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

The International Bureau of Weights and Measures (BIPM), 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.

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;
- evaluating reference materials, reference measurement procedures and reference measurement services for laboratory medicine with respect to conformity with appropriate international standards;
- producing educational materials and activities promoting the value of traceability in laboratory medicine and raising awareness amongst stakeholders;
- promoting close links between Reference Laboratories in Laboratory Medicine and National Metrology Institutes;
- facilitating the identification and prioritization of 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;

JCTLM Structure and Operation:

1. The JCTLM has been created through this Declaration of Cooperation between the BIPM, 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. The JCTLM Executive Committee is the impartial final decision making organ, only accountable to the Executive Committee Member Organizations. Additional Organizations can be invited to join the Executive Committee provided they fulfil the conditions set out in Appendix IV.

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. The operating budget for the JCTLM Secretariat will be presented and discussed between the sponsoring organizations at the annual Executive meeting preceding the year for which the budget is set.

6. Membership status of the JCTLM is open to those organizations that fulfill the criteria described in Appendix IV. Member Organizations of the JCTLM are listed in Appendix I††.

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 Member organizations of the JCTLM. Experts can be invited from other organizations that are not members of the JCTLM. Details of established Working Groups are given in Appendix II††.

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 services for laboratory medicine. (Appendix III)

†† Updated versions of Appendices I and II are 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.
Date and Signature

For the BIPM
Dr Martin Milton,

Date:

For the IFCC
Prof. Maurizio Ferrari,

Date:

For the ILAC
Mr Peter Unger

Date:
Appendix 1: JCTLM Members (BIPM Website)

Appendix II: JCTLM Working Groups (BIPM Website)
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 services for laboratory medicine, a Joint Committee for Traceability in Laboratory Medicine (JCTLM) has been formed. Its Executive oversees the Joint Committee, and is the impartial final decision making organ, only accountable to the Executive Committee Member Organizations. With the creation of the JCTLM a Framework has been established which can be used for the international recognition of such materials, procedures and measurement services from laboratories.

The Framework

The JCTLM Framework lays down a process whereby reference materials and reference measurement procedures and reference measurement services are examined with respect to conformity with appropriate international documentary standards.

The outputs of the Framework is a database of available higher-order reference materials and higher-order reference measurement procedures as well as reference measurement services provided by calibration (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 the evaluation by the JCTLM Database Working Group of nominated reference materials and reference measurement methods and their implementation in reference measurement laboratories against relevant international documentary standards.

The relevant standards with which compliance is evaluated are listed in the Quality Manual of the JCTLM Working Group, and the list updated when necessary.

The proper use of the higher-order reference materials and reference measurement procedures calls for the existence of competent calibration laboratories for specified measurands. Such calibration 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. The standards on which calibration laboratory accreditation is based are listed in the Quality Manual of the JCTLM Working Group, and the list updated when necessary.

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

The higher-order reference materials, reference measurement methods and reference measurement services that are endorsed by this process will be published in a database by the BIPM and will be publicly available with links from the IFCC website and other websites as necessary.

**Users of the Database**

The database has been established for use by all interested parties, including:

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

In using the data, users recognize the Framework that has been established to enable the development of the database, and are advised to make reference to the JCTLM and associated database 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 member organizations of the JCTLM Executive Committee.

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 member organizations of the JCTLM Executive Committee.

This Framework is of an exclusively recommendatory nature. It will not create any binding legal effect in national or 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 organizations within the JCTLM is to secure for the Committee expert information, advice and resources required to carry out its activities, including the tasks set for its Working Groups.

Participation enables 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
Organizations may be recognized in three different member designations within JCTLM. These are: JCTLM Executive Committee Member Organizations; JCTLM National and Regional Members; and JCTLM Stakeholder Members.

A. JCTLM Executive Committee Member Status
The JCTLM Executive Committee is the impartial final decision-making organ, only accountable to the Executive Committee Member Organizations.

The JCTLM Executive Committee establishes Working Groups to undertake the activities within the mission of the JCTLM; provides oversight of the processes to evaluate reference materials, reference measurement procedures and reference measurement services against appropriate international documentary standards; and promotes the value and use of the JCTLM database.

Organizations eligible for JCTLM Executive Committee Member Status
Intergovernmental and international non-governmental organizations and bodies having technical competence in the field or a subspecialty, 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

Note 1. The following organizations are founding members of JCTLM and currently constitute the Executive Committee:

a) BIPM
b) IFCC
c) ILAC

B. JCTLM National and Regional Member Status
The following organizations shall be eligible for JCTLM National and Regional Member Status:
National and regional organizations that adhere to and/or contribute to the activities of the intergovernmental and international non-governmental organizations that are members of the JCTLM Executive Committee and that have expertise in traceability in laboratory medicine and demonstrate a willingness to provide experts for JCTLM Working Groups and Review Teams.

