Report of the 5th meeting of the JCTLM Executive Committee 1 December 2006, BIPM, Sèvres, France

List of participants:

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

Dr R I Wielgosz (JCTLM Secretariat, BIPM)

Dr G. Jones (ILAC)

Dr W.E. May (JCTLM WG1 Chair)

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)

Apologies received:

Dr R. Kaarls (BIPM)

Dr H. Schimmel (JCTLM WG1 Chair)

Report of meeting:

1. Approval of the agenda [JCTLM-EXEC/06-01]

Prof J-C. Forest welcomed Dr Graham Jones from ILAC to the meeting.

Dr Wielgosz asked for an additional agenda point to be added to allow a discussion of the review of reference materials with properties having assigned values on a nominal or ordinal scale. Prof Forest agreed that this could be dealt with under point 4.1 of the agenda.

2. Report of 4th JCTLM Executive Committee Meeting

There were no comments related to the report of the 4th Executive Committee meeting, which had been finalized in January 2006 and published on the JCTLM website.

2.1 Review of action points arising from the 4th meeting

Prof Forest reviewed the action points from the previous meeting. All action points had been addressed throughout the year. The following points were noted by the Committee:

- Actions A/04-03, regarding funding of the JCTLM Secretariat would be treated under a separate agenda point;
- Actions A/04-08 and 9, related to WG and review team membership, would be treated in detail during the reports from the JCTLM Working Groups;
- Action A/04-11, the development of JCTLM Secretariat and Executive Procedures, was an on-going activity and would be dealt with in a later agenda point;
- Action A/04-14, Dr Hicks of IFCC and Drs. May and Koch of NIST are discussing the establishment of an IFCC award scheme for contributions to standardization and traceability in Laboratory Medicine.

3. JCTLM Framework and Declaration of Cooperation

3.1 JCTLM membership

Dr Wielgosz informed the Committee that three organizations had applied for membership of the JCTLM (JCTLM-EXEC/06-15). The Committee approved the membership of all three organizations: NMIJ, the National Metrology Institute of Japan; JCCLS, the Japanese Committee for Clinical Laboratory Standards; and JACRI, the Japan Association of Clinical Reagents Industries.

3.2 Representation, Chair and Secretariat

Prof Forest pointed out to the Committee that the Declaration of Cooperation only referred to the Chairmanship of the JCTLM for the first two year period, and no further rules on the duration of the appointment had been defined. After some discussion, the Committee agreed that the positions of Chair and Secretary of the JCTLM should be reviewed every two years, with the next review due in 2007.

Dr May stated that it was important that both the IVD industry and regulators be represented on the JCTLM. Dr Jones added that this should be an agenda point for the next meeting of JCTLM Members and Stakeholders. Dr Wallard noted that the possibility of establishing a liaison with the Global Harmonization Task Force (GHTF), a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the USA, Canada, Japan and Australia should be investigated by the Secretariat.

Actions:

Action(A/05-01): JCTLM Secretariat to investigate the possibility of establishing liaison with the GHTF.

3.3 JCTLM Working Groups

A request to form a third JCTLM working group had been received from JCTLM Member Organizations. This point would be discussed under agenda point 6.

3.4 Funding of the JCTLM Secretariat

Dr Wielgosz reported that the work of the secretariat for 2006 had been supported by financial contributions from the IFCC and the BIPM. The budget for the work to be undertaken by the Secretariat for 2007-2010 had been prepared and was presented (JCTLM-EXEC/06-16). The operating costs of the JCTLM Secretariat were expected to remain approximately constant over the next five year period, with both organizations contributing 55 k Euro per annum to meet the operating costs of the secretariat. It was foreseen that in five years time it might be necessary to redesign and update the JCTLM database due to changes in web technology, and this would result in an increase in expenditure at this time.

3.5 JCTLM Secretariat Procedures

Dr Wielgosz presented document JCTLM-EXEC/06-14, which summarized the procedures which were being developed for the Secretariat, and complemented the quality manuals for the JCTLM working groups. The procedures themselves had already been drafted, and the Secretariat had been helped in this by Dr C. Jackson, the JCTLM WG Quality Systems Team leader. The procedures still needed to be cross-checked against the BIPM's own internal quality system, and then would be distributed to the Executive for approval.

