Report of the 13th meeting of the JCTLM Executive Committee
4-5 December 2014, BIPM, Sèvres, France

List of participants:
Prof. M. Müller (JCTLM Chairman, IFCC)
Dr G. Beastall (IFCC)
Mrs R. Robertson (ILAC)
Dr G. Jones (ILAC)
Dr R. I. Wielgosz (JCTLM Executive Secretary, BIPM)
Dr R. Kaarls (CIPM)
Dr H. Schimmel (JCTLM WG 1 Chair)
Prof. L. Thienpont (JCTLM WG 2 Chair)
Prof. L. Siekmann (IFCC, JCTLM WG 2 Chair)
Dr S. Maniguet (JCTLM Secretariat, BIPM)
Dr G. Myers (IFCC)

Apologies received:
Dr K. Phinney (JCTLM WG1 Chair)
Dr. M. Milton (BIPM)
Dr. W.E. May (CIPM)

1. Approval of the agenda [JCTLM-EXEC/14-01]

The agenda was approved with no changes.

2. Report of 12th JCTLM Executive Committee Meeting

There were no comments on the report of the 12th Executive Committee meeting, which had been finalized in February 2014, and published on the BIPM JCTLM website.

2.1 Review of action points arising from the 12th meeting [JCTLM-EXEC/14-02, 27]

Dr Wielgosz summarized the action items that were still outstanding:

Action (A/13-01): JCTLM Secretariat to circulate the information available in the two NIST SRM certificates of analysis to the JCTLM WGs, as the basis for discussion at the next WG meeting on drafting guidance on the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values.
Dr Wielgosz reported that this action was not completed, and added that this technical issue would need to be raised amongst the technical experts of the WGs by the Chairs, in order to draft the appropriate guidance document on the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values. The Executive Committee agreed with this proposal.

Action (A/13-02): Dr Phinney to draft a proposal to define the required criteria to remove a reference measurement method from the database for discussion at the next WG meeting.
This action was not yet completed, and this issue will be dealt with under the agenda point 6.2.

Action (A/13-03): Dr Schimmel (as WG1 co-Chair) to finalize the document for the review team terms of reference, to circulate the final version among the Review teams, and to send it for approval by the Executive Committee.
Dr Schimmel reported that the latest draft of the document for the terms of reference of the JCTLM review teams (JCTLM-EXEC/12-05) had been circulated among the leaders of the review teams, and that nine of thirteen review teams had sent their agreement for the scope of activity for their review team. He added that he would be able to circulate the final document to the members of the Executive for their approval as soon as he would have received feedback from the remaining teams.

Action (A/13-04): JCTLM WG Chairs and Quality Review Team to develop a process for the review of modified methods and their validation data to enable publication and listing of the method and service related to it.
Prof. Thienpont reported that the issue of the publication of improved methods with reference to methods listed in the database was discussed at the previous WGs meeting, and it was agreed that the validation report of an improved reference measurement method based on a listed reference measurement method would be published in the JCTLM database, only if the technique/principle of measurement remained the same. The Executive Committee agreed with the proposal considering that the experts of the review team would be reviewing the validation report of the improved method against the former one, and requested that the WG procedures should be modified for implementing the criteria of acceptance at the next review cycle. The Committee pointed out that the JCTLM procedures should clearly state that a peer-reviewed publication of a modified methods was the preferred route for fulfilling JCTLM requirements. An alternative, if the former was not possible, would be through the production of a method validation report, which would need to be reviewed and accepted by the experts of the review team confirming that there was no biases observed between the measurement results obtained from the original and modified method.

Dr Wielgosz added that the database would have to be updated in order to enable the system to publish the reference of the validation report of the modified method in addition to the reference of the method which was modified and used by a provider to deliver its measurement service.

Action (A/13-05): NIST/Dr Phinney to submit a nomination for the total protein measurement method described in the Doumas' reference together with appropriate reference to the calibrator involved with the method for review by WG1 at the next review cycle.
This action was not completed, and Dr Phinney had written to JCTLM that they have been informed that there had been some discussion at the recent IFCC Scientific Division meeting about clinical measurements for total protein, and that the IFCC was considering the formation of a working group. She had further indicated that NIST would be pleased to see an international effort to address the larger question of how total protein should be determined, and asked if the IFCC would be willing to put forward a method nomination for biuret titration.
The IFCC representative indicated that the new Working Grouping on total Protein would need to be proposed for approval at the next IFCC Executive Board, and he would follow up on the issue.

Action (A/13-06): Dr Beastall to discuss the final document for the traceability statement with the IFCC corporate members before JCTLM can proceed to its distribution to the IVD industry
Drs Jones, Wielgosz and Beastall agreed to review the latest draft of the document for traceability statement (JCTLM-EXEC /13-13), before Dr Beastall circulates the final version to the IFCC corporate members for consultation, and for wider distribution to the IVD industry by February 2015. It was agreed that the traceability statement would be distributed in the second issue of the JCTLM Database Newsletter in February 2015.

Action (A/13-10): Dr Wielgosz/WGs Chairs to review the tasks for WG Chairs and Secretariat, and to revise the procedure document JCTLM EXEC-P01, and P02.
The action was outstanding and this issue on the revision of role and activity of the WGs Chairs and Secretariat will be dealt with under agenda point 6.4.

Action (A/13-13): Dr Beastall to contact the leader of the review team for Coagulation factors to verify if it would be possible to contact the ICSH for potential candidates for review team membership.
Dr Beastall said that he contacted the leader of the review team for Coagulation Factors, and had had no responses from the International Council for Standardization in Hematology (ICSH). He further proposed that JCTLM should contact the International Society on Thrombosis and Haemostasis (ISTH) which had an activity related to the Coagulation factor team's scope of activity.

