

**DECLARATION OF COOPERATION BETWEEN  
THE CIPM, IFCC AND ILAC,  
FOR THE ESTABLISHMENT OF A JOINT COMMITTEE FOR  
TRACEABILITY IN LABORATORY MEDICINE (JCTLM)**

The International Committee of Weights and Measures<sup>†</sup> (CIPM), the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC) agree to cooperate to establish a Joint Committee for Traceability in Laboratory Medicine, with the acronym JCTLM.

The goal of the JCTLM is to provide a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

<sup>†</sup> For the purposes of this Declaration the International Committee of Weights and Measures (CIPM) will be represented by the International Bureau of Weights and Measures (BIPM).

**JCTLM Mission Statement:**

The aim of the Joint Committee is to support world-wide comparability, reliability and equivalence of measurement results in Laboratory Medicine, for the purpose of improving health care and facilitating national and international trade in *in vitro* diagnostic devices, by:

- promoting the concept of traceability of measurement results to the Système International d'Unités (SI) or, where necessary, to other internationally agreed references;
- promoting close links between Reference Laboratories in Laboratory Medicine and National Metrology Institutes;
- coordinating and giving guidance in the establishment of Reference Measurement Systems with respect to medical needs;
- identifying and prioritizing the measurands requiring international traceability and comparability and thereby encouraging appropriate organizations to accept responsibility for the development of suitable reference methods and measurement procedures and certified reference materials;
- encouraging the in-vitro diagnostic (IVD) industry to apply the agreed reference measurement systems;
- encouraging EQAS organizers to apply the agreed reference measurement systems;
- providing support for Reference Laboratories preparing for accreditation;
- publicising widely relevant information to interested parties;
- providing scientific and organizational expertise to the parties involved.

**JCTLM Structure and Operation:**

1. The JCTLM has been created through this Declaration of Cooperation between the CIPM, IFCC and ILAC.

2. The work of the JCTLM shall be based on existing international or inter-governmental agreements and the JCTLM will operate by consensus.
3. The operation of the JCTLM will be overseen by its Executive which will comprise nominated representatives of the BIPM, IFCC and ILAC. For the first two years, the Chairman will be from IFCC, and the Secretariat from the BIPM.
4. The role of the Secretariat will include: the calling of meetings; preparation of agendas and action lists; and the maintenance of the JCTLM databases and website.
5. Costs of involvement in JCTLM activities will be met where they arise and will be the responsibility of each participating body; there will, for the time being, be no JCTLM budget.
6. Membership status of the JCTLM is open to those organizations that fulfill the criteria described in Appendix IV. Present Members of the JCTLM are listed in Appendix I<sup>††</sup>.
7. Organizations wishing to apply for Member status of the JCTLM, having consulted Appendix IV, may do so by contacting the JCTLM Secretariat.
8. The JCTLM Executive will establish Working Groups to undertake the activities within its Mission Statement. The Chairs of the Working Groups are invited to participate in meetings of the JCTLM Executive, at the discretion of the Executive. Expert membership of the Working Groups will be drawn from organizations that are Member organizations of the JCTLM. Expert observers can be invited from other organisations that are not members of the JCTLM. Details of established Working Groups are given in Appendix II<sup>††</sup>.
9. The JCTLM will establish a Framework for the international recognition of available higher-order reference materials and higher-order reference measurement procedures as well as reference measurement laboratories for laboratory medicine.(Appendix III)

<sup>††</sup> Updated versions of Appendices I and II will be maintained on the JCTLM website.

### **Revision and Termination of the Declaration**

1. The Declaration shall be subject to revision by agreement between the BIPM, IFCC and ILAC.
2. This Declaration may be terminated by any of the three parties, with written notice given six months in advance of the termination date.

### **Entry into Force**

The Declaration of Cooperation shall come into force upon its signature by all three parties.