Actions:

Action(A/05-02): JCTLM Secretariat to complete draft Secretariat procedure and forward to the Executive Committee for approval.

3.6 JCTLM Executive Procedures

Dr Wielgosz reminded the Committee that the declaration of cooperation established a broad operating structure for the JCTLM and its Executive Committee, but detailed procedures for the Executive had not been developed.

Prof Muller replied that he expected that the procedures could be brief, but should contain the list of decisions that needed to be taken by the Executive Committee. Dr Panteghini added that at the same time it would be useful to establish a timetable for actions for the working groups and the Executive, which would leave sufficient time for review and approval of nominations.

Actions:

Action (A/05-03): JCTLM Secretariat to draft Executive procedures.

4. JCTLM WG1 – Reference Materials and Reference Measurement Procedures

4.1 Approval of Cycle III RM and RMP nominations

Dr May gave a presentation on the activities of JCTLM WG1 and a summary of the outcomes of their recent meeting that had been held in conjunction with WG2 at the LGC in November 2006. Cycle III had resulted in 26 nomination of reference materials and 40 nominations of reference methods. Following the WG1 meeting, 13 reference materials and 16 reference methods had been considered to fulfil the criteria for listing in the JCTLM database, and these would be recommended for approval to the Executive, once all review reports had been received by the Secretariat. He noted that that a number of submitted nominations had not been reviewed, notably: in the area of drugs, since the nomination had been classed in the group of metabolites and substrates; for proteins and glycated haemoglobins; for nucleic acids since these materials have properties on a nominal scale; for blood cell counting, since this was a new area and a review team had not yet been established for this type of analyte. He noted that it was the intention of WG1 to review these outstanding nominations as soon as possible, rather than include them in the Cycle IV review process.

Dr Wielgosz asked how reference materials having properties with values assigned on a nominal/ ordinal scale should be dealt with by the JCTLM. He referred to the statement on the scope of ISO 17511 which stated specifically that the standard was not applicable to properties involving nominal scales, i.e. where no magnitude is involved (e.g. identification of blood cells). He concluded that this would lead to difficulties in deciding how to interpret 'higher order', which was used to mean 'higher metrological order' for such reference materials.

Professor Siekmann replied that this issue had been discussed in ISO TC 212, and that at that time a further standard had been proposed to cover reference materials with properties assigned on a nominal scale. However, to this date no such standard had been developed.

Dr May proposed that an appropriate course of action was for the three review teams currently dealing with reference materials with properties assigned on a nominal scale, namely nucleic

acids, microbial serology, and blood groupings to each develop a position paper on how to review such materials. This proposal was accepted by the Executive.

In the area of blood cell counting, Dr May proposed the formation of a new review team. He would ask the JCCLS to propose a review team leader for this area, and that the review team would need to include representatives from the International Committee for Standardization in Haematology (ICHS), and the review team composition should be presented and approved by the Executive. Prof Siekmann added that an expert from the PTB should be invited to join the team, as they had been active in establishing reference methods in this area. The Executive accepted the proposal and recommend that the Secretariat write to ICHS on this matter and also invite them to consider membership of the JCTLM.

In the area of proteins, Dr May proposed that an interim review team leader be appointed to deal with Cycle III nominations. He also pointed out that since review teams were now working on WG1 and WG2 activities, it would be appropriate for the Executive to appoint review team leaders on the recommendation of WG Chairs. This was accepted.

Dr May proposed that the final set of recommendations for Cycle III would be forwarded to the Secretariat for Executive Approval by 1 February 2007. This was approved, and an approval and publication date of 1 March 2007 set for the Executive Committee.

Actions:

Action (A/05-04): JCTLM WG1 to review outstanding nominations from Cycle III. **Action (A/05-05):** JCTLM Review Teams on nucleic acids, microbial serology, and blood groupings to be requested to each develop a position paper on how to review reference materials having properties with values assigned on a nominal/ ordinal scale.

Action (A/05-06): JCTLM Secretariat to write to ICHS on the establishment of a review team for Blood Cell Counting and also invite them to consider membership of the JCTLM.

