

SCIENTIFIC DIVISION

51st MEETING
Milano, Italy (2013 05 18- 19)

MINUTES (final 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	2 nd	2013 01 - 2015 12
David BUNK (NIST Representative)	DB		Consultant
Heinz SCHIMMEL (IRMM Representative)	HS		Consultant
Mathias MÜLLER (JCTLM Representative)	MM		Consultant

EXECUTIVE SUMMARY - SCIENTIFIC DIVISION 51st MEETING, MILANO, ITALY, MAY 18-19, 2013.

Present: Ian Young (Chair), Philippe Gillery (Vice-Chair), Gary Myers (Secretary), Christa Cobbaert, 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. Linda Thienpont (May 19), Apologies received from Giampaolo Merlini.

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. The SD was advised of a new EFLM Working Group on "Patient Focused Laboratory Medicine" created under the EFLM Science Committee with the aim to improve patient ownership of their disease and provide a service that better reflects patients' expectations.

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 three day meeting of JCTLM (December 3-5, 2013) will be held in Paris; meeting of JCTLM Review Teams - 3 December; meeting of JCTLM Stakeholders and Members – December 4-5; meeting of the JCTLM Executive Committee – December 6. A half-day free symposium on traceability will be offered.

6.22.2 JCGM: JCGM WG 1 (Expression of Uncertainty in Measurement) met at BIPM, Paris – Tuesday 27th – 30th November 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. The CCU will hold its 21st meeting at BIPM, Paris on 11-13 June, 2013.

6.31 INSTITUTE FOR REFERENCE MATERIALS AND MEASUREMENTS (IRMM):

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

6.37 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST):

NIST is developing calibration materials for CRP and HSA for use with appropriate reference measurement procedures.

7.40 OTHER BUSINESS

CCLM Special Issue

The following SD Cs/WGs contributed to a special issue of CCLM to promote their work:

- Progress towards standardization: an IFCC Scientific Division Perspective (Editorial) – PG and IY.
- Recommendations for clinical laboratory science reports regarding properties, units, symbols: the NPU format. (C-NPU)
- External Quality Assessment Scheme for reference laboratories – review of 8 years' experience. (C-TLM)
- Utility of a panel of sera for the alignment of test results in the worldwide multicenter study on reference values. (C-RIDL)
- Protocol and standard operating procedures for common use in the worldwide multicenter study on reference values. (C-RIDL)
- Quantitative Clinical Chemistry Proteomics (qCCP) using mass spectrometry: general characteristics and application. (WG-cMSP)
- Analytical goals for the determination of HbA₂ (WG-SHbA₂)
- Glucose meters – fit for clinical purpose (WG-GPOCT)
- Defining acceptable limits for the metrological traceability of specific measurands. (WG-AETR)
- A reference system for urinary albumin: current status. (WG-SAU)
- Toward standardization of carbohydrate-deficient transferrin (CDT) measurements: III. Performance of native serum and serum spiked with disialotransferrin proves that harmonization of CDT assays is possible. (WG-CDT)

8.2 MAIN ACTIVITIES OF COMMITTEES:

8.2.6 C-NPU: An NPU stakeholder meeting was held in Copenhagen, April 18, 2013. Minutes of the meeting were circulated. The terminology database is now on the IFCC server and searchable via the web. Turkey has requested permission to translate the NPU codes into Turkish.

8.2.11 C-MD: The C-MD has been reorganized. The new Terms of Reference are: foster dynamic exchanges between IFCC and molecular diagnostic laboratories and industry; produce guidelines on clinical validation of tests, conduct and report on molecular diagnostic tests; provide reference materials; and create a network of locus-specific IFCC Molecular Diagnostics Centres.

8.2.21 C-RSE: The C-RSE continues to work on the development of a reference measurement procedure for pancreatic lipase. The C-RSE decided to proceed only with the DODG method for the following reasons:

- Promising results presented by the Japanese group indicating the possibility of method transferability (improvements in substrate preparation)
- Good analytical performances of the method

- Lack of interferences from Hb, bilirubin or turbidity
- Complete elimination of activity by heating the samples
- No interference from carboxyl esterase
- Reaction product monitored is well-defined with known molar absorptivity

The evaluation of commutability for ALT, LDH, and CK as CRMs is being done in collaboration with IRMM.

8.2.23 C-TLM: A meeting of the C-TLM was held in conjunction with the General Conference in Kuala Lumpur. Minutes of the Committee were distributed. JCTLM proposed that the JCTLM and IFCC RELA websites should promote each other, as their activities were closely related. C-TLM and the RELA organizer were asked to add the JCTLM logo and appropriate text explaining that "Participation in the RELA Scheme satisfies a requirement for JCTLM listing of Reference Measurement Services" to the IFCC RELA website. The link to the IFCC RELA webpage from the JCTLM webpage would need to be reorganized with some recent RELA information.

