Report of the 6th meeting of the JCTLM Executive Committee 14 December 2007, BIPM, Sèvres, France

List of participants:

Prof J-C. Forest (JCTLM Chairman, IFCC)

Dr R I Wielgosz (JCTLM Secretariat, BIPM)

Dr G. Jones (ILAC)

Prof M.Müller (IFCC)

Dr M. Panteghini (IFCC)

Prof L. Siekmann (JCTLM WG 2 Chair)

Mr A. Squirrell (ILAC)

Prof L. Thienpont (JCTLM WG 2 Chair)

Prof A. Wallard (BIPM)

Dr. S. Maniguet (BIPM)

Dr H. Schimmel (JCTLM WG1 Chair)

Dr R. Kaarls (BIPM)

Apologies received:

Dr W.E. May (JCTLM WG1 Chair)

Report of meeting:

Prof J-C. Forest opened the meeting. He said that this had been a very sad year for the JCTLM with the passing away of Dr Richard Miller. Dr Miller had been highly active in the JCTLM and his hard work and expertise were highly appreciated.

1. Approval of the agenda [JCTLM-EXEC/07-01]

Prof Forest requested that an additional agenda point related to the Robert Schaeffer award be dealt with under any other business.

2. Report of 4th JCTLM Executive Committee Meeting

There were no comments related to the report of the 5th Executive Committee meeting.

2.1 Review of action points arising from the 5th meeting

Dr Wielgosz summarized the action items that were still outstanding:

(A/05-01) The BIPM would write to the GHTF to investigate the possibility of establishing a liaison with them.

(A/05-09) The JCTLM Secretariat had developed a new nomination forms that would be consistent with the revised ISO 15194 standard and these would be issued in 2009.

(A/05-12) Changes to the quality manual requiring 'extent of equivalence' data would be developed as part of new procedures for 2009.

(A/05-13) The JCTLM secretariat would draft a request letter for experts to join the JCTLM review teams.

(A/05-17) Deputy Review Team leaders need to be named for a number of review teams. (A/05-22) The JCTLM Secretariat will write to the CCQM President requesting further NMI input into the work of the JCTLM.

3. JCTLM Framework and Declaration of Cooperation

3.1 JCTLM membership

Dr Wielgosz informed the Committee that no new organizations had applied for membership of the JCTLM. Mr. Squirrell replied that candidate member organizations should be approached. Prof Müller states that a stakeholder's meeting next year would be the ideal forum for this.

3.2 Representation, Chair and Secretariat

The Committee agreed that the positions of Chair and Secretary of the JCTLM would be reviewed next year following the adoption of the Executive Committee Procedure documents which would be discussed under agenda point 3.6.

3.3 JCTLM Working Groups

3.3.1 Review of JCTLM Review Teams and RT Members

Dr Wielgosz presented document JCTLM/07-12 which summarized review team membership by working group and analyte type. Each team was reviewed for its current membership. The Committee made a number of comments:

- Dr R. Kaarls and Prof M. Müller will contact NMIs and Manufacturer's linked to IFCC respectively for further experts for the Drugs Review Team;
- Prof Siekmaan stated that Prof Schumann had offered to take over the role of Review Team Leader for the Electrolytes and Blood gases team for both WG1 and WG2 processes. The Committee approved Prof Schumann as Review Team Leader;
- Dr Panteghini reported that Dr C. Jackson had applied for membership of the Enzyme Review Team and this was approved;
- -Dr Schimmel asked the JCTLM secretariat to contact Dr D. Tai and representatives from NIM to see if they were willing to continue to participate in the Non-peptide hormone review team:
- Dr Kaarls stated that he would contact NMIs via the CCQM to request nominations for experts for Vitamin and Non-peptide hormone review teams.
- Mr Squirrell expressed his wish to join the Quality Systems team, and this was approved.
- The Committee approved Dr K. Fujimoto as Review Team Leader of the Blood Cell Counting Review Team. Prof Siekmann requested that further representatives of manufacturers and the haematology community be asked to participate in the review team. The Committee asked that this request be passed on to Dr Fujimoto, and that the additional experts be approved prior to the review of nominated Reference Measurement Methods.