Action (A/13-14): Dr Wielgosz to contact Dr Giroud to verify the current status for microbial serology review team, and to clarify if it would be appropriate to rename the review team to ensure a better visibility of the metrological traceability in the field of biological measurements.
Dr Wielgosz reported that Dr Giroud recognized that the microbial serology team has been dormant for years, and agreed on the renaming of the team as well as on the need to broaden the scope of activity of the review team. The recommendation from the WGs was to rename the team "Infectious diseases". The Executive Committee agreed with this recommendation and requested that NIBSC, as being a Designated Institute signatory of the CIPM MRA for biological measurements, should be contacted to anticipate if they would be willing to participate in the group.

Action (A/13-15): JCTLM Secretariat to update the generic presentation of the JCTLM to include the current number of measurands covered for materials, methods, and services.
This action was not completed, and the issue on the promotion of JCTLM activity will be dealt under agenda point 3.4.

Action (A/13-16): EC to comment on the final draft document JCTLM-EXEC/13-13, 14, 16, and 22 by the 15th of January 2014, for their publication on the JCTLM webpages.
Dr Wielgosz reported that the document for the comparison of ISO15194: 2002 vs. ISO 15194: 2009 (JCTLM-EXEC/13-16), and the JCTLM Frequently Asked Questions (JCTLM-EXEC/13-14) have been published on the JCTLM website. The publication of the document on traceability statement related to JCTLM (JCTLM-EXEC/13-13) was pending the consultation by the IFCC corporate members, and would be followed by the action A/14-06.

Dr Jones agreed to finalize the paper on history and activities of the JCTLM (JCTLM-EXEC/13-22) in consultation with Dr Jackson, and to submit it for publication to the Clinica Chemica Acta.

Action (A/13-22): JCTLM Secretariat to contact the three laboratory service providers having not participated sufficiently regularly in RELA scheme from 2010-2012, and to remind them that they would need to participate in the next RELA scheme by the end of 2014 if they wish that their services remain listed in the database after the 1st January 2015.

Dr Maniguet reported that three laboratory service providers (two reference laboratories and one NMI) that had not participated sufficiently regularly in the RELA scheme during 2010-2012 had been contacted in April. The two reference laboratories confirmed their participation in the RELA 2014 for the measurands for which their services would need to be compliant with the JCTLM criteria (one laboratory had confirmed after the meeting). Prof Siekmann added that he had been in contact recently with the NMI which seemed not to be aware of the JCTLM requirements with regards to the RELA participation of the laboratories providing services for each measurand listed every three year and for each group of measurands every year.

The committee requested that the NMI should be contacted to remind them of the current JCTLM criteria applied, and to verify if they wish to withdraw their services or remain listed after 1st January 2015.

Action (A/13-23): JCTLM Secretariat to contact the Enzymes review team leader to verify if any corrections would be required to harmonize the expression of the expanded uncertainty of the enzymes reference measurement services among the service providers.

Dr Maniguet presented the document JCTLM-EXEC/14-27 which included the Enzyme Review team`s proposal for the harmonization of the expression of the uncertainty for enzyme reference measurement services among the service providers listed in the database. Their recommendation was to rename the headings of the Excel template as "Calibration and measurement capability", and to change the structure of the template to allow the service provider to declare the uncertainty as a range with the minimum uncertainty value stated in the certificate for accreditation. The Executive Committee stated that the nomination template was used for all analytes, and it would not be feasible to introduce changes just for one analyte category, and alternative solutions should be sought. Prof Siekmann agreed to contact the Leader of the review team to discuss the technical issues raised by the Enzymes review team.

Action (A/13-25): Prof Thienpont to liaise with the AACC harmonization project team at their next meeting in February 2014 to clarify/define the items that would come out from their project and that were anticipated for nomination for listing in the JCTLM database.

Prof. Thienpont reported that it was difficult from the meeting in February to anticipate the items for listing in the database that would result from the harmonization project.

Dr Myers said that a call for submissions had been made for measurands of interest for harmonization, and the WG had prioritized two measurands, the human Growth Hormone (hGH) and the thyroglobulin. The two candidate measurands were proposed at the IFCC Scientific Division that requested some further study on the state of the art of the thyroglobulin measurement prior to go through harmonization. It was said that the IFCC SD was currently considering standardization for the hGH measurand, and in addition that CCQM

had proposed an inter-laboratory comparison piloted by the PTB which had developed a measurement method for hGH measurement.
The issue of the compliance with ISO 15194 and other documented standards for the outputs of the harmonization process was also raised by the members of the Executive Committee.

New Actions:
Action (A/14-01): WG1/WG2 Chairs in consultation with the technical experts of the WGs to draft a guidance document on the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values, and circulate it for review and approval at the next Executive Committee meeting.
Action (A/14-02): Dr Schimmel to circulate the final version of the document for the Terms of Reference for approval by the members of the Executive, and publication on the JCTLM website.
Action (A/14-03): WG1/WG2 Chairs and Quality Review Team to update the JCTLM procedures to include the new acceptance criteria for listing a reference measurement service of a provider using a modified listed reference measurement method, 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/14-04): Secretariat to update the database to enable the publication of the validation reports of a modified method against the listed reference method used for a measurement service delivered by a provider.
Action (A/14-05): Dr Myers/IFCC to verify the status of the new IFCC WG on clinical total protein measurements, and if IFCC would be willing to put forward a method nomination for biuret titration for total protein measurement
Action (A/14-06): Drs Jones, Wielgosz and Beastall to review the latest draft of the document for traceability statement (JCTLM-EXEC /13-13), before Dr Beastall circulates -the final version to the IFCC corporate members for consultation, and for wider distribution to the IVD industry by February 2015. It was agreed that the traceability statement would be distributed in the second issue of the JCTLM Database Newsletter in February 2015.
Action (A/14-07): Secretariat to contact the leader of the review team for Coagulation factors to verify if it would be possible to contact the ISTH for potential candidates for review team membership.
Action (A/14-08): Secretariat to contact NIBSC and verify if they would be willing to participate in the JCTLM team for "Infectious diseases".
Action (A/14-09): Dr Jones to finalize the submission of the paper on history and activities of the JCTLM to Clinica Chemica Acta.
Action (A/14-10): Secretariat to contact the NMI not having participated sufficiently regularly in RELA scheme from 2010-2012, and to remind them of the current JCTLM criteria for regular participation of listed laboratories in RELA Scheme to underpin their services listed, and to verify if they wish to withdraw their services or remain listed after 1st January 2015.
Action (A/14-11): Prof Siekmann to liaise with the Enzymes team to verify if the technical issues that they had raised in their recommendation could not be anticipated with the current template.