Signed on behalf of:

BIPM

IFCC

ILAC

## Appendix 1

### JCTLM Members

Advanced Medical Technology Association [AdvaMed], Washington  
American Association for Clinical Chemistry [AACCC], Washington  
Centers for Disease Control and Prevention [CDC], Atlanta  
Chemical Science and Technology Laboratory of the NIST [NIST CSTL], Gaithersburg  
Clinical and Laboratory Standards Institute [NCCLS], Wayne  
European Committee For External Quality Assurance Programmes in Laboratory Medicine [EQALM]  
European Diagnostic Manufacturers Association [EDMA], Brussels  
HECTEF Standard Reference Center, Foundation Ltd [HECTEF Foundation], Kanagawa  
Institute for Reference Materials and Measurements [IRMM], Geel  
Institution for Standardisation and Documentation in the Medical Laboratory [INSTAND e.V.],  
Düsseldorf  
Japan Association of Clinical Reagents Industries [JACRI], Tokyo  
Japanese Committee for Clinical Laboratory Standards [JCCLS], Tokyo  
Korea Research Institute of Standards and Science [KRISS], Daejeon  
Laboratoire national de métrologie et d'essais [LNE], Paris  
Laboratory of the Government Chemist [LGC], Teddington  
National Association of Testing Authorities [NATA], Rhodes  
National Institute for Biological Standards and Control [NIBSC], Hertfordshire  
National Institute of Metrology [NIM], Beijing  
National Metrology Institute of Japan, AIST [NMIJ/AIST], Tsukuba  
Paul-Ehrlich-Institut [PEI], Langen  
Physikalisch-Technische Bundesanstalt [PTB], Braunschweig  
RCPA Quality Assurance Programs Pty Limited [RCPA QAP], Surry Hills  
Reference Institute of Bioanalysis [RfB], Bonn

## **Appendix II**

### **JCTLM Working Groups**

#### **Working Group 1: Reference Materials and Reference Procedures**

**Chair: NIST (W. May) and IRMM (H. Schimmel)**

#### **Working Group 2: Reference Measurement Laboratories**

**Chair: IFCC (Institut für Klinische Biochemie – L. Siekmann, University of Gent – L. Thienpont)**

## Appendix III

### **The JCTLM Framework: A Framework for the international recognition of available higher-order reference materials, available higher-order reference measurement procedures and reference measurement laboratories for laboratory medicine**

#### **Preamble**

In response to the need to establish lists of available higher-order reference materials, available higher-order reference measurement procedures and reference measurement laboratories for laboratory medicine, a Joint Committee for Traceability in Laboratory Medicine (JCTLM) has been formed. Its Executive, made up of representatives from the BIPM, IFCC and ILAC, oversees the Joint Committee. With the creation of the JCTLM a Framework has been established which can be used for the international recognition of such materials, procedures and laboratories.

#### **The Framework**

The JCTLM Framework lays down a process whereby reference materials and reference measurement procedures are examined with respect to conformity with appropriate international documentary standards, and whereby reference material properties are verified by measurements made in institutes with demonstrated competence in the field.

The outputs of the Framework are databases of available higher-order reference materials and higher-order reference measurement procedures as well as reference laboratories that can be used by the IVD industry and other users to meet requirements for traceability for *in vitro* diagnostic and laboratory medicine measurements.

#### **The Process, Technical Basis and Procedures**

The technical basis of the process is:

- (a) the evaluation by the JCTLM Working Groups of nominated reference materials and reference measurement procedures and their implementation in reference measurement laboratories against relevant ISO Standards and Guides, and WHO Guidelines; and
- (b) measurements to demonstrate the comparability of reference materials, the properties of which are expressed in SI units or, if not yet possible, international units of the WHO or other internationally agreed units.

Where measurements are required, these will be carried out by laboratories that have previously demonstrated their competence through their performance in relevant

international comparisons, for example in the CIPM MRA key comparisons or the IFCC EQAS for Reference Laboratories.

The proper use of the higher-order reference materials and reference measurement procedures calls for the existence of networks of competent reference measurement laboratories for specified measurands. Such reference measurement laboratories will have demonstrated their technical competence in the operation of a reference measurement procedure of higher order for a given measurand with demonstrated traceability and measurement uncertainty. The technical competence of the laboratories shall be demonstrated by their performance in international comparisons, and their operation of an appropriate quality system. International recognition of the implementation of the quality system is achieved via accreditation or equivalent documented peer review.

