

## **SCIENTIFIC DIVISION**

# 48<sup>th</sup> MEETING Milano, ITALY (2011 10 07-08) MINUTES *(Final Draft)*

| Members:  | Abbr. | Term and Time of Office           |
|---|-------|-----------------------------------|
| lan YOUNG (UK) (Chair)                            | IY    | 1 <sup>st</sup> 2011 01 - 2013 12 |
| Philippe GILLERY (FR) (Vice-Chair)                | PG    | 1 <sup>st</sup> 2011 01 - 2013 12 |
| Gary MYERS (US) (Secretary)                       | GLM   | 1 <sup>st</sup> 2009 01 - 2011 12 |
| Giampaolo MERLINI (IT)                            | GM    | 1 <sup>st</sup> 2011 01 – 2013 12 |
| Lothar SIEKMANN (DE)                              | LS    | 2 <sup>nd</sup> 2009 01 - 2011 12 |
| Naotaka HAMASAKI (JP)                             | NH    | 1 <sup>st</sup> 2009 01 - 2011 12 |
| Joseph PASSARELLI (US) (Corporate Representative) | JP    | 1 <sup>st</sup> 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 48th MEETING, MILANO, ITALY, OCTOBER, 7 & 8, 2011.

**Present:** Ian Young (Chair), Philippe Gillery (Vice-Chair), Gary Myers (Secretary), Giampaolo Merlini, 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. Apologies from David Bunk (NIST Representative).

- **6.1 WORLD HEALTH ORGANIZATION (WHO):** PG will attend the October, 2011 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:** WG meetings were held in Atlanta, USA in conjunction with the AACC Annual Meeting. Working Groups will review new submissions in December. Neil Greenberg was recommended as the new Chair for ISOTC212 Working Group #2. **6.22.2 JCGM:** A meeting of JCGM WG-1was held May 24-27, 2011 at BIPM, Paris. Graham White attended as IFCC Representative to WG-1. The latest version of the VIM 3<sup>rd</sup> edition and GUM are available on the IFCC website.

### **6.22.3 BIPM Consultative Committees**

SD received no correspondence from CCQM or CCU.

**6.31 INSTITUTE FOR REFERENCE MATERIALS AND MEASUREMENTS (IRMM):** IRMM waiting for finalized reference method for HbA2 before providing HbA2 reference material.

#### 6.37 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST):

Recently released SRMs by NIST include: SRM 968e, Fat soluble Vitamins and Carotenoids, August 2011; SRM 1950, Metabolites in human plasma, August 2011. SRM 3951 (Vitamin B12), SRM 900a (Antiepilepsy Drugs), SRM 3667 (creatinine in urine), and SRM 1951c (lipids in frozen human serum) are scheduled for possible release in late 2011. SRM 972a (Vitamin D in human serum) and SRM 2972a (25-Hydroxyvitamin D2 and D3 calibration solutions) are scheduled for 2012.

#### **8.2 MAIN ACTIVITIES OF COMMITTEES:**

- **8.2.6 C-NPU:** A manuscript entitled "Vocabulary for nominal properties and nominal examinations-Basic and general concepts and associated terms" adopted by IUPAC was put out for review. The document has been submitted to *Pure and Applied Chemistry* for publication. SD was under the impression that the document would be published in CCLM as a discussion document only. Extension of 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.
- **8.2.11 C-MD:** C-MD held a meeting May 16-17, 2011 in conjunction with the IFCC WorldLab Congress in Berlin, Germany.
- **8.2.13 C-PP:** C-PP has been closed. Members of the C were invited to propose the formation of WGs to take forward specific tasks of the C. A proposal to form a WG for the development and preparation of a new international reference material for cerebrospinal fluid proteins was approved. The aim of this project will be to develop an international reference material for cerebrospinal fluid (CSF).
- **8.2.21 C-RSE:** The C-RSE met on May 17, 2011 in conjunction with the IFCC WorldLab Congress in Berlin, Germany. The ALP method (IFCC Primary Reference Procedures for the Measurement of Catalytic Activity Concentrations of Enzymes at 37 °C. Part 9. Reference Procedure for the Measurement of Catalytic Concentration of Alkaline Phosphatase) was approved by the IFCC member societies via mail ballot and the manuscript was sent to CCLM for publication. The C-RSE continues to work on analytical issues related to the development of an RMP for lipase.
- **8.2.23 C-TLM:** The C-TLM met on May 16, 2011 in conjunction with the IFCC WorldLab Congress in Berlin, Germany. The committee reviewed the RELA Statistics available on the RELA website and also the extent of global participation in the RELA program. The C-TLM deliberations with respect to levels of equivalence are on-going.
- **8.2.24 C-RIDL:** The C-RIDL met on May 15, 2011 in conjunction with the IFCC World Lab Congress in Berlin, Germany. A meeting of the C-RIDL was held in July 2011 in conjunction with the AACC meeting in Atlanta, USA. The Committee agreed on a common collection protocol so that sample collection can proceed. The Committee agreed to bypass global reference intervals in favour of regional reference intervals following a common protocol.