8.2.24 C-RIDL: The C-RIDL continues to work to establish regional reference intervals. These regional reference intervals should be traceable to reference measurement procedures where possible.

8.2.25 C-STFT: The C-STFT continues to work on an approach for using an all-procedure trimmed mean of results for standardization purposes in place of a reference measurement procedure where one does not exist. A proof-of-concept paper has been written and is accepted for publication in Clinical Chemistry and Laboratory Medicine. In place of a reference material, a panel of patient samples that are value assigned by the all-procedure trimmed mean will be used.

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 continues to work to develop a reference method for CDT. A meeting of the WG-CDT was held October 22, 2012 in Amsterdam/Schiphol Airport. Minutes of the meeting were distributed. The Study 4 results have been summarized and submitted to Clinical Chemistry on behalf of the WG. A study (Study 5) was undertaken to confirm the harmonization potential of lyophilized and frozen calibrators determined in Study 4.

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. A manuscript "State of the Art for Measurement of Urine Albumin: Comparison of Routine Measurement Procedures to Isotope Dilution Tandem Mass Spectrometry" has been reviewed by SD and will be submitted to Clinical Chemistry.

8.3.40 WG-PAPPA: 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). Results from one of the companies were clearly out-of-line in comparison to those of the other companies; additional tests were performed by the Division of Biotechnology, University of Turku (DBUT) using the reagent combinations obtained from the discrepant company. The discrepant results could not be reproduced. It may require the outlier manufacturer to reformulate its assay.

8.3.42 WG-SIA: Establishment of insulin RMP is on-going.

8.3.43 WG-Tnl: The Troponin and Natriuretic Peptide tables on the IFCC website will continue to be updated by the WG-TNI. The WG proposes that results for serum troponin be reported in whole numbers and use nanogram per litre as the unit of measure which is acceptable to the Systeme Internationale.

8.3.44 WG-AETR: The WG-AETR is organizing a workshop on allowable errors for traceable results for the APFCB Congress to be held in Bali in October, 2013.

8.3.45 WG-HAT: A meeting of the WG-HAT was held on March 1, 2013 in Brussels. Minutes from the meeting were distributed. The WG has concentrated on developing materials for IgG antibodies

to myeloperoxidase and running a preliminary commutability study. Results indicate generally good agreement between the majority of methods evaluated. A mini-commutability study is planned to check the lyophilization and liquid frozen preparations on the material for IgG antibodies to cardiolipin and B2GP1 (PLM, SP).

8.3.47 WG–cMSP: The WG-cMSP prepared a review for CCLM on quantitative clinical chemistry proteomics. The WG continues to consider issues related to comparing mass spec methods with immunoassays available for measuring hepcidin and is it possible to establish a reference measurement procedure for hepcidin.

8.3.48 WG-PTH: The WG-PTH has undertaken preliminary work to assess the commutability of the 1st International Standard for Parathyroid Hormone (PTH) (WHO IS 95/646). WG determined criteria for sample selection for a commutability study.

8.3.49 WG–CSFP: The WG-CSFP has collected large amounts of CSF with the intent to develop a matrix-based reference material. Four laboratories (Waters, PPD, UPenn, and UGOT) are working on setting up an SRM based method for absolute quantification of A β in CSF with the aim to develop a reference method for this analyte. The overall aim of this pilot study is to do a first comparison of the different methods developed in the four laboratories.

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 α 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).

8.3.51 WG-COMM: This is a new WG created by the SD and approved by the IFCC EB. The Terms of Reference for the WG are as follows:

- Establish operating procedures for the formal assessment of the commutability of a reference material intended for use as a calibrator, trueness control or EQA sample, taking into account different measurement procedure properties and categories of traceability described in ISO 17511.
- Establish how to define the degree of commutability which is required for a given reference material, taking into account its intended use and the intended use of the measurand. The degree of commutability becomes the criteria used in the assessment process.
- Propose standard terminology to describe the degree of commutability of a reference material, taking into account its intended use.
- Provide guidance to manufacturers and laboratories about what information should be provided by manufacturers in relation to the commutability of reference materials used to establish the calibration traceability of a measurement procedure.
- Advise IFCC Committees and Working Groups on how to assess the commutability of materials on which they are working.
- Develop educational materials regarding commutability for manufacturers, laboratories and users of laboratory results.

8.19 MEETINGS

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

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