The following other changes to review team membership were approved: Dr Chris Burns appointed to the Proteins Review Team (WG1); Mrs Naomi Culp appointed to the Blood Cell Counting Review Team (WG1); Dr Donald Wiebe appointed to the Vitamin Review Team (WG1 and WG2).

Dr Rafferty had written to the Committee informing them of his retirement and resignation from the Proteins Review team. The Chairman stated that he would write to Dr Rafferty to thank him for his work in support of the JCTLM.

Prof Siekmann asked why the composition of Review Teams was different for WG1 and WG2 reviews. Dr Wielgosz replied that this system had been put in place at the request of certain review team members who had volunteered to participate in the reviews of one of the working groups but not the other. The Committee stated a preference for volunteers to be active in both WG1 and WG2 activities, and requested that this topic be raised at the next WG

meetings to be held in 2008. The Committee also noted that at a minimum Review Team Leaders would need to lead review teams for both WG1 and WG2 processes.

Actions:

Action(A/06-01): Dr R. Kaarls and Prof M. Müller to contact NMIs and Manufacturer's linked to IFCC respectively for further experts for the Drugs Review Team;

Action(A/06-02): JCTLM secretariat to contact Dr D. Tai and representatives from NIM to see if they were willing to continue to participate in the Non-peptide hormone review team; **Action(A/06-03):** Dr Kaarls to contact NMIs via the CCQM to request nominations for experts for Vitamin and Non-peptide hormone review teams;

Action(A/06-04): JCTLM Secretariat to request Dr Fujimoto to contact further experts from manufacturers and the haematology community to participate in the review team on Blood Cell counting;

Action(A/06-05): Prof Forest to write to Dr Rafferty to thank him for his work in support of the JCTLM.

3.4 Funding of the JCTLM Secretariat

Dr Wielgosz reported that the work of the secretariat for 2007 had been supported by financial contributions from the IFCC and the BIPM. The budget for the work to be undertaken by the Secretariat in 2008 would be finalised in the next month The operating costs of the JCTLM Secretariat were expected to be in line with the five year budget as presented previously (JCTLM-EXEC/06-16), however a redesign and update the JCTLM database due to changes in nomination forms necessitated by the revision of ISO 15194 would result in an increase in expenditure for the year.

3.5 JCTLM Secretariat Procedures

Dr Wielgosz presented document JCTLM-EXEC/07-15, which contained the procedures which had been developed for the Secretariat, and complemented the quality manuals for the JCTLM working groups. The Secretariat had been helped in this by Dr C. Jackson, the JCTLM WG Quality Systems Team leader. The Chairman set a deadline of 31 January 2008 for any comments on the procedures to be sent to the Secretariat, after this the procedures could be considered as approved and published.

Actions:

Action(A/06-06): JCTLM Executive to provide comments on the JCTLM Secretariat procedures before 31 January 2008.

3.6 JCTLM Executive Procedures

Dr Wielgosz presented document JCTLM-EXEC/07-13, which contained the procedures which had been developed for the Executive Committee, and complemented the quality manuals for the JCTLM working groups.

The Committee discussed the procedure P-02 related to the Appointment of WG Chairs at length. A system with co-chairs for each of the working groups had been established with the establishment of the JCTLM. The Chairman requested that the Secretariat revise the procedure to include the tasks which were the responsibility of the WG Chairs, and noted that the consensus of the Committee was that the appointment of a Chair and Deputy Chair was preferable, and also confirmed that the chairs should be active in the review work of the working groups. The Chairman requested that a revised version of the procedure be prepared for 29 February 2008, and that comments from Committee members on the new version

should be sent to the JCTLM Secretariat before 30 April, at which point a final version would be distributed for approval.

For the remaining procedures a comment deadline of 31 January 2008 was set.

Dr Jones commented that the procedures needed to include a statement which recognised the Executive Committee as an organ within the JCTLM that had the right to undertake tasks that were not covered in the procedures.

Actions:

Action (A/06-07): JCTLM Secretariat to revise P-02 by 29 February 2008, with Executive Committee comments by 30 April 2008.

Action (A/06-08): Executive Committee to comments on remaining procedures by 31 January 2008.

3.7 JCTLM Database

Dr Wielgosz reported that Dr S. Maniguet at the BIPM had coordinated the development of the JCTLM database to include Reference Measurement Services. This work was now complete, and a updated version of the database was made available on the BIPM website in October 2007.