3. Future activities, structure, funding and impact of the JCTLM

3.1 Report back from ad-hoc group on JCTLM Future Structure [JCTLM-EXEC/14-03,04,05,06]

3.2 Proposals for increasing the number of JCTLM Executive Committee Organizations

3.3 The role and criteria for Ordinary JCTLM membership

3.4 Impact of JCTLM activities: Promotion and Education [JCTLM-EXEC/14-12]

3.5 Future funding of JCTLM activities

The issues raised under agenda points 3.1 to 3.5 were discussed simultaneously, and have all been reported in the following paragraph.

Dr Beastall presented the document JCTLM-EXEC/14-03 which included fourteen recommendations from the ad-hoc WG on JCTLM future structure at the teleconference on 10 September 2014. The Executive reviewed all the points, and of these agreed on the following:

1) An aim for the future would be to increase the level and recognition and acknowledgement of the JCTLM and the database that it produces.
2) The Executive agreed to establish a JCTLM working group on Education and Promotion on Traceability for which the terms of reference, and the membership would need to be defined. Dr Myers agreed to identify the Chairman of the WG. Some of the roles discussed for the new WG included the organization of member and stakeholder meetings as well as online education tools or JCTLM webinars, and a branded JCTLM presentation.
3) The JCTLM mission role should be revised to better emphasize the outputs of the JCTLM and its database.
4) The issues of JCTLM membership and funding of the JCTLM should remain decoupled.
5) The promotion of JCTLM would be enhanced by more demonstrable involvement in the JCTLM of organizations that use and/or benefit from Traceability in Laboratory Medicine, in addition to organizations with expertise on Reference Measurement Systems.
6) It was agreed that there should be two categories of ordinary membership.
7) The document JCTLM-EXEC/13-06 which included the role and criteria for ordinary membership would be revised to take into account the two categories of ordinary members: those organizations having as their primary responsibility the development and provision of reference measurement systems and able to provide experts to peer review JCTLM database nominations; and those organizations that were major beneficiaries and /or users of the entries listed in the JCTLM database.
8) The meeting of Members and Stakeholders should be organized by the WG on Promotion and Education every two years and be referred to as a Members' meeting. In future such meetings could be held in conjunction with large Laboratory Medicine conferences. This would allow sponsorship and registration fees to be charged for the meeting, and any surplus revenue donated to JCTLM activities.
9) The JCTLM Executive would be strengthened by inclusion of other international and global organizations active in the broader field of Laboratory Medicine. It was agreed that the Working Group would further consider which organizations could be approached as members and that list of those to be approached as well as criteria for membership would be finalised in early 2015.

10) The document JCTLM-EXEC/14-05 which included the JCTLM Executive Committee Membership would be revised with respect to the paragraphs on the criteria and candidates for Executive Committee Membership
11) It was agreed that a request for donations to the running costs of the JCTLM Secretariat would be made to every Executive Committee Member Organization, with the expectation that Executive Committee Organizations would agree to make donations to support the JCTLM activities either financially or 'in kind'.

Actions:
Action (A/14-12): Dr Myers to identify the Chairman for the Working Group on Education and Promotion on Traceability.
Action (A/14-13): Drs Beastall, Kaarls and Wielgosz to update the draft for the document on the role and criteria for ordinary membership to include two categories for ordinary members, and circulate the final document for comment to the members of the Executive
Action (A/14-14): Dr Beastall to update the draft of the document on JCTLM Executive Committee Membership, and circulate the draft for comment to the members of the Executive

4. Representation on the JCTLM

4.1 JCTLM Chair [JCTLM-EXEC/14-07,08,09]

4.2 JCTLM 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 nomination of Dr Gary Myers from the IFCC was received for JCTLM Chair, and no alternative nominations for the Secretariat were received.
The JCTLM Executive approved the Chairmanship of Dr Gary Myers, and the BIPM's continued role as Secretariat for the JCTLM.

Actions:
Action (A/14-15): JCTLM Secretariat to contact the sponsoring organizations and inform them of the appointment of the new Chairman, and update the JCTLM website.

4.3 JCTLM WG Chairs

Prof. Linda Thienpont had written to the committee to inform them of her resignation from the Chairmanship of WG2, and of her willingness to remain a member of the JCTLM Review Team for Non Peptide Hormones.
The Committee thanked Prof. Linda Thienpont for her important contribution and great work in support of the JCTLM, and thanked her for her continued participation as a member in the JCTLM Review Team for Non Peptide Hormones.

Dr Wielgosz pointed out that the review of the JCTLM procedures with regards to the tasks and role of the WG Chairs and JCTLM Secretariat was being made, and should be completed by June 2015. This would be dealt with under agenda point 6.4. He further added that the term of the WG1 and WG2 Chairs would come to an end in December 2015, and proposed that the process for the identification and appointment of a new co-chair of WG2 started after completion of the revision of the procedures.

