Members:

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<tr>
<th>Name</th>
<th>Abbr.</th>
<th>Term and Time of Office</th>
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<tr>
<td>Ian YOUNG (UK) (Chair)</td>
<td>IY</td>
<td>1st 2011 01 - 2013 12</td>
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<td>Philippe GILLERY (FR) (Vice-Chair)</td>
<td>PG</td>
<td>1st 2011 01 - 2013 12</td>
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<td>Gary MYERS (US) (Secretary)</td>
<td>GLM</td>
<td>1st 2009 01 - 2011 12</td>
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<td>Giampaolo MERLINI (IT)</td>
<td>GM</td>
<td>1st 2011 01 – 2013 12</td>
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<td>Lothar SIEKMANN (DE)</td>
<td>LS</td>
<td>2nd 2009 01 - 2011 12</td>
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<td>Naotaka HAMASAKI (JP)</td>
<td>NH</td>
<td>1st 2009 01 - 2011 12</td>
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<td>Joseph PASSARELLI (US) (Corporate Representative)</td>
<td>JP</td>
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<td>David BUNK (NIST Representative)</td>
<td>DB</td>
<td>Consultant</td>
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<td>Heinz SCHIMMEL (IRMM Representative)</td>
<td>HS</td>
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<td>Mathias MÜLLER (JCTLM Representative)</td>
<td>MM</td>
<td>Consultant</td>
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EXECUTIVE SUMMARY - SCIENTIFIC DIVISION 47th MEETING, BERLIN, GERMANY, MAY, 14 &15, 2011.

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

**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:** The 9th meeting of the JCTLM Executive Committee was held December 2-3, 2010. LS was accepted as the new IFCC representative to the JCTLM Executive Committee.
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**

A meeting of JCGM WG-2 VIM was held November 29-30, 2010 at BIPM, Paris.

### 6.31 INSTITUTE FOR REFERENCE MATERIALS AND MEASUREMENTS (IRMM):

IRMM completed a larger commutability study of ERM-DA471/IFCC Cystatin C material. Overall the CRM turned out to be commutable with the majority of the assays. Commutability issues with one assay in the larger study were similar to those observed in smaller pilot study.

HbA2 - Waiting for finalized reference method for HbA2 before providing HbA2 reference material.

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


8.2 **MAIN ACTIVITIES OF COMMITTEES:**

8.2.6 **C-NPU:** The Executive Board agreed to support transfer of the database to be maintained by IFCC.

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 has been closed, and remaining tasks will be addressed by the establishment of relevant working groups. Possible projects include: preparation of a new international reference material for cerebrospinal fluid proteins, standardization of the Serum Soluble Transferrin Receptor, and measurement of serum free light chains.

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. Completed manuscript titled: 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.

8.2.23 **C-TLM:** The C-TLM deliberations with respect to levels of equivalence are ongoing. A new Term of Reference was proposed to evaluate the relationship between an RMP value and results from PT survey.

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:** WG-STFT prepared a manuscript describing a conventional reference procedure for the measurement of free thyroxine in serum.

8.3.35 **WG-HbA2:** WG-HbA2 will prepare a new batch of pilot material that is free of oxygen in vials. The first pilot batch of reference material had problems with oxygen in vials causing oxidation at higher temperatures.

8.3.36 **WG-CDT:** The WG-CDT prepared a draft document regarding the ISO 15193 requirements for reference method procedures which will serve as a basis for a publication with the working title “Validation of the IFCC HPLC reference method for CDT measurement”.

8.3.37 **WG-SCC:** 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 4050 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:** WG-GFRA is completing a 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 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 very slowly. The WG continues to wait on company assistance.

8.3.41 WG-GH: WG-GH has made very limited progress.

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

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-TNII 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.

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