

SCIENTIFIC DIVISION

46th MEETING
Seoul, KOREA (2010 10 2-3)
MINUTES (*Final Draft*)

Members:	Abbr.	Term and Time of Office
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 Representative)	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 46th MEETING, SEOUL, KOREA OCTOBER 2 & 3, 2010.

Present: Ian Young (Vice-Chair), Gary Myers (Secretary), Philippe Gillery, Lothar Siekmann, Naotaka Hamasaki, Joseph Passarelli (Corporate Representative), Mathias Müller (JCTLM Representative) Heinz Schimmel (IRMM Representative) and Ms Paola Bramati (IFCC Office) were in attendance. Mauro Panteghini (former SD Chair) and Graham Beasall (IFCC President - 10/2/2010 only) were also in attendance. Apologies from David Bunk (NIST Representative).

6.1 WORLD HEALTH ORGANIZATION (WHO): PG will serve as the new IFCC representative to WHO-ECBS.

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

6.22.1 JCTLM: Business meetings of WGs 1, 2 and 3 were held July 24, 2010 prior to the AACC meeting in Anaheim, USA. The last publication to the database was made February 2010. LS will replace MP on the Executive of JCTLM.

6.22.2 JCGM: A meeting of JCGM WG-1 GUM was held May 25-28, 2010 at BIPM, Paris. A meeting of JCGM WG-2 was held May 19-21, 2010 at BIPM, Paris. The latest version of the VIM 3rd edition and GUM are available on the IFCC website.

6.22.3 BIPM Consultative Committees

6.22.3.1 CCQM: Held a meeting on April 14-16, 2010..

6.22.3.2 CCU: Held meeting on September 14, 2010.

6.31 INSTITUTE FOR REFERENCE MATERIALS AND MEASUREMENTS (IRMM):

IRMM completed a larger commutability study of ERM-DA471/IFCC Cystatin C material. Commutability issues in larger study similar to those observed in smaller pilot study.

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 new reference materials in preparation by NIST include: vitamin B6 (late 2010), vitamin B12 (mid 2011), metabolites in human plasma (late 2010), antiepilepsy drugs (late 2010), fat soluble vitamins and carotenoids (late 2010), drugs of abuse (late 2010), creatinine in urine (mid 2011), lipids in frozen human serum (mid 2011).

8.2 MAIN ACTIVITIES OF COMMITTEES:

8.2.6 C-NPU: The Danish Board of Health sent a letter to the SD indicating it will not support the English version of the NPU database after December, 2010. This will result in lags between the Danish version and English version. The Danish version will be the Master File, while the English version will remain frozen if not supported for translation and updating

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

8.2.13 C-PP: C-PP will be closed at the end of this year, and remaining tasks will be addressed by the establishment of relevant working groups.

8.2.21 C-RSE: The C-RSE continues to work on analytical issues related to the development of RMPs for ALP and lipase, respectively.

Three C-RSE manuscripts have recently been published:

- 1) "IFCC reference procedures for measurement of the catalytic concentrations of enzymes: corrigendum, notes and useful advice" - Clin Chem Lab Med 2010; 48(5): 615-621
- 2) "Standardization in clinical enzymology: a challenge for the theory of metrological traceability" - Clin Chem Lab Med 2010; 48(3): 301-307
- 3) "Traceability of values for catalytic activity concentration of enzymes: a Certified Reference Material for aspartate transaminase" - Clin Chem Lab Med 2010;48(6):795-803.

8.2.23 C-TLM: The C-TLM continues to work on the details of an IFCC project proposal on Master Comparisons for manufacturers of diagnostic assays.

8.2.24 C-RIDL: The C-RIDL continues to develop plans 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:

8.3.33 WG-STFT: Plans for the Phase III study include a new method comparison with clinical FT4 and TSH samples that is intended to answer the question whether assay performance on samples with hypo- and hyperthyroid FT4 and TSH concentrations is identical to the performance on samples covering the euthyroid range.

8.3.35 WG-HbA2: WG-HbA2 is working on analytical issues to improve the reference measurement procedure for HbA2. WG needs to document adequate digestion efficiency (could be currently only about 30% comparing with the digestion efficiency of other proteins under the same digestion conditions).

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

8.3.37 WG-SCC: Results of full commutability study for ERM-DA471/IFCC indicate commutability issues in the larger study similar to those observed in smaller pilot study.

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

8.3.39 WG-SAU: WG-SAU is focusing on the following projects: evaluation of urine albumin adsorption by collection containers, harmonization of urine albumin methods, and development of a urine albumin reference measurement procedure.

8.3.40 WG-PAPPA: The WG proposed plan for standardization of PAPPA has progressed very slowly. The WG continues to wait on company assistance. Five companies agreed to contribute 15 000 CHF each. Three have provided funds/ 2 have not. Must clarify situation with remaining two manufacturers.

8.3.41 WG-GH: A consensus statement among several scientific bodies was drafted for publication. Manuscript was returned for revisions. Final revised version submitted to Clinical Chemistry.

8.3.42 WG-SIA: Single donor samples are being collected for insulin assay harmonization. WG provided 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 a study protocol for method comparison, commutability and stability of assays for cardiac troponin I measurement. WG-TNI assumed responsibility for maintaining up to date information in the table of “Analytical characteristics of commercial and research high sensitivity cardiac troponin I & T assays per manufacturers” and also a similar table on BNP assays, both available on the IFCC website. WG publication: Standardization of cardiac troponin I measurement: past and present. *Pathology*, 2010;45(5):402-408.

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

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

8.19.48 48th SD meeting, Milano, Italy. October 7-8, 2011