



SCIENTIFIC DIVISION

45th MEETING Corfu, GR (2010 04 16-17) MINUTES (*final draft*)

Members:	Abbr.	Term and Time of Office
Mauro PANTEGHINI (IT) (Chair)	MP	2 nd 2009 01 - 2011 12
Ian YOUNG (UK) (Vice-Chair)	IY	2 nd 2009 01 - 2011 12
Gary MYERS (US) (Secretary)	GM	1 st 2009 01 - 2011 12
Philippe GILLERY (FR)	PG	2 nd 2009 01 - 2011 12
Lothar SIEKMANN (DE)	LS	2 nd 2009 01 - 2011 12
Naotaka HAMASAKI (JP)	NH	1 st 2009 01 - 2011 12
Joseph PASSARELLI (US) (Corporate Rep.)	JP	1 st 2010 01 - 2012 12
David BUNK (NIST Representative)	DB	Consultant
Heinz SCHIMMEL (IRMM Representative)	HS	Consultant
Mathias MÜLLER (JCTLM Representative)	MM	Consultant

EXECUTIVE SUMMARY - SCIENTIFIC DIVISION 45th MEETING, CORFU, GREECE APRIL 16 & 17, 2010.

Present: Mauro Panteghini (Chair), Ian Young (Vice-Chair), Gary Myers (Secretary), Philippe Gillery, Lothar Siekmann, Naotaka Hamasaki, Joseph Passarelli (Corporate Representative), Mathias Müller (JCTLM Representative) David Bunk (NIST Representative) and Heinz Schimmel (IRMM Representative) with Ms Paola Bramati (IFCC Office) were in attendance. F. Pontet, M. Pazzagli, F. Ceriotti, K. Ichihara, A. Kessler, G. Miller, N. Greenberg, R. Paleari, J. Tate, and R. Tirimacco attended 04/17/2010 to update the SD on activities of their respective Committees and Work Groups.

6.1 WORLD HEALTH ORGANIZATION (WHO): IY appointed IFCC representative to WHO-ECBS. The next meeting is scheduled for October 2010.

6.2 CLSI: The complete list of cooperative IFCC/CLSI joint projects is available on the IFCC website.

6.22.1 JCTLM: JCTLM Executive held a meeting in December, 2009 at BIPM in Paris, Mathias Müller appointed as JCTLM Executive Committee Chair. To be listed as a laboratory providing a reference service, a laboratory will need to be accredited by January 2011. *Labs must participate at least once in 3 years for each measurand listed in the JCTLM data base by the lab.* The next cycle for call for nomination of new materials, methods, and services concludes at the end of April 2010. Meeting of WGs 1 and 2 will be held July 2010 prior to the AACC meeting in Anaheim, USA.

6.22.2 JCGM: The latest version of the VIM 3rd edition and GUM are available on the IFCC website.

6.22.3.1 CCQM: The CCQM held a meeting in April 2010 just before the IFCC General Conference.

6.31 INSTITUTE FOR REFERENCE MATERIALS AND MEASUREMENTS (IRMM): Cystatin C material (ERM-DA471/IFCC) will be released with a statement on commutability based on results from the pre-commutability study. IRMM will launch a larger commutability study to include ~20 vendors worldwide scheduled for the 2nd half of 2010. HbA1c – New lots of primary and secondary reference materials are under development. HbA2 - Waiting for finalized reference method for HbA2 before providing HbA2 reference material. CLINBIOTRACE project – project with 4 National Metrology Institutes with purpose to select proteins to relate mass of proteins to functional activities in immunoassays.

6.37 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST): Report on NIST reference materials: Vitamin D in serum – new lot in planning; Vitamins B₆/B₁₂ - new material to be released in late 2010; Metabolomics material being developed; SRM 909b renewal – will be 909c (frozen human serum) scheduled for late 2010; SRM967 renewal – creatinine in serum.

Other materials projected – drugs of abuse; creatinine in urine; proteomics material.

Reference Measurement Procedures under development – albumin in urine; C-Reactive Protein; Prostate-Specific Antigen.

8.2 MAIN ACTIVITIES OF COMMITTEES:

8.2.6 C-NPU: The NPU database will be transferred to the IFCC website. Draft 1 of the international vocabulary for nominal examinations in scientific communication inspired by VIM3 is under review.

8.2.11 C-MD: Eleven Molecular Diagnostic Centers have been accepted to the IFCC Molecular Diagnostic Centers Network.

8.2.13 C-PP: The C-PP continues work on certification of ERM-DA470k/IFCC material for β 2-microglobulin and analytical and clinical evaluation of serum free light chain measurement.