Action (A/05-07): Dr May to propose an interim review team leader for proteins and glycated haemoglobins to deal with Cycle III nominations

Action (A/05-08): JCTLM WG quality manual to be modified to require Executive Committee appointment of review team leaders based on the recommendation of WG Chairs **Action (A/05-09):** Final set of recommendations for JCTLM WG1 Cycle III nominations to be forwarded to the Secretariat by 1 February 2007

4.2 Delisting of RMs and RMPs

Dr Wielgosz reminded the Committee that 24 reference materials were no longer listed in the JCTLM database. The majority of these had been removed from the JCTLM lists either because the material's expiration date had been reached, or that stocks of the material were depleted.

Prof Siekmann asked what would happen if a reference measurement method was delisted? Would this mean that reference measurement services would automatically be delisted? Dr Wielgosz replied that no reference methods had yet been delisted, but the database for laboratory reference measurement services could be constructed so that links between methods and services would be clear, and allow such actions to be taken.

4.3 Progress / plans for Cycle IV call for RMs and RMPs

Dr May stated that the call for Cycle IV nominations would be made in January 2007, with a deadline for receipt of nominations on 20 April. After review for completeness the JCTLM

Secretariat would distribute the nominations to review teams on 20 May. Completion of the review process by review teams was expected by 1 October, and approval of recommendations by the Executive in December.

He noted that not all nominations had been received with the same level of completeness, and sometimes the supporting documentation was not easily available. This created a considerable amount of extra work for the review teams. Dr Wielgosz replied that the criteria for completeness of submitted nominations could be tightened, which should streamline the process. He proposed that the first step was to provide examples of ideally completed submissions for a reference material and reference measurement procedure to act as guidelines for future nominations, and then the Secretariat should work with the WGs to define which missing data would render a nomination incomplete.

Dr Panteghini stated that there seemed to be levels of duplication of effort for the entry of review comments in excel sheets, check lists and the review reports. He asked whether this system could be simplified. Dr Wielgosz replied that together with the Quality systems team, the Secretariat would see what could be done to streamline the process.

Actions:

Action (A/05-10): JCTLM Quality Systems Team and Secretariat requested to develop 'ideal' nomination dossiers, and propose clear criteria that if not met would render a nomination incomplete.

Action (A/05-11): JCTLM Quality Systems Team and Secretariat to develop proposal to simplify review process and forms.

4.4 JCTLM WG1 quality manual

Dr May reported that no requests for changes to the WG1 quality manual had been received, and that the periodic review of the quality manual would be carried out in 2007. He noted that a number of related issues should also be dealt with in 2007, notably: regional training sessions for review team leaders and their teams; comparisons of nominated and published reference materials and reference methods/procedures to demonstrate their extent of equivalence; a common quality system for WG1 and WG2.

The Committee discussed various ways of demonstrating the comparability of reference methods and materials. Mr Squirrell stated that although the results of interlaboratory comparisons could be analysed to give information on the comparability of methods, it should not be forgotten that the primary purpose of the comparisons was to examine laboratory performance, and if the data was used for other purposes this should always be taken into account.

Dr May stated that the only way to ensure that reference material and method comparability studies were undertaken, was to insist on these being a prerequisite for publication in the JCTLM database. He proposed that nominations of new materials or methods would need to include 'extent of equivalence' data relative to materials and methods already published in the database, and that reviews of materials and methods already within the database would also need to focus on this issue. In response to a question from the Secretariat, he replied that these changes would require a change in the quality manual, and proposed that these changes and additional requirements be introduced with the Cycle V call in 2008. This was accepted by the Executive.

Actions:

Action (A/05-12): JCTLM WG1 to develop proposed changes to the Quality Manual requiring nominations of new materials or methods to include 'extent of equivalence' data relative to materials and methods already published in the database.

4.5 Review of WG1 and Review Team Membership

Dr May informed the Committee, that the work of the review teams was the cornerstone of the activities of the JCTLM, and that without appropriate experts, reviews of materials and methods could not be performed. He noted that there was a drop in attendance of review team leaders at the last meeting of the JCTLM WGs, and that the number of active members in a number of review teams had dropped, and this needed to be addressed urgently.