3.8 JCTLM Symposium, Beijing October 2007

Dr Wielgosz reported on the Symposium entitled 'Activities and Challenges of Standardization and Traceability in Laboratory Medicine' that had been organized as part of the APCCB meetings in Beijing. The symposium had been a great success with approximately 250 participants. Abstracts and presentations from the Symposium were available on the BIPM website at http://www.bipm.org/cc/AllowedDocuments.jsp. The morning of the symposium had been dedicated to National and International systems for ensuring the traceability of measurement results. Representatives from China and Japan gave presentations on National systems and Committees that had been established to ensure traceability of measurement results.

Prof Müller commented that these were important developments, and it would be important to ensure that national and international systems were compatible and equivalent. He further proposed that the next stakeholder's meeting address the theme of 'aligning national and international committees in traceability in laboratory medicine'. He proposed that the next JCTLM Stakeholder's meeting /symposium could be held during the 18th IFCC – EFCC EUROPEAN CONGRESS OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE Innsbruck, Austria (June 7th-11th, 2009) or alternatively at the BIPM. Prof Siekmann added that the symposium should include presentations from representatives of countries with well established systems in addition to those currently developing theirs.

3.9 Use of the JCTLM logo

Dr Wielgosz introduced document JCTLM-EXEC/07-16, which was a letter from a JCTLM member organization requesting the use of the JCTLM logo in their Reference Materials Catalogue.

The consensus of the Committee was that rules for use of the JCTLM logo had not yet been established, and therefore Prof Wallard would write explaining the logo should not be used in Reference Material Catalogues at this time. Furthermore, it was noted that statements on

Reference Materials being listed in the JCTLM database should be accompanied by a date of publication of the material in the database.

Actions:

Action (A/06-09): Prof Wallard to write explaining the JCTLM logo should not be used in Reference Material Catalogues at this time.

4. JCTLM WG1 – Reference Materials and Reference Measurement Procedures

4.1 Report from the JCTLM WG1 meeting, October 2007, Beijing

Dr Schimmel gave a brief overview of the JCTLM WG1 meeting that had been held in October, and brought a number of issues to the attention of the Committee.

The Committee confirmed that a material would need to be available before it could be listed in the JCTLM database.

During the WG1 meeting Prof Kuwa had raised the issue of how Reference Materials and Methods should be listed in the area of Enzymes. The measurand in this case was defined by the procedure used, and currently the Reference Methods used in Japan differed from those recommended by the IFCC. Dr Panteghini reminded those present that this matter had been discussed previously several times, and that the Committees decision had been that when an Internationally agreed Reference Measurement Procedure was published in the JCTLM database for a procedurally defined measurand, national measurement procedure should be removed or would no longer be published for that measurand.

Dr Jones stated that if Prof. Kuwa did not agree with this approach he should be encouraged to present new arguments for his position directly to the Executive Committee.

4.2 Outstanding issues from Cycle III and approval of Cycle IV RM and RMP nominations

Dr Maniguet presented document JCTLM-EXEC/07-18 'JCTLM WG1 Review Team Recommendations for Approval for Cycle 4 nominations'. For Cycle IV there had been 50 nominated Reference Materials, and thirty one of these had been reviewed, and of these twenty five were being recommended for approval and publication in the JCTLM database. Sixteen nominations for Electrolytes had not been reviewed, and organizing a fast track review of these would be the task of Prof Schumman, the newly appointed review team leader. Three nominations for Nucleic Acids remained unreviewed as criteria for their review had not been finalised by the review team.

There were also fifteen nominated Reference Methods in Cycle IV, seven had been reviewed and six recommended for approval and publication. Nominations in the Blood Cell Counting, Electrolytes and Proteins category had not been reviewed.

The Chairman requested that all comments related to the recommendations should be sent to the Secretariat before 31 January 2008, after which uncontested recommendations would be approved.

Actions:

Action (A/06-10): JCTLM Executive to send comments related to the WG1 recommendations to the Secretariat before 31 January 2008, after which uncontested recommendations would be approved.

4.3 Delisting of RMs and RMPs

No reference materials were delisted from the JCTLM database this year.