The Executive Committee agreed with the proposal, and Prof Siekmann agreed to act as the Chair for WG2 until a new co-chair can be appointed at the end of 2015.

4.4 JCTLM membership [JCTLM-EXEC/14-29]

Dr Wielgosz informed the members of the Committee that one organization had applied for membership of the JCTLM: China National Accreditation Service for Conformity Assessment (CNAS) from Beijing.The Committee reviewed the application JCTLM-EXEC/14-29 and approved the JCTLM membership of CNAS.

Action (A/14-16): Secretariat to write to CNAS to confirm the Executive's approval of membership.

4.5 JCTLM Working Groups

Dr Wielgosz reported to the members of the committee that a WGs meeting was held on 3rd December 2014 at the BIPM, and brought to their attention that there was a small attendance to the meeting with only three members of the review teams who attended. He further added that this contrasted with last year, and reinforced the need for organizing the WGs meeting in conjunction with JCTLM Stakeholder and Members, technical Workshops/Symposium or satellite meeting to large laboratory medicine conferences.

4.6 JCTLM Review Teams and RT Members [JCTLM-EXEC/14-31, 32, 34, JCTLM-EXEC/12-05]

Dr Maniguet reported that a call for nominations among the JCTLM member organizations had been launched in April for experts for the following review teams: Drugs, Non-electrolyte metals, Non-peptide hormones, Proteins and Vitamins, and that the NCLSI had extended it to its members.

There were ten applicants from NMIs, IVD industry, clinical laboratory, university or accreditation body who volunteered to participate in the JCTLM review teams for Blood grouping, Drugs, Metabolites and Substrates, Microbial serology, Non-electrolyte metals, Non-peptide hormones, Proteins and Vitamins. All these nominations had been sent for review to the review teams, and four new members have been accepted as members of the following review teams:

Dr Zhu Zhu (Beckman Coulter) as a member of the Drugs team (WG1 and WG2 review activity),

Dr Liu Qinde (HSA) as a member of the Metabolites and Substrates and Non-peptide hormones teams (WG1 review activity),

Dr Richard Shin (HSA) as a member of the Non-electrolyte metals team (WG1 review activity),

Dr Akiko Takastu (NMIJ) as a member of the Non-electrolyte metals (WG1 review activity),

Dr Hiroshi Ihara (Chiba Institute of Science) as a member of the Vitamins team (WG1 and WG2 review activity).

There were four outstanding nominations for JCTLM review team membership that were still under review by the review teams, and of these three were for the Proteins team, and one was for the Drugs team.

The Executive Committee would review the recommendations made by the review teams for the remaining nominations by 15 January 2015.

Action (A/14-17): Executive Committee to send their comments on the RT recommendations for the nominations for JCTLM Membership by the 15 January 2015

4.7 JCTLM Database upgrades

In February 2014, twenty-three certified reference materials, 6 reference measurement methods, and 14 reference measurement services were published following the approval by the Executive Committee of nominations reviewed during WG1 cycle 10 and WG2 cycle 9.

The current status of the database as of December 2014 was as follows:
- 318 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),
- 167 reference measurement methods covering 81 analytes, and
- 106 reference measurement services covering 37 analytes. These services were delivered by 10 reference laboratories accredited for compliance against ISO 15195 and IEC/ISO 17025 as calibration laboratories, and by 2 National Metrology Institutes (NMIs).

A pop-up window was launched on 17 November on the home page of the JCTLM database website in order to investigate who were the users of the database and what information they were looking for. At the date of the Executive meeting, there were only preliminary results available for this survey, and the trend of these results showed that that the users were in majority coming from the clinical laboratory and even from the IVD industry. Additional responses will be collected until January 2015, and the results would be reported at the next Executive meeting.

4.8 Funding of the JCTLM Secretariat for 2015

Dr Wielgosz reported that the invoice which was sent in December 2014 to the IFCC was based on the time sheet record in use at the BIPM. The operating costs of the JCTLM Secretariat included the tasks related to the organization of JCTLM Executive meeting and related documentation, the processing of JCTLM submissions and reviewed nominations, the development and the maintenance of JCTLM Database, the activity for liaison with external organizations related to JCTLM, the organization and attendance to the WGs meeting, the drafting of the report meetings. The effective cost for 2014 JCTLM Secretariat appeared to be in line with that foreseen and presented in the document JCTLM-EXEC/10-24 which was the financial support required for the JCTLM Secretariat activities for 2011 to 2015 that was produced based on that of 2010 with an increase of 2% per year for inflation.
It was clarified that the major costs of the JCTLM Secretariat work is the BIPM staff time used to undertake these activities. Under BIPM funding rules, the funds given to the BIPM to support the JCTLM Secretariat work were considered as a donation.

Dr Beastall confirmed the IFCC financial position had improved over the last 2 to 3 years, and the IFCC was in a position to continue to contribute at its current rate to the running of the JCTLM Secretariat (the running costs of the JCTLM Secretariat had been split 50:50 between BIPM and IFCC in 2013 and similar costs were expected for 2014), with the proviso that the visibility and impact of the JCTLM could be improved with users of measurement methods in laboratory medicine. He welcomed proposals for the establishment of a WG on Education and

Promotion which could address the issues of visibility and impact, and noted that this would increase the overall expenditure of the JCTLM and additional income sources would be required in the future.

Dr Wielgosz informed the Committee that the BIPM had started to investigate the cost for the development of a web-based platform which would be used for the submission and the review of the JCTLM nominations. He further added that the draft of the technical specification was done with the view of providing a more professional service, and that external funding would be needed

5. JCTLM Documents

5.1 Traceability statement related to the JCTLM [JCTLM-EXEC/13-13]

This was discussed under agenda point 2.1, Action (A/13-06).