8.2.19 C-SMCD: The C-SMCD was terminated. The two tables “Analytical characteristics of commercial and research high sensitivity cardiac troponin I & T assays per manufacturer” and “Analytical characteristics of commercial BNP and NT-proBNP assays per manufacturer” are listed on the IFCC website on the SD section.

8.2.21 C-RSE: The C-RSE will submit the primary reference measurement procedure for alkaline phosphatase to JCTLM for review and consideration for listing as an accepted reference measurement procedure.

8.2.23 C-TLM: The C-TLM has two new terms of reference: to promote establishment and maintenance of IFCC reference laboratory networks for clinically relevant measurands (e.g. the IFCC HbA1c network) and to consider a strategy to determine what steps should be taken to decide whether standardization or harmonization should be followed for a particular measurand. C-TLM reviewed major amendments to RELA, which include: labs must participate at least once in 3 years for each measurand listed by the lab; Certificate of Participation in RELA will only be awarded to labs when their results are published; and alkaline phosphatase will be implemented in RELA surveys.

8.2.24 C-RIDL: The C-RIDL plans for 2010 include: a proposal for a global reference interval study to include Asia-Pacific, Europe and the USA that will focus on standardized analytes in order to produce universal reference intervals; improvement on statistical procedures; and development of flexible software for reference interval estimation.

8.3 MAIN ACTIVITIES OF WORKING GROUPS:

8.3.16 WG-SHCG: The WG-SHCG was terminated.

8.3.19 WG-HbA1c: The major work to establish an international reference system to standardize HbA1c has been completed; therefore the WG-HbA1c has been closed. An IFCC integrated project on implementation of IFCC HbA1c standardization has been established. The C-TLM now has oversight of the IFCC HbA1c Reference Laboratory Network.

8.3.33 WG-STFT: A separate survey group within RELA specifically for total hormones will be created. WG needs to make final recommendation for RMP for FT4 in order to put method approval to ballot vote.

8.3.35 WG-HbA2: The next steps for the RMP development include defining the purity of internal standards and the calibration procedure. A second batch of secondary reference material will be prepared at IRMM and evaluated under various storage conditions, accelerated degradation experiments, and for commutability.

8.3.36 WG-CDT: The WG-CDT has prepared a manuscript for the CCLM special issue.

8.3.37 WG-SCC: The Certification Report for ERM-DA471/IFCC is going through the final review and normal release procedure by IRMM. The WG aims for release of the ERM-DA471/IFCC in summer 2010. IRMM has sent out invitations to approximately 20 companies to participate in the full commutability study.

8.3.38 WG-GFRA: WG-GFRA is completing data analysis and draft manuscript of results from the creatinine specificity study.

8.3.39 WG-SAU: WG published recommendations in 2009 (Clin Chem 2009;55:24). Highlights include: report Albumin/Creatinine Ratio (ACR), not concentration alone; “mg/mmol” or “mg/g” should be used uniformly in a country or region; first morning sample preferred; discontinue terms “microalbuminuria” and “macroalbuminuria”. The development of a reference system for listing by JCTLM is major priority.

8.3.40 WG-PAPPA: The WG is waiting for company assistance. Five companies agreed to contribute. Work will begin when funds are available.

8.3.41 WG-GH: A consensus statement among several scientific bodies was drafted for publication. A GH reference panel of sera is in preparation.

8.3.42 WG-SIA: Funding was provided by NIH to support the collection and preparation of a panel of single donor samples for insulin assay harmonization. WG is providing input on laboratory requirements for the WHO project to replace 1st IRP 66/304, insulin for immunoassays, with a recombinant preparation in conjunction with replacement of WHO 83/500, IS for human insulin, used to assay pharmaceutical preparations.

8.3.43 WG-TnI: WG-TnI is working on the development of a candidate higher level immunoassay procedure and on the characterization of a secondary reference material for TnI.

8.3.44 WG-AETR: This is a newly created WG. The Term of Reference of the WG is to define clinically acceptable limits for the metrological traceability of specific analytes.

8.3.45 WG-HAT: This is a newly created WG. The Terms of Reference of the WG are:

- to evaluate what are the main causes of variability for a number of diagnostically critical autoantibody measurements.
- to identify autoantibody tests where a common calibrator could reduce the inter-assay variability

8.3.46 WG-GPOCT: This is a newly created WG. The Term of Reference of the WG is to investigate the quality specifications required for glucose POCT meters in different health care settings.

8.19 MEETINGS

8.19.46 46th SD meeting, Seoul, Korea, October 2-3, 2010.

8.19.47 47th SD meeting, Berlin, Germany, May 14-15, 2011