4.4 Progress / plans for Cycle V call for RMs and RMPs

Dr Wielgosz confirmed that the new call for nominations for Reference Materials, Methods and Measurement Services would be launched in January 2008.

4.5 Revisions of ISO 15194 and 15193

Dr Wielgosz gave a presentation on the new revisions of ISO 15194 and 15193. A number of the members of the JCTLM had been active in ISO TC 212 WG2 which had been charged with revising the document.

He pointed out that the new title of ISO 15194:2007 had been changed to include the phrase 'Requirements for certified reference materials and the content of supporting documentation'. The new version of the standard was consistent with related standards developed by ISO REMCO, and this was evident from the list of normative referenced documents within the standard. The new standard had been organized with three main sections:

- Section 4. Systematic format of properties in the supporting documentation of a CRM
- Section 5. Properties, production and characterization of a CRM
- Section 6. Content of supporting documentation.

It was expected that the new version of the standard would be published in 2008, and that a full implementation of the new ISO 15194 standard for the JCTLM review process would occur in January 2009 with the Cycle VI call for nominations of Reference Materials.

The Committee discussed the issue of how the JCTLM review process should be modified with the publication of the new standard. The following process was agreed by the Committee:

- The Cycle VI (2009)nomination and review process will be based on ISO 15194:2007;
- The review criteria for the Cycle V(2008) call will be expanded and require compliance with ISO 15194:2003, ISO Guide 34, and self declaration that the statement on commutability of the material is consistent with its scope of applicability which will be provided;
- Three years after the publication of ISO 15194:2007, Reference Materials in the JCTLM database from Cycles I to IV will be re-reviewed against the ISO 15194:2007 criteria;

He also presented new nomination forms that had been developed by S. Maniguet and C. Jackson which were consistent with the ISO 15194:2007 standard. The JCTLM database would need to be modified as a result, and the new forms and simplified review process would be presented to the WGs in their 2008 meeting.

Actions:

Action (A/06-11): The review criteria for the Cycle V(2008) call for Reference Materials to be expanded to require compliance with ISO 15194:2003, ISO Guide 34, and self declaration that the statement on commutability of the material is consistent with its scope of applicability which is to be provided.

4.6 JCTLM WG1 quality manual

Dr Wielgosz reported that no requests for changes to the WG1 quality manual had been received.

5. JCTLM WG 2 – Reference Measurement Laboratories 5.1 Report from the JCTLM WG2 meeting, October, 2008

Prof Siekmann reported that WG2 had also held its meeting in October in Beijing. He reminded the committee that the Cycle I nomination process for Reference Measurement Services had resulted in 190 nominations. 98 of these services from thirteen laboratories had been approved, the remaining 92 services from 8 different laboratories had not.

A number of issues related to Cycle I nominations were clarified during the meeting, notably:

- for enzyme RMSs a number of applicable matrices had been stated in Cycle 1 nominations including calibration solutions and pure materials, but the values and uncertainties applied to the measurements on serum materials. Dr Panteghini stated that the methods could be applied to serum or pure materials, but not calibration solutions. The values and uncertainties for pure materials should be stated separately. The JCTLM Secretariat sent the nominations concerned to M. Panteghini for distribution to nominators for further information on the service applied to pure materials.
- it was noted that RMSs for enzymes were expressed in U and not in SI. Dr Panteghini stated that only a conversion factor needed to be applied to the value in U/L in order to express it in µkat/L. He would send this conversion factor to the JCTLM Secretariat. The measurement service should be converted into SI, and the conversion factor listed in the comments box.

5.2 Outstanding issues from Cycle I and approval of Cycle II Laboratory RMS nominations

Prof Siekmann summarized the current status of reviews of Cycle II nominations for RMSs, listed in JCTLM-EXEC/07-19.

He remarked that there had been some confusion on how to enter uncertainty data into the nominations. It was pointed out that a simple relationship with concentration could not always be assumed due to matrix effects. Therefore the min/max should simply refer to the smallest and largest uncertainties over that range without link to the concentration.

The required entries for applicable matrix / matrix category were also not understood. The JCTLM Secretariat was requested to develop an explanatory document on how to enter date into the forms as it had done for the WG1 nomination forms. Some suppression of columns in the nomination forms was foreseen.

The Chairman requested that all comments related to the recommendations should be sent to the Secretariat before 31 January 2008, after which uncontested recommendations would be approved.