#### 8.3 MAIN ACTIVITIES OF WORKING GROUPS:

- **8.3.33 WG-STFT:** The WG-STFT held a meeting on July 26, 2011 in conjunction with the AACC Meeting in Atlanta, USA. The IFCC international conventional reference measurement procedure (RMP) for serum FT4 has been approved by the IFCC SD and EB. The manuscript will be published in *Clinical Chemistry and Laboratory Medicine*. In parallel, the FT4 conventional RMP has been submitted to voting by the IFCC National Society members. SD approved the closure of the WG-STFT at the end of 2011 and the formation of a committee on thyroid function .
- **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 release the HbA2 reference material.
- **8.3.36 WG-CDT:** The WG-CDT met on May 18, 2011in conjunction with the IFCC WorldLab Congress in Berlin, Germany. The WG-CDT continues to work on the evaluation of the HPLC candidate reference measurement procedure for CDT measurement. A draft manuscript describing the HPLC candidate reference method is in preparation.
- **8.3.37 WG-SCC:** The WG-SCC met on May 17, 2011 in conjunction with the IFCC WorldLab Congress in Berlin, Germany. The WG-SCC, in cooperation with major diagnostic companies, is working to establish a method-independent cystatin C-based GFR-prediction equation, using samples from 4000 patients with known GFR. In this process they are also studying if specific GFR-prediction equations are required for specific subgroups of patients (or healthy persons).
- **8.3.38 WG-GFRA:** The WG-GFRA participated in a joint meeting of the NKDEP Lab Working Group held on July 28, 2011 at the AACC meeting in Atlanta, USA. The WG is awaiting editorial/reviewer comments on Draft #2 of the creatinine measurement specificity study manuscript submitted to *Clinical Chemistry*.
- **8.3.39 WG-SAU:** The WG-SAU participated in a joint meeting of the NKDEP Laboratory Working Group on July 28, 2011 held at the AACC meeting in Atlanta, USA. The WG is focusing on the following projects: harmonization of urine albumin assay methods and development of a urine albumin reference measurement procedure.
- **8.3.40 WG-PAPPA:** WG-PAPPA proposed plan for standardization of PAPPA has progressed slowly. The WG finally secured participation of five companies (including funding and reagents). A project agreement was made between IFCC and the University of Turku, Finland. Company antibodies (2/company) + 8 index antibodies from Hytest (selected from a previous epitope map study) were tested in all two-site combinations: 18 Mabs 324 combinations.
- **8.3.41 WG-GH:** WG-GH has made very limited progress. WG will be terminated. **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-TnI:** The WG-TNI met on July 25, 2011 in conjunction with the AACC Meeting in Atlanta, USA. A POINT/COUNTERPOINT article concerning troponin I standardization appeared in *Clinical Chemistry* online September 22, 2011 –POINT-Put Simply, Standardization of Cardiac Troponin I Is Complicated. Robert H. Christenson, David M. Bunk, Heinz Schimmel, and Jillian R. Tate, on behalf of the IFCC Working Group on Standardization of Troponin I COUNTERPOINT Standardization of Cardiac Troponin I Assays Will Not Occur in My Lifetime. Fred S. Apple. The articles are planned for publication in the January 2012 issue of *Clinical Chemistry*.
- **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:** The WG-HAT has concentrated on developing materials for IgG antibodies to myeloperoxidase and running a preliminary commutability study. The IRMM produced 18 candidate materials in total a combination of different plasmaphoresis samples and affinity purified IgG antibodies to myeloperoxidase and prepared in a variety of ways. This was specifically to address the impact of preservatives, freeze drying, and freezing.
- **8.3.46 WG-GPOCT:** The WG-GPOCT held its first meeting on May 18, 2011 in conjunction with IFCC World Lab meeting in Berlin, Germany. The WG will focus on glucose testing performed in the intensive care/critical care unit. This setting was chosen first as it potentially poses the highest risk to patients if not performed properly. The WG meeting in July 27, 2011 in conjunction with the AACC meeting in Atlanta, USA. The WG meeting included representatives from the US FDA and CLSI to discuss POCT glucose quality specifications.
- **8.3.47 WG cMSP:** This is a newly created WG. The WG met on May 19, 2011 in conjunction with the IFCC WorldLab in Berlin, Germany. The goal of the WG that is composed of members with strong links with clinical practice is to move mass spectrometry to a maturity needed for clinical application.

#### 8.19 MEETINGS

8.19.48 48<sup>th</sup> SD meeting, Milano, Italy. October 7-8, 2011

8.19.49 49<sup>th</sup> SD Meeting, Marrakech, Morocco, April 30-May 1, 2012, under review based on issues in Middle East.

8.19.50 50<sup>th</sup> SD Meeting – Kuala Lumpur, Malaysia, 16-17 November, 2012.