Publication of the database of higher-order reference materials, reference measurement procedures and reference laboratories

**The higher-order reference materials, reference measurement procedures and reference laboratories that are endorsed by this process will be published in databases by the BIPM and the IFCC and will be publicly available on the BIPM and IFCC websites with links from other websites as necessary.**

Users of the Databases

The databases have been established for use by all interested parties, notably:

- IVD-industry
- quality assurance organizations in the field of laboratory medicine
- regulatory authorities
- international organizations
- NMIs and other producers of higher-order reference materials
- professional societies in the field of laboratory medicine

In using the data, users recognize the Framework that has been established to enable the development of these databases, and are advised to make reference to the JCTLM Framework and associated databases in any relevant documentation they produce.

### **Responsibility**

It is wholly the responsibility of the producers of the materials listed in the database that they meet their stated specifications and continue to be available, and not the responsibility of the JCTLM or the BIPM, IFCC or ILAC.

Responsibility for reference measurement procedures meeting their stated specifications remains with the laboratory that performs the measurement, and is not the responsibility of the JCTLM or the BIPM, IFCC or ILAC.

**This Framework is of an exclusively recommendatory nature. It will not create any binding legal effect in national and international law.**

## **Appendix IV: Participation of Organizations in the JCTLM**

### **Principles concerning the participation of Organizations in the JCTLM**

#### **Purpose**

The purpose of participation of organisations within the JCTLM is to secure for the Committee expert information and advice, and enable organizations which are authorities in their fields of professional and technical competence to express the views of their members in the Committee, and to play an appropriate role in providing a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

#### **Type of participation**

Only one type of participation shall be recognized, namely 'member'.

#### **Organizations eligible for 'member status'**

The following shall be eligible for Member Status:

- i) intergovernmental organizations having technical competence in the field;
- ii) national governmental organizations having technical competence in the field;
- iii) international, regional and national non-governmental organizations having technical competence in the field, that:
  - a) are representative of the specialized field of interest in which they operate;
  - b) are concerned with matters covering a part or all of the Committee's activities;
  - c) have a permanent directing body, authorized representatives and systematic procedures for communicating with its membership
- iv) Organizations that are signatories to the CIPM-MRA

#### **Procedure for obtaining 'member status'**

##### **Intergovernmental and governmental organizations**

Intergovernmental and governmental organizations should inform the Secretariat of the Committee of their desire to participate in the work of the Committee.

##### **CIPM-MRA signatories**

CIPM-MRA signatories should inform the Secretariat of the Committee of their desire to participate in the work of the Committee.

## **International, regional and national non-governmental organizations**

International, regional and national non-governmental organizations should inform the Secretariat of the Committee of their desire to participate in the work of the Committee, and supply the information outlined in the Annex to these procedures. The Secretariat shall transfer these to the Executive of the Committee. Upon confirmation that the organisation is in a position to make a significant contribution to advancing the purposes of the committee, 'member status' shall be granted.

### **Privileges of Member Status**

Organizations that are members of the Joint Committee:

- a. shall be entitled to send representatives to meetings of the full Joint Committee;
- b. shall receive information about meetings of the full Joint Committee and have access to all working documents and discussion papers of the full Joint Committee;
- c. shall be entitled to participate in working groups of the Joint Committee;
- d. shall be able to nominate members to the working groups of the Joint Committee, membership to be ratified by the Working Group Chair;
- e. may submit written statements, under the authority of its governing body, on matters before the Joint Committee, to the Secretariat, who may communicate them to the Joint Committee or its Executive as appropriate.

### **Review of Member Status**

The Executive may terminate an organization's 'member status' if it no longer meets the criteria for membership.

If an organization wishes to terminate its member status it shall inform the Secretariat of this in writing.

Annex: Information required of non-governmental organizations requesting 'member status'

1. Official name of the organization (with acronym).
2. Full postal address, Telephone, Telex address, Facsimile and Email as appropriate.
3. The name and contact details of the contact person(s) for the organization.
4. Aims and subject fields of the organization.
5. Member organizations (where applicable).
6. Structure (indicating the form of governing body).
7. Name function and address of the person providing the information.