5.2.1 Extension of the accreditation deadline

Prof Siekmann requested the deadline for laboratories to apply for accreditation be extended to 1 January 2009, with a deadline for obtaining an accredited status for

specific Reference Measurement Services set at 1 January 2010. Laboratories not meeting these deadlines, would have their services removed from the JCTLM database.

Mr Squirrell drew the Committee's attention to document JCTLM-EXEC/07-04, which contained the results of an ILAC questionnaire to National Accreditation Bodies on their willingness to provide accreditation services according to ISO 15195. Sixteen accreditation bodies had replied that they would be willing to establish this service is approached.

The Committee requested that this information should be made publicly available, and Mr Squirrell would provide the JCTLM Secretariat with appropriate contact names for laboratories wishing to contact the accreditation bodies concerned.

5.2.2 Frequency of performing Reference Measurement Services

Dr Panteghini reported that the frequency that a particular laboratory performed a reference measurement service had been questioned during the review of a nomination. Prof Siekmann confirmed that the frequency of performing the reference measurement service (other than for participation in appropriate inter-laboratory comparisons) was not a criteria used for deciding on publication within the JCTLM database.

Actions:

Action (A/06-12): JCTLM Secretariat to develop an explanatory document on how to enter date into the WG2 nomination forms;

Action (A/06-13): JCTLM Executive to send comments related to the WG2 recommendations to the Secretariat before 31 January 2008, after which uncontested recommendations would be approved.

Action (A/06-14): WG2 procedures to be modified to extend the deadline for laboratories to apply for accreditation to 1 January 2009, with a deadline for obtaining an accredited status for specific Reference Measurement Services set at 1 January 2010;

Action (A/06-15): A. Squirrell to provide the JCTLM Secretariat with contact names for accreditation bodies prepared to accredit according to ISO 15195.

5.3 Progress/plans for Cycle III call for Reference Measurement Services

Dr Wielgosz confirmed that the new call for nominations for Reference Measurement Services would be launched in January 2008 in parallel to the call for Reference Materials and Methods.

5.4 JCTLM WG2 procedure/quality manual

Prof Siekmann reported that the JCTLM Secretariat had revised the WG2 procedures as requested by the Executive at the last meeting (JCTLM-EXEC/07-14), and that he recommended the modified procedures for approval. The Committee approved the revised procedures.

5.5 Update on IFCC EQAS results

Prof Siekmann informed the Committee on developments in establishing limits of equivalence for the performance of laboratories in the IFCC EQAS scheme. The approach was based on taking a median value, which would only be established if more than five results were based on JCTLM listed methods. Limits of equivalence would be set around the

median value, and these were based on one quarter of the tolerance values used for routine laboratory testing assessments.

5.6 Revision of ISO 15195

Prof Siekmann reported that the revised version of ISO 15195 now included a normative reference to ISO 17025, and finalization and publication of the document was now in ISO's hands.

5.7 Report of the ad-hoc task group on Laboratory Network Accreditation

Dr Wielgosz presented the outcomes (JCTLM-EXEC/07-22) of the ad-hoc task group that had met the day before. The ad-hoc group requested that the following work items be approved by the Executive:

- development of a definition(s) for 'Laboratory Network';
- development of a section on the JCTLM website with links to 'Networks of JCTLM Member Organizations';
- development of a preamble for this section of the website;
- a search for other networks which could be linked to;
- development of a proposal for the future development of Networks within JCTLM activities (C. Weycamp and JCTLM Executive Committee Members)
- A paper study on how an accreditation of a Central and Satellite Laboratory system could be performed (M. Kimberly (CDC) and R. Robertson (ILAC) to take forward)

The Executive Committee approved the work items and confirmed that the task group should report back to JCTLM WG2 during the JCTLM meetings planned at the next AACC meeting in 2008 (July 2008, Washington DC).

5.8 Comparison with CMCs published in the BIPM key comparison Database

Dr Wielgosz presented document JCTLM-EXEC/07-17 which listed calibration and measurement capabilities of NMIs that had been published in the BIPM key comparison database and potentially could be listed as Reference Measurement Services. Dr Kaarls said that he would discuss this at the next CCQM meeting, and that if NMIs were offering Reference measurement Services they should be urged to also submit them for listing in the JCTLM database.

