Liaison with EQA organizations to help with training in traceability
- Translating educational material into different languages
- Producing generic abstract and poster for poster presentations
- Producing and promoting generic symposium structure
- Promoting new logo and strap line

Dr Beastall presented the third draft programme for the 2017 Members and Stakeholders meeting [JCTLM EXEC/16-15], and added next step would be to confirm the speakers, and start to publicize the meeting programme early 2017.

8.1 Reference to standards/ requirements for publication

Dr Jones pointed out to the Committee that there was a need to harmonize the literature describing procedures developed by manufacturers. He suggested guidance should be provided to authors and journal editors on how to describe assay performance in journal articles (especially when referring to traceability). The Committee supported his view and invited Dr Jones to draft a guidance document which could be used by the authors and journal editors with the aim to publish it on the traceability website.

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

9. 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 13 for materials and methods and cycle 11 for services.

There were eleven nominations for reference materials for three groups of analytes, seven nominations for reference measurement methods for five groups of analytes which had been submitted for CRM/RM review cycle 13, as well as 39 nominations for services for five groups of analytes which had been submitted for RMS review cycle 11.

9.1 Approval of Cycle 13 RM and RMP and Cycle 11 RMS nominations and outstanding issues from previous Cycles

The review team' recommendations for approval and publication in the JCTLM Database are summarized in the following sub-sections for each group of analytes.

9.1.1 Drugs [JCTLM-EXEC/16-16]

There was one nomination for a reference measurement method for Drugs. This had been reviewed, and was being recommended for publication in the JCTLM database providing that the publication would be provided with no major modifications to the accepted manuscript which had been used for the technical assessment conducted by the review team.

The review team commented that the primary calibrator which was used for developing the new method for the gentamicin quantification would be useful for a laboratory intending to implement the procedure for establishing a measurement service delivery. However a full characterization of this material would be needed prior to its nomination for inclusion in the JCTLM Database.

The Committee approved the DB WG's recommendation for amending the review report to inform the organization that their method developed for a new measurand would be subject to further comparability study when a new method would become available for gentamicin measurement in blood serum, with the possibility of requests for corrective action if different results were obtained for the two methods applied.

There were two nominations for reference measurement services for digoxin and digitoxin in blood serum and plasma that had been reviewed, and were being recommended for listing in the JCTLM Database.

Action (A/16-24): Secretariat to amend the review report for the reference measurement method for the determination of gentamicin to inform the method developer that the publication would be deferred until the major non-compliance with regard to the lack of final publication would be resolved and that the method when published could be subject to further comparability assessment when a new method becomes available, with the possibility of requests for corrective action if different results were obtained for the two methods applied.

9.1.2 Electrolytes [JCTLM-EXEC/16-17]

There was one nomination for a reference measurement method for Electrolytes which had been reviewed, and was not accepted for publication in the JCTLM database.

There were two nominations for reference measurement services for potassium and sodium in urine that had been reviewed. These were being recommended for listing in the JCTLM Database only after the laboratory would have provided validation data from EQAS results for review by the review team, given that these services were using a reference measurement method developed for measurement of potassium and sodium in serum material only.

The Committee approved the DB WG's recommendations for clarifying the acceptance criteria when a reference laboratory was submitting a nomination for a reference measurement service based on a listed method which was applied to new material or matrices. It further requested that the laboratory having submitted these two services should provide the validation report for assessment by the review team and publication in the JCTLM Database, taking into account the JCTLM process already in place for listing services that used modified listed procedures.

The Committee requested that the relevant DB WG procedure documents should be modified to extend the JCTLM acceptance criteria to require validation data and report for assessment by the review team and publication in the JCTLM Database when a laboratory was implementing a listed reference measurement procedure which had been extended it to new applicable matrices.

Action (A/16-25): Secretariat to update the relevant JCTLM procedures to clarify the acceptance criteria for listing a reference measurement service of a provider using a listed reference measurement method applied to new materials or matrices, with the provision that the basic principle of measurement was maintained and that the validation report would have been made available to and approved by the review team, and published in the database.

9.1.3 Enzymes [JCTLM-EXEC/16-18]

There were twenty-three nominations for reference measurement services for Enzymes that have been submitted by four laboratories. All had been reviewed and of these seven were being recommended for publication in the JCTLM database.