Dr Wielgosz presented document JCTLM-EXEC/06-18, which summarized the completed nomination/application forms and CVs received from review team members. Only just above 40% of review team members had returned completed nomination forms/ CVs indicating which review teams and process (WG1 or WG2) they would be involved in. In general, there were fewer members active in WG2 compared to WG1.

Prof Siekmann requested that future communication with candidates for membership of the review teams should indicate that responsibility for the process rested with the JCTLM and its sponsoring organizations and not individuals carrying out reviews. Dr Panteghini added that further experts should be invited to be members of review teams since conflict of interest issues stopped a number of review team members carrying out the review of laboratory measurement services, and that some members may feel competent to review material and method nominations but not measurement services.

Prof Forest summarised that it was important to recruit further experts for the review teams, and that the JCTLM member organizations, NMIs, the IFCC Scientific Division should be contacted with this request. He also requested the Secretariat to relaunch a call for nomination forms and CVs from currently active members, and that lists of members should be modified according to the responses received.

Actions:

Action(A/05-13): Secretariat to: draft letter requesting experts for Review teams; forward for comment to Executive; and distribute.

Action(A/05-14): Secretariat to re-launch call for CVs and nomination forms from members of review teams (reply deadline 20 January 2007)

4.6 Progress with the JCTLM database

Dr Wielgosz introduced Dr S. Maniguet from the BIPM, who had been active in the development of the JCTLM database and would act as the database coordinator. The database would be completed in a few weeks and then would be publicly available from the BIPM and IFCC websites. Prof Forest thanked the Secreatriat for their work on the JCTLM Database, which would be a valuable resource for the IVD industry and regulators.

5. JCTLM WG 2 – Reference Measurement Laboratories

5.1 Approval of Cycle I Laboratory RMS nominations

Prof Siekmann presented an overview of the status of review of reference measurement service (RMS) nominations received to date (JCTLM-EXEC/06-09). He had reviewed the information received from the review teams, and had a number of comments which he would send to individual review teams for consideration. As with WG1 nominations, final recommendations for WG2 were expected to be sent to the Secretariat by 1 February 2007.

He noted that no reports had been received on proteins and glycated haemoglobins, and proposed that for each review team a deputy review team leader should be appointed.

Dr Panteghini raised the issue of difficulties in achieving accreditation to ISO 17025 and 15195, as few accreditation bodies offered this service. Prof Siekmann replied that only the DKD in Germany offered this service, and only 4 out of the 26 laboratories which had nominated RMSs were accredited and all were based in Germany.

Prof Forest asked the ILAC representatives to what extent it could be expected that other countries develop accreditation services to ISO 17025 and 15195, especially since ILAC's Accreditation Committee had decided 'to keep this item on hold' and concentrate its resources firstly on 15189, in its report to the ILAC General Assembly (13 and 15 November 2006).

Mr Squirrell replied that the rate of development of accreditation schemes would depend on the number of requests received by the accreditation bodies, and that cross-border accreditation may need to be envisioned. He requested the Secretariat to send him a simplified list of laboratories and their countries that had nominated RMSs, so that he could contact the national accreditation bodies in these countries informing them on the requirements to establish an accreditation service to ISO 17015 and 15195.

Dr Wielgosz reminded the Committee that at the last meeting of WG2 an official statement on a laboratory's accreditation or intention to seek accreditation would be requested by the JCTLM as part of the nomination procedure. This would take the form of either a copy of the accreditation certificate, or a letter of intent from the laboratory regarding accreditation. The committee agreed that certificates and letters should be requested from laboratories with measurement services approved for publication. These should be received by the JCTLM Secretariat by May 1 2007, or the measurement service would be removed from the JCTLM database.

Actions:

Action(A/05-15): WG2 Chairs to send comments on reviewed RMS nominations to review teams.

Action(A/05-16): Final set of recommendations for JCTLM WG2 Cycle I nominations to be forwarded to the Secretariat by 1 February 2007

Action(A/05-17): JCTLM WG Chairs to recommend deputy review team leaders for endorsement by the Executive Committee

Action(A/05-18): JCTLM Secretariat to send a list of laboratories and their countries nominating RMSs to ILAC, so that they can contact the national accreditation bodies in these countries informing them of the requirements to establish an accreditation service to ISO 17015 and 15195.