Actions:

Action (A/06-16): Dr Kaarls to request NMIs offering Reference Measurment Services to submit these for review and publication in the JCTLM database.

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

6.1 Letter from AFSSAPS to IRMM on IVDs for Cortisol Measurements
Dr Schimmel reported that the IRMM had received a letter from AFSSAPS, informing the
IRMM of the less than satisfactory results of Cortisol IVD test kits in a study that the
AFSSAPS had coordinated, and a request for a reference measurement system to be
established for cortisol. He explained that a meeting with AFSSAPS would be held in January
2008, and that the topics under discussion would include the specificity of such assays at low
concentration levels.

7. Liaison with the EC

7.1 Correspondence from J. Brennan (DG Enterprise)

Prof Wallard presented document JCTLM-EXEC/07-05, which summarized the view of the Commission, which was proposing to publish a note on its website relating to reference materials and methods of higher order. The note was still in draft stage, and stated that:

'Reference Materials and Reference Measurement Procedures of a Higher Order within the framework of Directive 98/79/EC on *in vitro* diagnostic medical devices can be taken to mean:

- a) those referred to in Commission Decision 2002/364/EC on common technical specifications for in vitro-diagnostic medical devices;
 - and thereafter
- b) those in compliance with the harmonised standard EN ISO 17511:2003 "In vitro diagnostic medical devices Measurement of quantities in biological samples Metrological traceability of values assigned to calibrators and control materials".

Organisations developing procedures and materials that could be considered to be of 'higher order' and thus used for the purposes of Directive 98/79/EC should align themselves accordingly.'

Prof Wallard stated that the JCTLM could proceed by simply stating that the reference materials and methods published in the JCTLM database were in compliance with the note.

In the discussion that followed, the Committee noted that the note only referred to the harmonised standard EN ISO 17511:2003, and not the other standards that had been mandated according to the IVD Directive, notably prEN ISO 15193; prEN ISO 15194; EN ISO 15195; EN ISO 17511; EN ISO 18153; and furthermore, a new version of the standard EN ISO 15194 was soon to be published. The Committee agreed that Prof Wallard would write to the Commission requesting that the note referred to the full list of mandated standards, and also request that the note be published following the publication of the new ISO standard.

Actions:

Action (A/06-17): Prof Wallard to write to the Commission requesting that their note be modified to refer to the full list of mandated standards, and also request that the note be published following the publication of the new ISO 15194 standard.

7.2 Liaison with the Global Harmonization Task Force (GHTF)

Prof Wallard stated that he would draft a letter to the GHTF and circulate it to the Executive for comment.

Actions:

Action (A/06-18): Prof Wallard to draft a letter to the GHTF and circulate it to the Executive for comment.

8. Liaison with the WHO

8.1 Issues arising from the WHO-ECBS meeting

Prof Forest circulated document JCTLM-EXEC/07-21 which was his report on the ECBS meeting which he had attended. He remarked that it was very encouraging to see that the discussion at the WHO had included Metrological traceability.

9. Liaison with ISO TC 212

Dr Wielgosz brought the Committee's attention to document JCTLM-EXEC/07-10. He noted that both ISO TC 212 and the JCTLM had been contacted by ISO REMCO that had established an ad hoc group to look at guidelines for reference materials for qualitative testing, which was directly relevant to ISO TC 212's discussions on guidelines for reference materials with properties on a nominal or ordinal scale.

10. Publicity for the JCTLM

Dr Wielgosz brought the Committee's attention to the leaflet advertising the JCTLM activities which was also available on the internet http://www.bipm.org/jctlm/JCTLM_Database_Leaflet.pdf

11. Future meetings of the JCTLM

11.1 Meetings for 2008 and 2009

Dr Wielgosz announced that JCTLM WG1 and 2 meetings would be held on 25 and 26 July 2008 in Washington DC USA, which was just before the AACC meeting. The meeting venue was being arranged by Drs May and Jackson.

11.2 JCTLM Symposium and Stakeholder's meeting

Prof Forest stated that it had been sometime since a JCTLM Members and Stakeholders meeting had been held, and that this event should be organized again. Dr Wallard replied that this could be organized at the BIPM in conjunction with the Executive Meeting. Provisional dates of 11 and 12 December 2008 were set for this. The Committee agreed that the topic of National and International Systems for traceability would be an appropriate topic for the meeting.

