

SCIENTIFIC DIVISION

50th MEETING Kuala Lumpur, Malaysia (2012 11 16- 17) MINUTES (*Third Draft*)

Members:	Abbr.	Term and Time of Office
Ian YOUNG (UK) (Chair)	IY	1 st 2011 01 - 2013 12
Philippe GILLERY (FR) (Vice-Chair)	PG	1 st 2011 01 - 2013 12
Gary MYERS (US) (Secretary)	GLM	2 nd 2012 01 - 2014 12
Christa COBBAERT (NL)	CC	1 st 2012 01 - 2014 12
Naotaka HAMASAKI (JP)	NH	2 nd 2012 01 - 2014 12
Giampaolo MERLINI (IT)	GMI	1 st 2011 01 - 2013 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 50th MEETING, KUALA LUMPUR, MALAYSIA, NOVEMBER 16-17, 2012.

Present: Ian Young (Chair), Philippe Gillery (Vice-Chair), Gary Myers (Secretary), Giampaolo Merlini, Naotaka Hamasaki, David Bunk (NIST Representative), Joseph Passarelli (Corporate Representative), Mathias Müller (JCTLM Representative), Heinz Schimmel (IRMM Representative) and Ms Paola Bramati (IFCC Office) were in attendance. Apologies from Christa Cobbaert

5.4 EUROPEAN FEDERATION of CLINICAL CHEMISTRY and LABORATORY MEDICINE (EFLM):

The EFLM Scientific Committee and SD leadership agreed there should be close liaison and communication between the two groups. Minutes of SD meeting in Marrakech were provided to the EFLM.

6.1 WORLD HEALTH ORGANIZATION (WHO): PG attended the October, 2012 meeting of the WHO-ECBS.

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

6.22.1 JCTLM: A meeting of JCTLM was held in Paris, December 6-7, 2012.

6.22.2 JCGM: JCGM circulated a copy of the final approved version of Document JCGM 106:2012 – evaluation of measurement data, the role of measurement uncertainty in conformity assessment. The document was prepared by the Joint Committee for Guides in Metrology, Working Group 1 of which the IFCC is a member. JCGM WG 1 met at BIPM, Paris – Tuesday 12th – 15th June 2012. Graham White attended as IFCC Representative. Minutes of the meeting were distributed.

6.22.3 BIPM Consultative Committees

SD received no correspondence from CCQM or CCU.

6.31 INSTITUTE FOR REFERENCE MATERIALS AND MEASUREMENTS (IRMM):

IRMM will play role in implementation of new EU IVD legislation. Regulation is intended to be implemented in 2016.

6.37 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST):

NIST is developing a vitamin D in human serum reference material (SRM 2973) that will contain 8—100 nmol/L of vitamin D3.

8.2 MAIN ACTIVITIES OF COMMITTEES:

8.2.6 C-NPU: The terminology database is now on the IFCC server and searchable via the web. The revision of the "Silver Book": Compendium of Terminology and Nomenclature of Properties in Clinical Laboratory Sciences (IUPAC and IFCC Recommendations 1995) has been extended. The objective is to finalize the updating of the first edition of the Silver Book (project #2007-033-1) by inserting a new chapter on nominal properties and adding a concise summary of the content as a double sheet leaflet.

8.2.11 C-MD: The Proposal PEGASUS submitted by F. Rousseau with the active participation of the IFCC-C-MD has been successfully granted by the Canadian Government.

8.2.21 C-RSE: The C-RSE continues to work on the development of a reference measurement procedure for pancreatic lipase. The experimental results were contradictory and not satisfactory for both methods, therefore optimization of both methods is proceeding in parallel. The evaluation of commutability for ALT, LDH, and CK as CRMs is being done in collaboration with IRMM.

8.2.23 C-TLM: RELA 2010 and RELA 2011 had been finalized and the results are published online (www.dgkl-rfb.de:81/). The number of participants and submitted results, respectively, is still increasing. Participation is global with a considerable number of laboratories from China.

8.2.24 C-RIDL: The C-RIDL has agreed on a common collection protocol so that sample collection can proceed. C-RIDL also agreed to bypass global reference intervals in favour of regional reference intervals following a common protocol.

8.2.25 C-STFT: The C-STFT met in Los Angeles in conjunction with the 2012 AACC Annual Meeting. Minutes were distributed. A reference measurement system for TSH based on the "all-procedure trimmed mean (APTM)" calculated by Principal Component Analysis (PCA) is under construction. A proof-of-concept paper has been written and is accepted for publication in Clinical Chemistry and Laboratory Medicine.