The remaining sixteen reference measurement service nominations were not recommended for inclusion in the JCTLM Database and the review team recommended that the linearity statement should be revised where the measurement limits did not match those defined using the IFCC reference measurement procedures. The Committee concurred with the DB WG's decision to address the request from the Enzymes review team that JCTLM should inform the accreditation bodies that the theoretical lower and upper limits of the enzyme measurement range were an essential element of the respective IFCC procedure.

It further agreed with the DB WG' recommendation for providing training for the laboratory service provider to overcome these non-compliances when a laboratory implements IFCC reference measurement procedures for Enzymes, and suggested that a Workshop should be scheduled at the next JCTLM Members' and Stakeholders' Meeting venue in December 2017.

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

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

9.1.4 Metabolites and substrates [JCTLM-EXEC/16-19]

There was one nomination for a pure reference material for Metabolites and Substrates which had been reviewed. The material was being recommended for approval and publication in the JCTLM Database with the provision that the producer send appropriate information to the review team in response to the major non-compliance observed concerning the assessment of the stability of the material under transport conditions.

There were two nominations for reference measurement methods for Metabolites and Substrates. Both of these had been reviewed, and were recommended for publication in the JCTLM Database. There was a first nomination for a reference measurement method for Glucose in blood serum for which the review team would update the review report to clarify the status of two observed non-compliances.

There was a second nomination for a reference measurement method for free Glycerol in blood serum for which a major non-compliance related to the lack of information on comparisons with other measurement procedures, or inter-laboratory comparison results was observed. Due to the importance of free glycerol measurement the review team recommended the method be listed despite this non-compliance, and also encouraged the owner to carry out a bilateral comparison with the laboratory having the free glycerol method listed by JCTLM. This review team's recommendation had been discussed at the DB WG, and was fully supported considering that the published JCTLM acceptance criteria did not include the requirement when an organization submits a nomination for listing higher order method, to provide evidence for comparability of the measurement results with a previously listed method for the same measurand. This issue was discussed earlier (under

agenda point 7) and would be addressed after revision of the JCTLM DB WG Quality Manual Procedures.

There were eight nominations for reference measurement services for Metabolites and Substrates. All had been reviewed, and of these two were being recommended for approval and publication in the JCTLM database. For the remaining six nominations, the services used a method listed by JCTLM which was developed for measurements in serum only. The review team recommended the services for JCTLM listing with the provision that the laboratory would provide a validation report for these measurement procedures in materials/matrices other than serum for review by the review team.

The Committee requested that the laboratory having submitted these services should provide the validation report for assessment by the review team and publication in the JCTLM Database, considering the JCTLM process already in place for listing services that were based on modified listed procedures.

9.1.5 Non-peptide hormones [JCTLM-EXEC/16-23]

There were eight nominations for reference materials, two nominations for reference measurement methods and five nominations for reference measurement services, and all were still under review at the time of the meeting. Preliminary review reports and recommendations for listing had been communicated by the review team leader, and were being circulated for comments among the members of review team.

Drs Phinney and Myers agreed to review the final version of the report and review team's recommendations for non-peptide hormones. As of 23 December 2016, these final review documents have been circulated to the two members of the EC for their review by mid-January 2017.

9.1.1 Proteins [JCTLM-EXEC/16-22]

There were two nominations for HbA1c reference materials, and all were still under review at the time of the meeting. Preliminary review reports and recommendation for listing were being circulated for comments among the members of review team and final consensus review team's recommendations were expected by the end of December.

Drs Phinney and Myers agreed to review the final version of the report and review team's recommendations for both HbA1c materials. As of 23 December 2016, these final review documents have been circulated to the two members of the EC for their review by mid-January 2017.

9.1.2 Vitamins [JCTLM-EXEC/16-20]

There was one nomination for a Vitamin reference measurement method which had been reviewed and was recommended for publication in the JCTLM Database.

The Committee approved the DB WG's recommendation to inform the organization that their method would be subject to further comparability study when another method would become available for (24R),25-Dihydroxyvitamin D3 in human serum, and the possibility of requested corrective action if different results were obtained for the two methods applied.

Action (A/16-28): Secretariat to amend the review report for the reference measurement method for the determination of (24R),25-Dihydroxyvitamin D3 in human serum to inform the method developer that their method when published could be subject to further

comparability assessment when a new method becomes available, and the possibility of requested corrective action if the measurement results obtained between the two methods were different.