Action(A/05-19): JCTLM Secretariat to request copies of accreditation certificates and letters of intent from laboratories with measurement services approved for publication in the JCTLM database.

5.2 Progress/plans for Cycle II call for Laboratory RMSs

Prof Siekmann agreed that the Cycle II call for RMSs should be made in 2007 at the same time and in coordination with the WG1 call for RM and RMM/P nominations.

Actions:

Action(A/05-20): Cycle II call for RMSs to be made in 2007 at the same time and in coordination with the WG1 call for RM and RMM/P nominations.

5.3 JCTLM WG2 procedure/quality manual

Prof Siekmann requested a number of changes to the WG2 quality manual, notably related to: official notification of accreditation status by laboratories; the review of NMI nominations by JCTLM review teams; and the acceptance of the simultaneous submission of measurement services and methods for review by the JCTLM.

Dr Wielgosz requested that reference to the CCQM Executive Secretary should be removed from the procedures, and replaced by the JCTLM Secretariat, review teams or Working group Chair as appropriate.

These changes were approved by the Executive Committee.

Actions:

Action(A/05-21): Prof Siekmann to send modified WG2 procedures to the Secretariat.

5.4 Update on IFCC EQAS results

Prof Siekmann requested that more NMIs should participate in the IFCC EQAS scheme, thereby providing a clear link between the activities of metrology institutes and reference measurement service providers. Only one NMI had submitted their measurement services for review by the JCTLM.

Dr May pointed out that measurement capabilities of the NMIs were listed in the BIPM's key comparison database as CMCs, and that a possible reason why these had not been submitted for inclusion in the JCTLM database was the JCTLM's requirement for laboratories to participate in at least annual interlaboratory comparisons for any group of analytes.

Mr Squirrell added that ILAC was moving to 'needs based participation' in interlaboratory comparisons, rather than a requirement to have a rigidly fixed maximum period between comparisons, and suggested that the JCTLM may need to accept this type of approach.

Prof Forest summarized that NMIs should be encouraged to submit their measurement services for listing in the JCTLM database, and the frequency of needs based participation in interlaboratory comparisons to be discussed during the next review cycle.

Actions:

Action(A/05-22): JCTLM Secretariat to forward a request to NMIs active in CCQM for participation in IFCC EQAS and to submit RMS nominations for review by the JCTLM.

5.5 Review of Review Team Membership and Review Teams

Dr Wielgosz reported that during meetings establishing the JCTLM a list of participants wishing to be members of WG2 was drawn up. However, WG2 was now operating through review teams. He proposed that the Secretariat should write to those on the original list of WG2 members and inform them of the activities of the group and invite nominations for review team membership. The Committee agreed to this.

Actions:

Action(A/05-23): JCTLM Secretariat to write to the list of WG2 members and inform them of the activities of the group and invite nominations for review team membership.

5.6 Progress with the JCTLM database for Laboratory RMSs

Dr Wielgosz reported that the web based JCTLM database would be extended to include Reference Measurement Services in 2007, but the first publication of approved RMS early in 2007 would be presented as Excel tables.

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

Prof Forest introduced two letters which had been sent by the CDC and the HbA1c network, and both addressed the issue of accreditation of Networks of Laboratories, and proposed that a third JCTLM WG should be established to lead this work.

Mr Squirrell added that taking into account current practice, only processes requiring accreditation of each laboratory within the network were available.

Dr May replied that a number of these networks had been active for many years and operated quality systems within the networks. A pragmatic way forward would be to investigate to what extent the current activities of the networks were sufficient in demonstrating compliance with ISO 17025 and 15195, whether the networks included processes equivalent to those used as the basis of accreditation e.g. documented peer review, and if so, how accreditation could take these activities into account.

Prof Siekmann noted that it had been originally envisioned that laboratories offering reference measurement services listed by the JCTLM would interact to form networks, rather than the JCTLM listing networks of laboratories. Nevertheless, he stated that the involvement of a laboratory within a network was useful additional information which could be included in the database.