5.2 History and activities of the JCTLM [JCTLM-EXEC/13-22]

This was discussed under agenda point 2.1, Action (A/13-16).

5.3 JCTLM Newsletter 2015

Dr Maniguet reported that the first issue of the JCTLM Database Newsletter had been released in April 2014, and was distributed as a PDF by email to the JCTLM contact list. The second issue would be made in collaboration with Dr Murthy from the UKAS and was planned for release in the course of February 2015. Dr Wielgosz said the he had received positive feedback on this first issue as well as some requests to include external contributions to promote measurement result traceability in laboratory medicine.

6. JCTLM WG1

6.1 Approval of Cycle 11 RM and RMP nominations and outstanding issues from previous Cycles

Dr Maniguet presented the nominations for reference materials and measurement methods with the final review teams' recommendations which had been submitted for review to WG1. There were twelve nominations for reference materials for one group of analyte, and nine nominations for reference measurement methods for three groups of analytes which had been submitted for review cycle 11.

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

6.1.1 Total protein method

This issue of the resubmission for review by WG1of the biuret titration method for total protein measurement described in the Doumas' reference together with appropriate reference to the calibrator involved with the method was discussed under agenda point 2.1, Action (A/13-05), followed by (A/14-05).

6.1.2 HbA1c IFCC method

Dr Schimmel reported that Dr Kaiser made the request to replace the 2006 reference by another reference published in 2008 Clin Chem 2008;54:1018-22, that described another modified measurement procedure currently used by the IFCC HbA1c Network laboratories.

The protein review team was requested to give its view on whether the 2008 publication can replace the 2006 publication (GMS Ger.Med. Sci., 2006, Doc. 06.) or whether it should be added as a new reference in the list of publications in IFCC HPLC/MS-ESI method, or whether it would eventually introduce new aspects which have not been looked at so far. In accordance with the review team's view, WG1 recommended that the IFCC should be contacted in order to confirm which method (i.e. combination of modifications and original procedure) was used within the network and the appropriate reference could then be added in the JCTLM Database.

The Executive Committee approved the recommendation.

Action (A/14-18): Secretariat to contact IFCC Scientific Division in order to confirm which method (i.e. combination of modifications and original procedure) is used within the network and include appropriate reference in the JCTLM Database.

6.1.3 Drugs (Cycle 11) [JCTLM-EXEC/14-18, 24], (Cycle 10) [JCTLM-EXEC/14-25]

There was one nomination for reference measurement method for Drugs, which had been reviewed, and was being recommended for approval and publication in the JCTLM database.

There was also one outstanding nomination for reference measurement methods reviewed during the previous review cycle 10, and for which the review team had requested complementary material documenting that the corrections have been made according to cycle 10 review findings. The review team had completed the second review of the nomination after having received the supplementary documentation, and the nomination was being recommended for approval and publication in the JCTLM database.

The Executive Committee has approved the recommendation for publishing the two nominations for reference measurement methods for Drugs in the JCTLM Database.

6.1.4 Electrolytes (Cycle 11) [JCTLM-EXEC/14-15]

There were six nominations for reference measurement methods for Electrolytes. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database.
The Executive Committee commented that further review was needed in order to clarify the terminology of the quantity being measured prior to proceed further in the approval of these nominations.

Action (A/14-19): Executive Committee/Dr Jones to review the nominations for reference measurement methods for Electrolytes and draft the comment to be addressed to the review team leader for further consideration.

6.1.5 Metabolites and substrates (Cycle 11) [JCTLM-EXEC/14-19,26]

There were twelve nominations for reference materials for Metabolites and Substrates. All of these had been reviewed, and were being recommended for approval and publication in the JCTLM database.

The Executive Committee reviewed these nominations, and approved the recommendation for publishing the six high purity certified reference material nominations, and has not approved the recommendation for publishing the six nominations for the serum certified reference

material nominations. It requested that the review team should reconsider these latter nominations in order to either reclassify the non-compliances stated in the report as major non compliances with ISO 15194 requirements, notably those related to the missing statement in the certificate of analysis for compliance with ISO guide 34, and the lack of the scope of application that should be in line with the results from the commutability studies performed, or to verify if this information can be provided by the CRM producer, and thus request the revision of the certificate accordingly.

Action (A/14-20): Secretariat to contact the review team leader to address the issue raised by the Executive with regards to the certificate of analysis non-compliances with ISO 15194 requirements for the six serum certified reference material nominations.

6.1.6 Proteins (Cycle 11) [JCTLM-EXEC/14-21]

There were two nominations for reference measurement methods for Proteins. The review team leader had not sent any feedback until December 2014.

6.1.7 HbA1c material (Cycle 10) [JCTLM-EXEC/14-13]

The JCTLM Executive Committee deferred the publication of the nomination reviewed in the previous review cycle 10 until corrective action was made by the nominating organization, and requested that the certificate should be modified to have the statement on commutability in line with the intended use (calibration of routine assays) on the certificate, as required by ISO 15194.
The review team had completed the second review of the nomination after the nominating organization had sent supplementary documentation, and the nomination was being recommended for approval and publication in the JCTLM database.

The Executive Committee has approved the recommendation for publishing the material in the JCTLM Database.

6.2 Criteria for delisting methods from the JCTLM Database

Dr Wielgosz reminded the committee that there had been no progress on the issue on defining criteria for delisting the methods from the JCTLM Database. He further added that in case where this would be required, the appeal JCTLM procedure could be followed by any parties to address the difference of the measurement results obtained between the improved method and the original method.

6.3 Progress / plans for Cycle 12 call for RMs and RMPs

Dr Wielgosz confirmed that the new call for nominations for Reference Materials, and Methods would be launched on the 1st of February 2015 with a deadline for submissions in May 2015.