The Executive approved the review team's recommendations for publishing materials, method and services in the JCTLM Database.

Action (A/16-29): Drs Phinney and Myers to review the final version of the report and review team's recommendations for Proteins and Non-Peptide Hormones nomination by mid-January 2017

Action (A/16-30): Secretariat to publish the nominations recommended for publication in the JCTLM Database by end of January 2017, and send out the report on the outcome of the review to the nominating organizations.

9.2 Approval of outstanding nominations from previous cycle

9.2.1 Methods listed for Sodium measurement

Dr Maniguet reminded the Committee that during the review of the nomination for a new ICP MS method for the measurement of Sodium in blood serum, the JCTLM requested the owner of this method to clarify the terminology of the quantity being measured, and to specify whether the method was measuring sodium in mmol/L where the volume is the water in the serum or plasma sample, or the volume of serum or plasma including the proteins and lipids. As a follow up of the review, the owners of other JCTLM listed methods were contacted and asked to check if the description of their method or service in the JCTLM database gave clear instructions to the users on the form of sodium targeted by the method, and the influence of the sample content in proteins and lipids on the measurement result, and to propose a note to be inserted in the JCTLM Database.

Dr Jones commented that in view of the responses provided by the organizations for each of the methods listed, it would be more appropriate to add a common comment to all five measurement methods listed. He proposed the following statement "The method measures the amount of sodium per volume of serum (or plasma). This provides results suitable for traceability of indirect ion-sensitive electrode measurements". The Committee agreed with his proposal.

Action (A/16-31): Secretariat to add the generic statement to the Sodium methods listed in the JCTLM Database to give clear instructions to the users on the form of sodium targeted by the methods, and the influence of the sample content in proteins and lipids on the methods' measurement result.

9.2.2 Metabolites and Substrates Methods nominations from review cycle 12 (2015) [JCTLM-EXEC/16-19.1]

There were two nominations for reference measurement methods for which the developers had provided complementary information in response to the non-compliances reported by the review team during the previous review cycle 12. Consequently, the review team carried out a second review for both nominations, and recommended for publication and approval in the JCTLM Database the total triglycerides ID GC MS measurement method applied in blood serum. The remaining nomination for the quantification of Glucose in human serum using a GC MS procedure had not been recommended for publication, as the observed major non-compliance regarding the systematic assessment of factors influencing the results in the validation of the reference measurement procedure had not been resolved.

The Executive approved the revised review team's recommendation for inclusion of the total triglycerides ID GC MS in the JCTLM Database.

Action (A/16-32): Secretariat to publish the outstanding ID GC MS reference measurement method for the quantification of total triglycerides in human serum in the JCTLM Database.

9.3 Update on IFCC EQAS results

Prof Siekmann drew the Committee's attention to the existing customs' problems and delays when distributing the RELA samples in China, and said that CNAS (China) had offered to assist the coordinating organization in distributing the samples in this region. The Committee welcomed CNAS' proposal noting that about 50% of the RELA participants were from China. It further requested that Prof Siekmann should follow up closely with CNAS the establishment of this new route/network for distributing samples in China.

Prof Siekmann said that he would initiate in January 2017 the re-review of the JCTLM database entries which was based on once every 3 year EQAS participation requirements, and this work would be carried out in collaboration with Dr A. Kessler at the RfB Institute (Bonn) who would be the new liaison person for RELA activity and RELA advisor.

As discussed at the previous EC meeting JCTLM could not endorse a particular PT provider. However, it was agreed that a clearer mention should be made that the IFCC RELA EQAS was a proficiency testing service provider for reference laboratories in support of the requirement for being or remaining listed in the JCTLM Database. The Committee further requested that the text of the BIPM webpage for RELA should be modified to clearly state that since 2003 IFCC has provided EQAS that meet the requirements described in sections 6.4.13 and 7 of the procedure document WG2-P-02 that were addressing the requirements for suitable proficiency testing provider at the international level.

Action (A/16-33): Prof Siekmann/Secretariat to carry out the re-review of the reference laboratories having reference measurement services listed in the JCTLM Database with respect to status of their EQAS participation and accreditation for compliance with ISO 15195 + ISO/IEC 17025 as Calibration laboratories.