Prof Forest summarized that this was a topic that fell within the scope of JCTLM WG2, but that it was not the purpose of JCTLM to act as an accreditor. He proposed that the issue be dealt with as a task within WG2, and the output should be a position paper on possibilities and processes for the accreditation of laboratory networks. The group charged with the task should include a representative from ILAC, as well as those who had proposed the action. He requested the Secretariat to draft a response to both organizations taking into account the comments of ILAC and the WG Chairs.

Actions:

Action(A/05-24): JCTLM Secretariat to reply to the CDC and HbA1c network informing them of the Executive Committee's decision .

7. Liaison with the EC

7.1 Report of Meeting with DG Enterprise (30 November)

Prof Forest, Müller and Wallard and Drs Panteghini and Wielgosz had attended a meeting with DG Enterprise on the previous day. Dr Emons of IRMM had also attended the meeting. DG Enterprise was represented by Mr Selles and Brennan. The representatives of DG Enterprise had explained that the meeting was fortuitous, since the Medical Devices Expert Group (MDEG) would be meeting in two weeks and would amongst other things be discussing the traceability requirements of the IVD directive. Prof Forest presented an overview of the JCTLM activities, indicating how the activities filled an important gap in the implementation of the IVD directive. Prof Wallard stated that he intended to follow up the meeting with a letter to DG Enterprise, in which he would highlight the points raised in the presentation and request DG Enterprise to consider how they could recognise the JCTLM activities.

Actions:

Action(A/05-25): Prof Wallard to write to DG Enterprise.

8. Liaison with the WHO

8.1 Issues arising from the WHO-ECBS meeting

Prof Forest and Dr Wielgosz had attended the WHO-ECBS meeting. Dr Forest stated that during the meeting WHO had discussed a five year plan for biological standardization. Unfortunately, the plan did not mention metrological traceability, although the WHO had announced that they would be looking at the issue of reference materials whose properties could now be expressed in terms of SI units rather than in IU. The IFCC would be writing to the WHO to ask them to include metrological traceability in their future work.

9. Liaison with ISO TC 212

9.1 Revisions of ISO 15193 and ISO 15194

Dr Wielgosz brought the Committee's attention to document JCTLM-EXEC/06-03, which was the latest revised version of ISO 15194. He explained that the structure of the document was clearer, and consistent with ISO-REMCO guides on the production and characterization of reference materials. The revised standard dealt with the production and characterization and intended use of reference materials in addition to the content of their supporting documentation. He pointed out that once the revised standard had been agreed, this would probably require a modification of the reference material nomination forms to include all mandatory requirements of the standard.

Mr Squirrell asked when ISO 15195 would be revised. Prof Siekmann replied that this would be discussed at the next meeting of ISO/TC 212 WG2, during which the normative reference to ISO 17025 should be inserted. Mr Squirrell added that there were other corrections which should be made to the standard, for example, the removal of sentences that stated that NMIs carried out accreditations, which was not correct.

10. Publicity for the JCTLM

Prof Forest stated that events that publicise the work of the JCTLM should be continued. Dr Wielgosz replied that work was underway to produce a leaflet explaining the work of the JCTLM and its database and that this would be finalised and distributed in 2007.

11. Future meetings of the JCTLM

Prof Forest reminded the Committee that the following meetings should be organized in 2007: a joint meeting of the working groups; a JCTLM symposium on standardization of technical activities; a JCTLM Members and Stakeholders meeting; the JCTLM Executive meeting.

Dr May replied that a possible meeting site for the working groups and symposium would be at the 11th Asian Pacific Congress of Clinical Biochemistry (APFCB) in Beijing (14-19 October 2007). In the discussion that followed it was agreed that a symposium would need to be held during and in the same facilities as the Congress, in order to ensure that participants from the Congress attended the JCTLM Symposium. It was agreed that the first choice for the date of the symposium would be 19 October 2007, with meetings of the JCTLM WGs preceding this. The symposium should cover international standardization activities, and could focus on new frontier areas. Dr May agreed to contact NIM, the Chinese NMI, to see if they could help in the organization of the meeting.

It was proposed that the next meeting of the JCTLM Executive would be held at the BIPM on 14 December and be preceded by a JCTLM Members and Stakeholders meeting on 13 December. An alternative date and place for the JCTLM symposium would be 12 December at the BIPM.