6.4 WG1 quality/ procedure manual (Review and Update)

Dr Wielgosz presented the summary of the role and activities of the Chairs of WGs and the Secretariat as described in the relevant JCTLM Procedure documents. He noted that the procedures did not now describe current practice, and this would require the descriptions of the process and duties of the WG Chairs and the Secretariat to be revised. For instance, the Chairs of WGs have always responded and advised the Secretariat on the technical issues raised by the review teams, or other parties, but it is currently the Secretariat that is coordinating the process of submission, review and publication of nominations between the actors involved in it. Dr Myers commented that it was clear that the JCTLM structures

described in the procedure documents were the ones that had been developed to start the JCTLM activities in 2002, and it would be appropriate to carry out a governance review at this point to determine the best structure for going forward.
In the discussion that followed, the following issues were raised by some members of the Executive for consideration in the review of the JCTLM Quality Procedures:
a) The participation of the WG Chairs in the activity of the review teams provided them an overview of the technical issues raised by the teams, and of how these were taken into account and classified as non-compliances with regards to the requirements of the harmonized standards. This has contributed to harmonize the review of the nominations among the teams, in particular when an organization had made submissions to several groups of analyte.
b) It was suggested that the WGs could be merged, with organizational activities for the WG residing with one Chair and technical overview of a number of review teams residing with the other co-chairs.
c) The importance of the WG meeting in appraising the outcomes of the review process for each cycle was emphasized.
d) The revised procedures should clarify and include the job descriptions of the WG Chairs and the Secretariat that will be adapted accordingly to the reorganization or new structure for the activity of the WGs.
d) It was suggested that Review Team Leader be able to recommend the need for an alternative group of experts when a new measurand was submitted for review.
e) In addition of annual WG meetings, webinars and e-conferences could be a good alternative to process the review of nominations.

The Executive Committee decided to establish an ad-hoc WG on JCTLM Governance which would be tasked to revise JCTLM procedures, and propose the most appropriate structure and assignment of duties to the JCTLM Executive, WG Chairs and the Secretariat.
Dr Myers, Dr Wielgosz, Dr Kaarls, Mrs Robertson, and Prof Siekmann agreed to participate in the ad-hoc WG. Dr Myers will act as Chair for the ad-hoc group.
The ad hoc WG would develop a first draft proposal by March 2015, and circulate it for comment to the members of the Executive for discussion in June 2015.

Actions:
Action (A/14-21): Ad-hoc WG (Dr Myers, Dr Wielgosz, Dr Kaarls, Mrs Robertson, and Prof Siekmann) on WG governance, Chaired by Dr Myers, to draft a proposal on the most appropriate structure and assignment of duties to the JCTLM Executive, WG Chairs and the Secretariat, by March 2015, and circulate it for comment to the members of the Executive for discussion in June 2015.

7. JCTLM WG 2 – Reference Measurement Laboratories

7.1 Approval of Cycle 9 Laboratory RMS nominations

Dr Maniguet presented the nominations for reference measurement services, which had been submitted for review as part of WG2 review cycle 9. There were 31 nominations for services for five groups of analytes.

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

7.1.1 Electrolytes (Cycle 9) [JCTLM-EXEC/14-16]

There were six nominations for electrolyte reference measurement services submitted by one reference laboratory. All had been reviewed, and were being recommended for approval and publication in the JCTLM database with the provision that the reference measurement methods for the same analytes (WG1 cycle 11 (2014)) used to deliver the services would be accepted for listing.

The Executive deferred the approval for these nominations until the nominations for reference measurement methods for the same analytes (WG1 cycle 11 (2014)) would be approved for publication in the JCTLM database.

7.1.2 Enzymes (Cycle 9) [JCTLM-EXEC/14-14]

There were fourteen nominations for enzyme reference measurement services submitted by three reference laboratories. All had been reviewed, and of these twelve were being recommended for approval and publication in the JCTLM database.
It was noted that the LDH measurement services could not be measured on plasma (whatever type).
The Executive Committee reviewed these nominations, and approved the recommendations for publishing the twelve enzyme reference measurement services in the JCTLM database.

The review team had deferred the recommendations to the Executive for the two remaining nominations for AMY and LDH for which the reported (accredited) measuring ranges were significantly narrow, if compared with the original IFCC reference procedures. The Executive Committee reviewed these nominations and approved the listing of the two nominations with the measurement ranges stated by the laboratory service provider with the request that an observation be included in the review report to clarify why the upper limits of the measurement ranges had been accredited with narrower values compared to the IFCC reference procedures for the same analytes.

7.1.3 Metabolites & Substrates (Cycle 9) [JCTLM-EXEC/14-20, 23]

There were eight nominations for metabolite and substrate reference measurement services submitted by four accredited laboratories. All had been reviewed, of these seven were being recommended for approval and publication in the JCTLM database, and one was not recommended for approval.

The Executive Committee reviewed these nominations, and approved the recommendations for publishing five metabolite and substrate reference measurement services, and deferred the recommendation for listing two services for HDL-Cholesterol and LDL-Cholesterol measurements until the service provider could provide a reference for inter-laboratory comparison results. They further requested that an observation be included in the JCTLM database for HDL-Cholesterol and LDL-Cholesterol measurement services to clarify to the user that the services used a method adapted from two listed methods (i.e. the ultracentrifugation CDC method and the IDMS).

7.1.4 Non-peptide hormones (Cycle 9) [JCTLM-EXEC/14-17]

There were two nominations for non-peptide hormone reference measurement services submitted by one reference laboratory. All had been reviewed, and were being recommended for approval and publication in the JCTLM database.

The Executive Committee reviewed these nominations, and approved the recommendations for publishing the two non-peptide hormone reference measurement services.