9.4 Progress/ plans for Cycle 14 for RMs and RMPs and Cycle 12 for RMSs

It was agreed that the new call for nominations for Reference Materials, Methods, and Services would be launched on the 1st of February 2017 with a deadline for submissions in May 2017.

10. Update on Gap Analysis Studies

Dr Jones presented the document JCTLM-EXEC/16-26, which included an update of the gap analysis of the missing reference materials, methods and services, with regards to the frequently requested measurements made in his clinical laboratory, as well as the widely used measurement services provided by the Australian EQAS for routine laboratory, and taking into account the items listed in the database for the corresponding health markers as of June 2016.

He pointed out to the Committee that linking up those data was important and remained difficult considering the nomenclature used by different sources in regard to the coding, test names or measurand definitions. He added that the gap analysis had been made manually and

involved a large volume of data regarding clinical health markers (450 laboratory tests in 2016) as well as the current database status (220 measurands in 2016) entries. He recalled the usefulness to publicize the outcome of the exercise either in a peer-reviewed paper, or a section in the newsletter, or possibly some other medium.

He further highlighted a number of health markers that were the most routinely measured and for which missing references could be identified from the gap analysis, notably in the field of haematology, serology, microbiology, blood gases, common chemistry or common immunoassays.

In the discussion that followed, the Committee concluded that the prioritization of key measurands obtained from this gap analysis would need to be combined with the data provided by the review teams when presenting their horizon scan on the standardization activity covering their team's scope of activity.

As discussed earlier the Committee recognized the need to inform the producers of CRMs, the developers of measurement procedures, and the providers of reference measurement services of the outcome of an annual update of the gap analysis, and requested that the selection of complete and not complete reference measurement systems would need to be published as an article in the annual issue of the JCTLM Database.

Action (A/16-34): Dr Jones to draft an article for the next issue of the JCTLM Newsletter describing complete and not complete reference measurement systems based on his gap analysis.

10.1.1 Review teams' environment scans

As a follow up of a decision taken at the 15th Executive Committee meeting, the twelve review teams' leaders were contacted prior to the Database WG meeting and were requested to present an horizon scan in regard to the standardization activity covering their team's scope of activity. Of these seven teams provided information in regard to the following four key points of discussion: the current status of entries in the JCTLM Database with respect to the existing standardized measurands, and the missing materials and methods and calibration services providers for standardized measurands; the key measurands for which Reference Measurement System Components existed that were not yet covered in the database; the new standardization projects that were underway that could lead to JCTLM Database entries in the future; and a contact list for reference material producers, developers of measurement procedures, providers of reference measurement services to be targeted/contacted by JCTLM with regard to missing and new nominations.

The document JCTLM EXEC/16-24 included the review teams' presentations and was discussed at the Database WG meeting during the week. The missing reference measurement system components as well as the new measurands not yet covered by JCTLM were identified by each the review teams as follows.

The Drugs team's highlighted on-going as well as future developments in the field of immunosuppressive drugs that would be of interest for the JCTLM.

The Electrolytes team's environment scan highlighted three missing measurands that were iMg, iCa and phosphate, as well as a prospective CRM producer.

The Metabolites and Substrates team gave a gap analysis in regard to the items listed in the JCTLM Database and highlighted the lack of a primary calibrator for (total) bilirubin after disruption of a previous lot of a listed material. The Database WG had recommended that the team should finalize its recommendation for any missing component for standardized reference measurement systems listed in the Database.

The Blood Cell Counting and Typing team highlighted components of standardized reference measurement systems that were missing in the database for the following measurands: red blood cell, white blood cell, and thrombocyte; missing reference materials for CD4+ cell counting and PNH (Paroxysmal nocturnal hemoglobinuria); and measurands in the List A and List B of the *In Vitro* Medical Devices Directive 98/79/EC (IVDD). The team pointed out the pressing need for standardization of blood cell subtype counting and expression analysis for cancer immunotherapy/oncology field, as well as antibody qualification issues.