8.3 MAIN ACTIVITIES OF WORKING GROUPS:

8.3.35 WG-HbA2: The WG-HbA2 continues to work on analytical issues to develop a reference measurement procedure for HbA2. IRMM is waiting for the completion of the reference measurement procedure to finalize the HbA2 reference material. A second batch of a candidate reference material was prepared at the IRMM in 2011 and is under testing for methemoglobin content, total hemoglobin concentration, and analysis of minor hemoglobins by HPLC.

8.3.36 WG-CDT: The WG-CDT continues to work on the evaluation of the HPLC candidate reference measurement procedure for CDT measurement. Study 3 demonstrated the commutability in pooled samples, but did not clearly indicate there was no patient dependent factor that could affect the commutability. As a final step, it was decided to perform a confirmatory calibration study (Study 4) based on native samples from 40 different individuals with variable CDT levels, according to CLSI protocol 14a/53 and using the HPLC reference method and available methods on the market.

8.3.39 WG-SAU: The WG continues to focus on the following projects: harmonization of urine albumin assay methods and development of a urine albumin reference measurement procedure.

8.3.40 WG-PAPPA: Based on the results from the first round of the project, the second phase was initiated in the spring of 2012. Samples from the candidate standard material (pregnancy derived), recombinant dimeric PAPP-A and pooled first trimester sera diluted into different matrices were distributed to five companies with a recommended test protocol. The results were obtained in August/September from seven different test platforms (2 companies having two different test platforms). The results have been compiled and a summary report is being prepared.

8.3.42 WG-SIA: Single donor samples have been collected for insulin assay harmonization. Establishment of insulin RMP is on-going.

8.3.43 WG-Tnl: The WG-Tnl developed the cTnl Pilot Study protocol to investigate the feasibility of preparing a commutable and stable secondary reference material for cTnl by use of serum pools. A preliminary data analysis was done to obtain a general assessment of commutability, imprecision, the degree of measurement harmonisation between different cTnl assays, presence of interferences, stability of pools, and comparability with the cTnl cRMP. The preliminary analysis indicated that all pooled serum samples appear to be commutable with all routine assays.

8.3.44 WG-AETR: The WG-AETR has prepared a manuscript for CCLM. Manufacturers have been asked to provide information on their specific traceability chains. The WG is organizing a meeting during EuroMedLab in Milan in 2013.

8.3.45 WG-HAT: The WG-HAT has concentrated on developing materials for IgG antibodies to myeloperoxidase and running a preliminary commutability study. The samples are currently being analyzed and data is being returned to the IRMM for evaluation. The WG made a conscious decision to embrace developing methodologies; therefore, a mixture of manual ELISA, automated ELISA and multiplex methods are included in the commutability studies.

8.3.46 WG-GPOCT: WG-GPOCT prepared a manuscript for CCLM providing an overview of glucose meters fit for purpose and highlighting the importance of education. WG-POCT also submitted a session to AACC for 2013 Annual Meeting in Houston. SD recommends closing the WG and transferring activities to the new IFCC Task Force on POCT.

8.3.47 WG-cMSP: The WG-cMSP will prepare a review for CCLM on quantitative clinical chemistry proteomics. They want to start a comparison study on clinical chemistry of quantitative mass spectrometry with different participants and have chosen to focus on the hepcidin assay.

8.3.48 WG-sPTH: The WG-sPTH has undertaken preliminary work to assess the commutability of the 1st International Standard for Parathyroid Hormone (PTH) (WHO IS 95/646). Confirmation of the commutability of the 1st IS is essential before the WG can actively begin to encourage manufacturers to recalibrate their methods in terms of this IS.

8.3.49 WG-CSFP: The WG on CSF Proteins (WG-CSFP) is a new WG established by the SD. The Term of Reference is to develop an international reference material for cerebrospinal fluid (CSF).

8.3.50 WG-SBMA: The WG on Standardization of Bone Marker Assays (WG-SBMA) is a new WG established by the SD. This is a joint activity with the International Osteoporosis Foundation. The Term of Reference is to standardize or harmonize (as technically feasible or appropriate at this time) clinical assays available for routine and research use, for the following two bone turnover markers; the serum assay for C-telopeptide fragments of collagen type I $\alpha 1$ chains containing the epitope Glu-Lys-Ala-His-Asp- β -Gly-Gly-Arg in an isomerized form (also known as serum Crosslaps (CTx)) and the serum assay for N-terminal Propeptide of Type I Procollagen (P1NP).

8.19 MEETINGS

8.19.50 50th SD Meeting – Kuala Lumpur, Malaysia, 16-17 November, 2012

8.19.51 51st SD Meeting – Milano, Italy, May 18-19, 2013

8.19.52 52nd SD Meeting – Bali, Indonesia, October 25-26, 2013