7.1.5 Proteins (Cycle 9) [JCTLM-EXEC/14-22, 35]

There was one nomination for reference measurement service for protein submitted by one accredited laboratory that was recommended for approval and publication in the JCTLM database.The Executive Committee reviewed the nomination, and approved the recommendation for publishing the HbA1c reference measurement services.

7.2 Review criteria for services based on modified methods

The issue on the review criteria for services based on modified methods was dealt with under agenda point 2.1, Action A(13-04), which was followed by Actions (A/14-03, -04)

7.3 Update on status of accreditation of Reference Measurement Service Providers

7.3.1 Update on IFCC EQAS results

Prof. Siekmann reported that the number of laboratories participating in the IFCC EQAS RELA Scheme had continued to increase over the last years, and that there were about fifty-five laboratories participating in the RELA. He explained that the laboratories intended to first participate in the RELA exercises prior to become accredited, and this could explain why there were only ten laboratories currently listed in the JCTLM database. He further gave an overview of the country of origin for the fifty-five laboratories participating in the RELA, of these about twenty-seven were from Asia, twenty were from Europe, two from North-America, and one from South-America. He commented that there would be an increasing and large contribution in the JCTLM activity in the next years of the laboratories coming from the Asian region.
Mrs Robertson pointed out that the laboratories from those countries could contact ILAC, if there was no Accreditation Body available to offer the accreditation for compliance against ISO 15195, and a solution would be provided to them.

7.3.2 Re-review of database entries (based on once every 3 year EQAS participation requirements)

This issue was discussed under agenda point 2.1, Action A(13-22), and was followed by the action A(14-10).

7.4 Progress / plans for Cycle X call for Laboratory RMSs

The new call for nominations for Reference Measurement Services would be launched in February 2015 in parallel to the call for Reference Materials and Methods.

7.5 WG2 quality/ procedure manual

There were no updates made to the WG2 procedure manual.

8. Gap analysis of missing reference materials, methods and services [JCTLM-EXEC/14-11]

Dr Jones presented the document JCTLM-EXEC/14-11, which included the gap analysis he carried out, of the missing reference materials, methods and services, with regards to the measurement requests made in his clinical laboratory, as well as the 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.

The Executive Committee welcomed this analysis, and commented that the gap analysis should be linked to medical impact and performance in EQAS schemes. Some members of the Executive pointed out that the prioritization for traceable measurements at the national level would be carried out at the level of each local economy and depend on the clinical need of the country rather than a global gap analysis.

Dr Jones pointed out that there was a need for harmonizing the terminology between the terms used for the health markers for the clinical laboratory tests, and the terms used for the measurands being defined by the organizations involved in the development of items serving to establish reference measurement systems for laboratory medicine, and ultimately listed in the database. He added that the CNPU-IFCC database terminology was currently available, but maybe a more user friendly alternative should be preferred and identified.
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, blood gases, or trace elements.
The Executive Committee requested that JCTLM should approach the CRM producers and the method developers to inform them that there was a need for clinical chemistry, and for instance, those participating in the CCQM activity for blood gases or trace elements.

In the discussion that followed, it was concluded the gap analysis should be initiated as a global initiative with the EQAS organizers. It was agreed that a JCTLM Workshop on Gap Analysis would be organized.

Action (A/14-22): BIPM to inform the members of the CCQM that the JCTLM database lacks entries for trace elements and blood gases.

9. Documents submitted by JCTLM Members and Stakeholders for consideration by the Executive Committee

There had been no documents submitted to the JCTLM Executive Committee.

10. Liaison with ISO TC 212 [JCTLM-EXEC/13-23]

10.1 Revision of ISO 17511:2003 [JCTLM-EXEC/13-12]

Dr Schimmel reported that the previous meeting of ISO/TC212/WG2 was held in November 2014 at Toronto, with the next version of the draft to be discussed by WG2 in April in Chicago.

10.2 Revision of ISO 15195

Dr Wielgosz reported that the revision of ISO 15195 had been drafted with ISO 17025 as a normative reference and was intended to be read as containing only points of clarification on ISO 17025 requirements for Reference Measurement Laboratories, as opposed to being a completely standalone standard. Dr Kaarls commented that he would report on this approach to ISO at the next OIML/ISO/BIPM/ILAC meeting.

10.3 Other work items in ISO TC 212

Dr Schimmel reported that the earlier version of the document of the Practical Guide for Estimation of Measurement Uncertainty has been cancelled, and the new draft would be available as a Committee document at the ISO/TC212/WG2 meeting in April.

11. Liaison with the EC

11.1 Update on revision to the IVD Directive

Dr Schimmel reported that the revised text of the EC Directive on IVD medical devices had been sent back to the European parliament, after the Council had disagreed on a number of the revised Directive's amendments, and that there was no clear timeline for the publication of the revised IVD directive. He further informed the Committee that it was no longer the unit DG Sciences, but DG Enterprise which was currently dealing with tasks related in vitro diagnostic medical devices.

12. Liaison with the WHO

12.1 Issues arising from the WHO-ECBS meeting (IFCC)

Dr Beastall said that he could only inform the committee that there had been contact with the WHO with the attendance of a representative of the IFCC at the WHO-ECBS meeting.

13. Future meetings of the JCTLM

13.1 Coordination of meetings with IFCC CTLM, CIRME, others

13.2 Meetings for 2015, 2016, 2017 (with EuroMedLab Paris June 21-25,2015)

13.3 JCTLM Symposium and Stakeholder meetings (2015/2016)

Dr Müller confirmed that a half-day symposium on JCTLM would be held at the international conference of EuroMedLab in Paris on 24th June 2015. It was proposed that a ad hoc JCTLM Governance WG / JCTLM Executive meeting could be held on 25-26 June. This would be confirmed at the start of 2015.