Prof Müller reminded the Committee that an alternative venue for the next JCTLM Stakeholder's meeting /symposium could be the 18th IFCC – EFCC EUROPEAN CONGRESS OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE Innsbruck, Austria (June 7th-11th, 2009).

12. Any other business

NIST, IFCC and CLSI have established a new award, The Robert Schaffer Award for Contributions to the Advancement of Reference Systems for Laboratory Medicine that will be made every 3 years. The first awardee will be announced at the 2008 ICCC in Fortaleza.

Prof Forest thanked the participants for their contributions and closed the meeting.

R.I. Wielgosz (BIPM) 25 January 2008

Actions outstanding from the 5th Executive Meeting:

(A/05-01) The BIPM would write to the GHTF to investigate the possibility of establishing a liaison with them.

(A/05-09) The JCTLM Secretariat had developed a new nomination forms that would be consistent with the revised ISO 15194 standard and these would be issued in 2009.

(A/05-12) Changes to the quality manual requiring 'extent of equivalence' data would be developed as part of new procedures for 2009.

(A/05-13) The JCTLM secretariat would draft a request letter for experts to join the JCTLM review teams.

(A/05-17) Deputy Review Team leaders need to be named for a number of review teams. (A/05-22) The JCTLM Secretariat will write to the CCQM President requesting further NMI input into the work of the JCTLM.

Actions from the 6th Executive Meeting:

Action(A/06-01): Dr R. Kaarls and Prof M. Müller tocontact NMIs and Manufacturer's linked to IFCC respectively for further experts for the Drugs Review Team;

Action(A/06-02): JCTLM secretariat to contact Dr D. Tai and representatives from NIM to see if they were willing to continue to participate in the Non-peptide hormone review team;

Action(A/06-03): Dr Kaarls to contact NMIs via the CCQM to request nominations for experts for Vitamin and Non-peptide hormone review teams;

Action(A/06-04): JCTLM Secretariat to request Dr Fujimoto to contact further experts from manufacturers and the haematology community to participate in the review team on Blood Cell counting;

Action(A/06-05): Prof Forest to write to Dr Rafferty to thank him for his work in support of the JCTLM.

Action(A/06-06): JCTLM Executive to provide comments on the JCTLM Secretariat procedures before 31 January 2008.

Action (A/06-07): JCTLM Secretariat to revise P-02 by 29 February 2008, with Excutive Committee comments by 30 April 2008.

Action (A/06-08): Executive Committee to comments on remaining procedures by 31 January 2008.

Action (A/06-09): Prof Wallard to write explaining the JCTLM logo should not be used in Reference Material Catalogues at this time.

Action (A/06-10): JCTLM Executive to send comments related to the WG1 recommendations to the Secretariat before 31 January 2008, after which uncontested recommendations would be approved.

Action (A/06-11): The review criteria for the Cycle V(2008) call for Reference Materials to be expanded to require compliance with ISO 15194:2003, ISO Guide 34, and self declaration that the statement on commutability of the material is consistent with its scope of applicability which is to be provided.

Action (A/06-12): JCTLM Secretariat to develop an explanatory document on how to enter date into the WG2 nomination forms;

Action (A/06-13): JCTLM Executive to send comments related to the WG2 recommendations to the Secretariat before 31 January 2008, after which uncontested recommendations would be approved.

Action (A/06-14): WG2 procedures to be modified to extend the deadline for laboratories to apply for accreditation to 1 January 2009, with a deadline for obtaining an accredited status for specific Reference Measurement Services set at 1 January 2010;

Action (A/06-15): A. Squirrell to provide the JCTLM Secretariat with contact names for accreditation bodies prepared to accredit according to ISO 15195.

Action (A/06-16): Dr Kaarls to request NMIs offering Reference Measurment Services to submit these for review and publication in the JCTLM database.

Action (A/06-17): Prof Wallard to write to the Commission requesting that their note be modified to refer to the full list of mandated standards, and also request that the note be published following the publication of the new ISO 15194 standard.

Action (A/06-18): Prof Wallard to draft a letter to the GHTF and circulate it to the Executive for comment.