Note 2. Eligible organizations can currently include:
   a) National and international metrology institutes and organizations that are signatories to the CIPM-MRA, or to Regional Metrology Organizations recognized by the CIPM
   b) National Laboratory Medicine Societies affiliated with IFCC
   c) Accreditation bodies that are signatories to the ILAC MRA for the relevant accreditation activities
   d) Recognized Regional Cooperation bodies whose regional MRA/MLA have been successfully peer evaluated by ILAC.

C. JCTLM Stakeholder Member Status
The following organizations shall be eligible for JCTLM Stakeholder Member Status:

   Properly constituted “non-profit” and “for-profit” organizations, with interest, expertise and a demonstrable record of working to reduce the between method variability in laboratory medicine measurements and a commitment to promote the JCTLM database and activities.

Note 3: Examples of organizations that may be eligible for JCTLM Stakeholder Member status include:

   a) National and regional organizations active in laboratory medicine
   b) EQAS providers
   c) Standards writing bodies
   d) In-vitro diagnostic instrument and reagent manufacturers
   e) Private laboratory organizations

Notification of JCTLM Executive Committee
Organizations should inform the Secretariat of the JCTLM Executive Committee (jctlm@bipm.org) 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 organization is in a position to make a significant contribution to advancing the purposes of the committee, the appropriate ‘member status’ shall be granted.

JCTLM National and Regional Members and JCTLM Stakeholder Members in particular are expected to actively and impartially contribute to the activities carried out by the JCTLM Working Groups.
The Benefits of JCTLM National and Regional Member Status and JCTLM Stakeholder Member Status

- Receipt of an annual report from JCTLM and updates of the JCTLM database
- Receipt of at least one JCTLM newsletter per year
- Notification of new listings on the JCTLM database of reference materials and reference measurement systems
- Invitation to Member’s Meetings
- Opportunities to run scientific or educational meetings under JCTLM auspices
- Access to all documents and discussion documents presented at the Members’ Meeting
- Opportunity to nominate individuals to serve on Working Groups and Review Teams where they have appropriate expertise
- Opportunity to be involved in education and public relations projects to promote the benefits of traceability in laboratory medicine
- Freedom to submit written documents to the Secretariat for consideration by the Executive Committee or at the Member’s Meeting
- Opportunity to comment on the Executive Committee reports and plans presented to the Members Meeting

The Relationship of Members to the Executive Committee

- All Members of JCTLM will be invited to attend the Members’ Meeting, which will be held once every two years, and submit a report of their activities in support of traceability in laboratory medicine over the preceding period.
- At each Members Meeting the JCTLM Executive will present a report on activities during the past two years and plans for the next two years.
- Members will be able to comment on the report and to pose questions on the plans for future activities

Organizational Responsibilities as JCTLM National and Regional Member Organization and JCTLM Stakeholder Member Organizations

- Members shall promote the concept of traceability of measurement results in Laboratory Medicine to the Système International d’Unités (SI) or, where necessary, to other internationally agreed references;
- Members shall work towards implementing reference measurements systems which are applicable to their activities;
- Members shall provide written reports on a biennial basis of their activities in the areas listed above, to be submitted to JCTLM Executive Committee a minimum of one calendar month prior to the annual meeting of the Executive Committee in the years that a report is due.
Financial Commitments of Membership

- There will be no membership fee for Members
- Members will be responsible for meeting the travel, accommodation and registration costs associated with attendance at the Members’ Meeting
- Where appropriate Members may make a financial donation to support the work of the JCTLM

Review of Member Status

- The Executive may terminate an organization’s ‘member status’ if it no longer meets the criteria for membership.
- The Executive may terminate an organization’s ‘member status’ if the organization’s activities are incompatible with the goals and mission of the JCTLM.
- The Executive may terminate an organization’s ‘member status’ if the organization does not participate in JCTLM activities.
- If an organization wishes to terminate its member status it shall inform the Secretariat of this in writing.

Annex: Information required of organizations requesting ‘JCTLM National and Regional Member status’ or ‘JCTLM Stakeholder 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. Summary of activities being undertaken by the organization to reduce the between method variability in laboratory medicine measurements
6. Description of any previous interaction/support of the JCTLM
7. Member organizations (where applicable).
8. Structure (indicating the form of governing body).
9. Name, function and address of the person providing the information.