The Nucleic Acid team highlighted needs in sequencing, stratified medicine (and CDx), IVDs for infectious diseases and AMR molecular diagnostics, and new standardization projects among which the following were identified

- GeT-RM which was a genetic testing RMs initiative,
- Quality Control for Molecular Diagnostics (QCMD) which was providing a wide range quality assessment service primarily focused on molecular infectious diseases to over 2000 participants in over 100 countries,
- IFCC C-MD - Molecular Diagnostics Committee
- Projects involving NMIs (EMPIR-BioSITrace, NeuroMET, AntiMicroResist, INFECTMET), Standardisation of gene amplification tests (SoGAT), Joint Initiative Metrology in Biology (JIMB).

The Non-Electrolyte Metals (NEM) team highlighted the development of new blood RMs for clinical diagnostic measurement of metals of implantable devices: Co, Cr, Mn, Mo, Ni, as well as the need for development of new RM of total iron in blood.

In addition, they reported on the development for new measurands for biomarkers of health and exposomes – anions and small molecules containing metal elements. These were non-traditional NEM measurands. A lack of reference measurement system components was identified for the following areas:

- a. Anions: currently RMs for nitrate and perchlorate were being listed by JCTLM, and there was a need for RM and RMP for nitrite, thiocyanate, and azide.
- b. Thyroid health – T3/T4, Tg, and TSH. There was an effort in the NEM community in developing elemental measurement techniques for iodine biomarkers. These efforts overlap the activities of the non-peptide hormones review team.
- c. Iron metabolism – hemoglobin, transferrin, and ferritin. Similarly, efforts were under way to use elemental measurement techniques for these biomarkers, and these efforts overlap the activities in the protein review team.

The NEM team commented as well on the lack of availability of reference measurement services from calibration laboratories because metal toxicity measurements were not traditional or routine clinical measurands. Such measurements were more often associated with epidemiology studies relating to specific environmental exposures.

The Enzymes team pointed out the missing materials for ALT, LDH, and CK, but also explained that the lack of CRMs was not a major issue for the implementation of enzyme measurement standardization, as manufacturers may better approach it by using a panel of native clinical samples values assigned by an accredited reference laboratory performing RMP and then calibrate their commercial systems. The Committee noted that JRC had released new batches for these materials and requested that it should be contacted at the next annual call for nominations.

The Enzymes team reported also that IFCC Committee on Reference Systems for Enzymes (C-RSE) was working on developing a reference measurement procedure for Lipase and a CRM for the calibration of field assays for pancreatic amylase and total amylase.

The Executive welcomed the contributions from all these review teams, and requested that the remaining teams should be contacted to provide their horizon scan for review by the DB WG and Executive members and further publication on their team's webpage.

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

Action (A/16-36): Secretariat to publish the environment scans on the respective BIPM JCTLM Review team webpage.

11. Liaison with ISO TC 212

Dr Wielgosz reported that two meetings of the ISO TC 212 WG2 have been held during the year in London (UK) on 20-21 June 2016, and in Kobe (JP) in September 2016, and the status of the drafting of the documents developed or revised by ISO-TC212/WG2 were progressing as follows: the draft of the revised text of the ISO 17511 was being circulated for comments until the end of the year, the paper on the guidance document on the estimation of uncertainty would be finalized by the end of the year, and there was no actions foreseen during the year for the revision of the text of the ISO 15195 which was pending the finalization of the ISO/IEC 17025 document.

12. Liaison with the EC

12.1 Update on revision to the IVD Directive

There was no information available on the status of the revised text of the IVD Directive.

13. Liaison with the WHO

Dr Wielgosz reported that he attended the annual meeting of the WHO Expert Committee on Biological Standardization (ECBS) in Geneva in October 2016 where there was discussion on newly developed documentation on the production of secondary biological standards for IVDs. He also added that he could foresee further collaboration with WHO representatives resulting from the BIPM-NIBSC meeting in January 2017, noting that NIBSC representatives were also acting as experts at the WHO ECBS meeting.

14. Future meeting of the JCTLM

14.1 JCTLM Members and Stakeholders meeting 2017

The Committee confirmed that the next JCTLM Members' and Stakeholders' meeting would be held at the BIPM on 4 and 5 December 2017. This would be followed by a Database WG meeting, a TEP-WG meeting, and a Workshop on the implementation of IFCC enzyme reference measurement procedures by service providers on 6 December as well as a JCTLM Executive meeting on 7 and 8 December 2017.

