EXECUTIVE SUMMARY - SCIENTIFIC DIVISION 49th MEETING, MARRAKECH, MOROCCO, APRIL 30-MAY1, 2012.

Present: Ian Young (Chair) April 30 only, 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. Apologies from Giampaolo Merlini

6.1 WORLD HEALTH ORGANIZATION (WHO): PG attended 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: May will begin the next request cycle for reference materials and reference methods for consideration by JCTLM. Important criteria for reference methods will be whether the method has been published in a peer-reviewed journal. For reference materials an important criterion will be whether the material has been evaluated for commutability and that there is a statement of commutability in line with its intended use.

6.22.2 JCGM: A meeting of JCGM WG-1 was held November 29-December 2, 2011 at BIPM, Paris. Graham White attended as IFCC representative to WG-1. A meeting of JCGM WG-2 was held December 5-6, 2011 at BIPM, Paris. Francois Pontet attended as IFCC representative to WG-2. The latest version of the VIM 3rd 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 is currently working on replacement materials for LD, CK and ALT. IRMM is waiting for finalized reference method for HbA2 before providing HbA2 reference material. A panel of calibrator solutions for HbA1c is in the process of being prepared.

6.37 NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY (NIST):
Recently released SRMs by NIST include: SRM 900a (Antiepilepsy Drugs), December 2011 SRM 3951 (Vitamin B12), SRM 3667 (creatinine in urine), SRM 1951c (lipids in frozen human serum) SRM 972a (Vitamin D in human serum), SRM 2972a (25-Hydroxyvitamin D2 and D3 calibration solutions) and SRM 927e (Bovine Serum Albumin -7% solution) are scheduled for 2012.

8.2 MAIN ACTIVITIES OF COMMITTEES:

8.2.6 C-NPU: IFCC continues to work on an MOU between IFCC, IUPAC, C-SC-NPU, and the Danish Board of Health. The purpose of this MOU is to support and ensure the maintenance, availability and development of the international NPU terminology for laboratory information and to clearly identify the roles and responsibilities of each party as they relate to the ownership, development and maintenance of the NPU database, NPU terminology and products thereof. The database is now on the IFCC server and searchable via the web. 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.

8.2.21 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 ALP method was approved by the IFCC member societies via mail ballot and the manuscript was sent to CCLM for publication and also sent to the JCTLM to be enlisted into the approved reference measurement procedure list.

8.2.23 C-TLM: The C-TLM is preparing a publication for the special issue of CCLM: 10 years of RELA - A Review; description of the scheme and discussion of the development. The C-TLM identified a problem with glucose in the 2011 RELA and has distributed new samples for glucose to evaluate the problem.

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 Committee on Standardization of Thyroid Function Tests (C-STFT) is a new committee. C-STFT’s current work involves a method comparison study for FT4 and TSH measurement in clinical samples; FT4 measurements to be assessed against the conventional reference measurement procedure, TSH against the all-procedure trimmed mean.

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.

8.3.36 WG-CDT: 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.

8.3.39 WG-SAÜ: 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: In results from the Phase I study company kit epitopes were successfully and unambiguously identified in relation to the reference antibodies used. Four companies do not differentiate between the free and complexed form of PAPP-A. Several-fold differences in signal intensity occur between the different assays (Note! Using the Univ Turku test technology) yet all assays appear sufficient regarding required detection limits.
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:** WG-TnI standardization activities planned in 2012 include: 1) a cTnI pilot study to investigate method comparability of the cRMP versus current commercial cTnI assays (up to 22 cTn methods), 2) a commutability study of serum-based materials, and a stability study will be conducted at NIST, and 3) development of plans to prepare the reference material and determine the method of value assignment.

8.3.44 **WG-AETR:** The WG-AETR is to define clinically acceptable limits for the metrological traceability of specific analytes. The WG has been working on combining a statistical approach with biological variation using two statistical approaches based on probability theory.

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 plasmapheresis 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 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. SD recommended that WG-GPOCT should be closed at the end of 2012 and work efforts incorporated into the new IFCC TF on Point of Care Testing.

8.3.47 **WG-cMSP:** The WG-cMSP will prepare a review for CCLM on quantitative clinical proteomics. They want to start a trial 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 on Serum Parathyroid Hormone (WG-sPTH) is a new WG established by the SD. The Terms of Reference include the following: 1. Collaborative educational effort to encourage worldwide implementation of PTH IS 95/646 and to assess the effect of this on between-method agreement, 2. Definition of inclusion / exclusion requirements for an appropriate panel of sera and plasma with which to establish reference intervals and establishment of such a panel with support from the clinical community and diagnostics’ manufacturers, and 3. Development of a reference measurement procedure for PTH(1-84) to a standard that would enable its adoption by the IFCC reference laboratory network.

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 Ia1 chains containing the epitope Glu-Lys-Ala-His-Asp-ß-Gly-Gly-Arg in an isomerised form (also known as serum Crosslaps (CTx)) and the serum assay for N-terminal Propeptide of Type I Procollagen (P1NP).

8.19 **MEETINGS**

8.19.49 49th SD Meeting, Marrakech, Morocco, April 30-May 1, 2012.

8.19.50 50th SD Meeting – Kuala Lumpur, Malaysia, 16-17 November, 2012 (C/WG Chairs to participate in SD meeting to provide update on C/WG activities).

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

8.19.52 52nd SD Meeting – Bali, Indonesia, October 4-5, 2013