It was agreed that a Technical Workshop would be held at the BIPM on 30th November 2015, with a morning session on High Impact Measurands, and on Gap Analysis in the afternoon. It would be followed by a Member and Stakeholder meeting on 1st December 2015.
This would be followed by a WGs meeting on the 2nd December as well as a JCTLM Executive meeting on the 3rd and 4th December 2015.

The possibility of running a "Workshop for Reference Laboratories and accreditors of ISO 15195 laboratories" as well as a "Workshop on gap analysis" was discussed, and Dr Wielgosz agreed to contact the Committee for Traceability in Laboratory Medicine in China to verify if it would be possible to organize JCTLM Workshops in the course of 2016.

The possibility of organizing JCTLM Workshop (satellite meeting) at the venue of the IFCC meeting in Athens in June 2017 was proposed, including focussing on topics such as 'Impact and performance driving reference measurement system development in Laboratory Medicine', and combining the topics of gap analysis and expected outcomes and impact of standardization. The organization of this meeting would be led by the newly formed WG on Education and Promotion.

Action (A/14-23): Secretariat to contact the Committee for Traceability in Laboratory Medicine in China to verify the possibility to organize JCTLM Symposia in the course of 2016

14. Close

The Chairman closed the meeting on 5 December at 15:00

S. Maniguet and R.I Wielgosz (15 January 2015) (Revised 12 February 2015)

Annex 1: Summary List of Actions

Actions from the 13th Executive Meeting:

Action (A/14-01): WG1/WG2 Chairs in consultation with the technical experts of the WGs to draft a guidance document on the correction factors that CRM users would need to apply for the conversion of mass fraction to concentration values, and circulate it for review and approval at the next Executive Committee meeting.
Action (A/14-02): Dr Schimmel to circulate the final version of the document for the Terms of Reference for approval by the members of the Executive, and publication on the JCTLM website.
Action (A/14-03): WG1/WG2 Chairs and Quality Review Team to update the JCTLM procedures to include the new acceptance criteria for listing a reference measurement service of a provider using a modified listed reference measurement method, 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/14-04): Secretariat to update the database to enable the publication of the validation reports of a modified method against the listed reference method used for a measurement service delivered by a provider.
Action (A/14-05): Dr Myers/IFCC to verify the status of the new IFCC WG on clinical total protein measurements, and if IFCC would be willing to put forward a method nomination for biuret titration for total protein measurement
Action (A/14-06): Drs Jones, Wielgosz and Beastall agreed to review the latest draft of the document for traceability statement (JCTLM-EXEC /13-13), before Dr Beastall circulates for approval the final version to the IFCC corporate members for consultation, and for wider distribution to the IVD industry by February 2015. It was agreed that the traceability statement would be distributed in the second issue of the JCTLM Database Newsletter in February 2015.
Action (A/14-07): Secretariat to contact the leader of the review team for Coagulation factors to verify if it would be possible to contact the ISTH for potential candidates for review team membership.
Action (A/14-08): Secretariat to contact NIBSC and verify if they would be willing to participate in the JCTLM team for "Infectious diseases".
Action (A/14-09): Dr Jones to finalize the submission of the paper on history and activities of the JCTLM to Clinica Chemica Acta.
Action (A/14-10): Secretariat to contact the NMI not having participated sufficiently regularly in RELA scheme from 2010-2012, and to remind them of the current JCTLM criteria for regular participation of listed laboratories in RELA Scheme to underpin their services listed, and to verify if they wish to withdraw their services or remain listed after 1st January 2015.
Action (A/14-11): Prof Siekmann to liaise with the Enzymes team to verify if the technical issues that they had raised in their recommendation could not be anticipated with the current template.
Action (A/14-12): Dr Myers to identify the Chairman for the Working Group on Education and Promotion on Traceability.
Action (A/14-13): Dr Beastall, Kaarls and Wielgosz to update the draft for the document on the role and criteria for ordinary membership to include two categories for ordinary members, and circulate the final document for comment to the members of the Executive

Action (A/14-14): Dr Beastall to update the draft of the document on JCTLM Executive Committee Membership, and circulate the draft for comment to the members of the Executive

Action (A/14-15): JCTLM Secretariat to contact the sponsoring organizations and inform them of the appointment of the new Chairman, and update the JCTLM website.
Action (A/14-16): Secretariat to write to CNAS to confirm the Executive's approval of membership.
Action (A/14-17): Executive Committee to send their comments on the RT recommendations for the nominations for JCTLM Membership by the 15 January 2015
Action (A/14-18): Secretariat to contact IFCC Scientific Division in order to confirm which method (i.e. combination of modifications and original procedure) is used within the network and include appropriate reference in the JCTLM Database.
Action (A/14-19): Executive Committee/Dr Jones to review the nominations for reference measurement methods for Electrolytes and draft the comment to be addressed to the review team leader for further consideration.
Action (A/14-20): Secretariat to contact the review team leader to address the issue raised by the Executive with regards to the certificate of analysis non-compliances with ISO 15194 requirements for the six serum certified reference material nominations.
Action (A/14-21): Ad-hoc WG (Dr Myers, Dr Wielgosz, Dr Kaarls, Mrs Robertson, and Prof Siekmann) on WG governance, Chaired by Dr Myers, to draft a proposal on the most appropriate structure and assignment of duties to the JCTLM Executive, WG Chairs and the Secretariat, by March 2015, and circulate it for comment to the members of the Executive for discussion in June 2015.
Action (A/14-22): BIPM to inform the members of the CCQM that the JCTLM database lacks entries for trace elements and blood gases.
Action (A/14-23): Secretariat to contact the Committee for Traceability in Laboratory Medicine in China to verify the possibility to organize JCTLM Symposia in the course of 2016