14.2 JCTLM events in 2017 and 2018

Dr Beastall recalled that a JCTLM Symposium on Traceability would be held at the EuroMedLab meeting in Athens on Wednesday 14 June 2017. The Committee further decided to hold its 18th Executive Committee meeting on the Sunday, June 11th 2017 at this venue. Dr Beastall added that a draft proposal was being made for a JCTLM Symposium for the AACC 2017 congress in San Diego in August 2017, for the COLABIOCLI congress in Uruguay in September 2017, and for the IFCC WorldLab in Durban in October 2017. He said that discussions with EQALM regarding a joint session at EQALM 2018 were underway.

15. Close

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

Annex 1: Summary List of Actions

Outstanding actions from the 15th and 16th Executive Meetings:

Action (A/15-32) : Secretariat to draft a template (pro forma) for the written activity reports to be submitted on a biennial basis by the JCTLM member organizations

Action (A/15-33) : Dr Myers to draft responses to the questions that CNAS (China) submitted in its activity report for comment by the EC

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

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

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

Actions from the 17th Executive Meeting:

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

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

Action (A/16-14): Secretariat to contact the organizations having sent an application for JCTLM Membership to confirm acceptance by the Executive Committee of their request to become a JCTLM Stakeholder or National and Regional Member.

Action (A/16-15): Dr Beastall to draft a second version of the text of the JCTLM Membership that would be more targeted to the IVD /Manufacturers.

Action (A/16-16): Secretariat to contact Dr Liu to verify if he would be willing to be Vice-Chair of the Database WG (covering the Drugs, Metabolites and Substrates, and Non-Peptide Hormones Review Teams).

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

Action (A/16-18): Secretariat to contact Dr Quaglia (LGC) to verify if she would be willing to take the lead of the Proteins review team.

Action (A/16-19): Secretariat to confirm Dr. Enea Pagliano (NRC Canada) and Dr. Rainer Stosch (PTB) as member of the Non Electrolyte Metals review teams

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

Action (A/16-21): Secretariat to revise the previous procedure documents WG1-P-04A, and P-04B as part of the Database WG Quality Manual.

Action (A/16-22): Secretariat to publish the revised and approved JCTLM Executive, Database WG and Secretariat procedure on the BIPM website.

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

Action (A/16-24): Secretariat to amend the review report for the reference measurement method for the determination of gentamicin to inform the method developer that the publication would be deferred until the major non-compliance with regard to the lack of final publication would be resolved and that the method when published could be subject to further comparability assessment when a new method becomes available, with the possibility of requests for corrective action if different results were obtained for the two methods applied.

Action (A/16-25): Secretariat to update the relevant JCTLM procedures to clarify the acceptance criteria for listing a reference measurement service of a provider using a listed reference measurement method applied to new materials or matrices, with the provision that the basic principle of measurement was maintained and that the validation report would have been made available to and approved by the review team, and published in the database.

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

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

Action (A/16-28): Secretariat to amend the review report for the reference measurement method for the determination of (24R),25-Dihydroxyvitamin D₃ in human serum to inform the method developer that their method when published could be subject to further comparability assessment when a new method becomes available, and the possibility of requested corrective action if the measurement results obtained between the two methods were different.

Action (A/16-29): Drs Phinney and Myers to review the final version of the report and review team's recommendations for Proteins and Non-Peptide Hormones nomination by mid-January 2017

Action (A/16-30): Secretariat to publish the nominations recommended for publication in the JCTLM Database by end of January 2017, and send out the report on the outcome of the review to the nominating organizations.

Action (A/16-31): Secretariat to add the generic statement to the Sodium methods listed in the JCTLM Database to give clear instructions to the users on the form of sodium targeted by the methods, and the influence of the sample content in proteins and lipids on the methods' measurement result.

Action (A/16-32): Secretariat to publish the outstanding ID GC MS reference measurement method for the quantification of total triglycerides in human serum in the JCTLM Database.

Action (A/16-33): Prof Siekmann/Secretariat to carry out the re-review of the reference laboratories having reference measurement services listed in the JCTLM Database with respect to status of their EQAS participation and accreditation for compliance with ISO 15195 + ISO/IEC 17025 as Calibration laboratories.

Action (A/16-34): Dr Jones to draft an article for the next issue of the JCTLM Newsletter describing complete and not complete reference measurement systems based on his gap analysis.

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

Action (A/16-36): Secretariat to publish the environment scans on the respective BIPM JCTLM Review team webpage.