A possible venue for 2008 JCTLM meetings was the 20th International Congress of Clinical Chemistry and Laboratory Medicine (ICCC) to be held in Fortaleza, Brazil (28 September – 2 October 2008).

Actions:

Action(A/05-26): Dr May to contact NIM and inform the JCTLM Secretariat on possibilities of organising a JCTLM Symposium on 19 October 2007 at the 11th Asian Pacific Congress of Clinical Biochemistry (APFCB).

12. Any other business

There was no other business. Prof Forest thanked the participants for their contributions and closed the meeting.

R.I. Wielgosz (BIPM) 12 December 2006 revised 22 January 2007

Annex 1: Summary List of Actions

Action(A/05-01): JCTLM Secretariat to investigate the possibility of establishing liaison with the GHTF.

Action(A/05-02): JCTLM Secretariat to complete draft Secretariat procedure and forward to the Executive Committee for approval.

Action (A/05-03): JCTLM Secretariat to draft Executive procedures.

Action (A/05-04): JCTLM WG1 to review outstanding nominations from Cycle III.

Action (A/05-05): JCTLM Review Teams on nucleic acids, microbial serology, and blood groupings to be requested to develop a position paper on how to review reference materials having properties with values assigned on a nominal/ordinal scale.

Action (A/05-06): JCTLM Secretariat to write to ICHS on the establishment of a review team for Blood Cell Counting and also invite them to consider membership of the JCTLM.

Action (A/05-07): Dr May to propose an interim review team leader for proteins and glycated haemoglobins to deal with Cycle III nominations

Action (A/05-08): JCTLM WG quality manual to be modified to require Executive Committee appointment of review team leaders based on the recommendation of WG Chairs **Action (A/05-09):** Final set of recommendations for JCTLM WG1 Cycle III nominations to be forwarded to the Secretariat by 1 February 2007

Action (A/05-10): JCTLM Quality Systems Team and Secretariat requested to develop 'ideal' nomination dossiers, and propose clear criteria that if not met would render a nomination incomplete.

Action (A/05-11): JCTLM Quality Systems Team and Secretariat to develop proposal to simplify review process and forms.

Action (A/05-12): JCTLM WG1 to develop proposed changes to the Quality Manual requiring nominations of new materials or methods to include 'extent of equivalence' data relative to materials and methods already published in the database.

Action(A/05-13): Secretariat to: draft letter requesting experts for Review teams; forward for comment to Executive; and distribute.

Action(A/05-14): Secretariat to re-launch call for CVs and nomination forms from members of review teams (reply deadline 20 January 2007)

Action(A/05-15): WG2 Chairs to send comments on reviewed RMS nominations to review teams.

Action(A/05-16): Final set of recommendations for JCTLM WG2 Cycle I nominations to be forwarded to the Secretariat by 1 February 2007

Action(A/05-17): JCTLM WG Chairs to recommend deputy review team leaders for endorsement by the Executive Committee

Action(A/05-18): JCTLM Secretariat to send a list of laboratories and their countries nominating RMSs to ILAC, so that they can contact the national accreditation bodies in these countries informing them of the requirements to establish an accreditation service to ISO 17015 and 15195.

Action(A/05-19): JCTLM Secretariat to request copies of accreditation certificates and letters of intent from laboratories with measurement services approved for publication in the JCTLM database.

Action(A/05-20): Cycle II call for RMSs to be made in 2007 at the same time and in coordination with the WG1 call for RM and RMM/P nominations.

Action(A/05-21): Prof Siekmann to send modified WG2 procedures to the Secretariat.

Action(A/05-22): JCTLM Secretariat to forward a request to NMIs active in CCQM for participation in IFCC EQAS and to submit RMS nominations for review by the JCTLM.

Action(A/05-23): JCTLM Secretariat to write to the list of WG2 members and inform them of the activities of the group and invite nominations for review team membership.

Action(A/05-24): JCTLM Secretariat to reply to the CDC and HbA1c network informing them of the Executive Committee's decision .

Action(A/05-25): Prof Wallard to write to DG Enterprise.

Action(**A/05-26**): Dr May to contact NIM and inform the JCTLM Secretariat on possibilities of organising a JCTLM Symposium on 19 October 2007 at the 11th Asian Pacific Congress of Clinical Biochemistry (APFCB).