

**DECLARATION OF COOPERATION BETWEEN
THE BIPM, IFCC AND ILAC,
FOR THE OPERATION OF
THE 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)**,

hereinafter referred to as the "Parties" collectively or the "Party" individually,

RECALLING that the Joint Committee for Traceability in Laboratory Medicine (JCTLM) was established in 2002 through a Declaration of Cooperation between the BIPM, IFCC and ILAC;

RECALLING the amendment of the Declaration of Cooperation in 2012, and its revision in April 2016, which foresaw increased membership of the JCTLM Executive Committee;

CONSIDERING that 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 metrological traceability to appropriate measurement standards;

HEREBY AGREE to cooperate towards achieving such goal and to work together to undertake the activities of the JCTLM.

I. JCTLM Mission Statement:

The aim of the JCTLM 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 metrological 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 metrological traceability in laboratory medicine and raising awareness amongst stakeholders;
- promoting close links between Calibration (Reference) Laboratories in Laboratory Medicine and National Metrology Institutes (NMIs);
- facilitating the identification and prioritization of measurands requiring international metrological 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.

II. JCTLM Structure and Operation:

1. The work of the JCTLM shall be based on existing international or intergovernmental agreements and the JCTLM will operate by consensus.
2. The operation of the JCTLM will be overseen by its Executive Committee which will comprise nominated representatives of the Parties and additional organizations that have acceded to the Executive Committee and are listed in Appendix I. Representatives are accountable to the Party or organization nominating them.
3. The JCTLM Executive Committee is the impartial final decision making organ. Additional organizations can be invited to join the JCTLM Executive Committee, *de facto* accepting the provisions of the present Declaration of Cooperation, provided that they fulfil the conditions set out in Appendix V.
4. The role of the JCTLM Secretariat will include the: (i) calling of meetings; (ii) preparation of agendas and action lists; and (iii) maintenance of the JCTLM database and website.
5. The operating budget for the JCTLM Secretariat will be presented and discussed between the Parties and other members of the JCTLM Executive Committee, at the annual meeting of the JCTLM Executive Committee preceding the year for which the budget is set.
6. Participation within the JCTLM is open to those organizations under the terms described in Appendix V. Members and Stakeholders of the JCTLM are listed in Appendix II.
7. Organizations wishing to participate in JCTLM activities, having consulted Appendix V, may do so by contacting the JCTLM Secretariat.
8. The JCTLM Executive Committee will establish Working Groups to undertake the activities within the JCTLM Mission Statement. The Chairs of the Working Groups may be invited by the JCTLM Executive Committee to participate in its meetings. Expert membership of the Working Groups will be drawn from Members 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 III.
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 IV).

III. Revision and Termination of the Declaration of Cooperation

The Declaration of Cooperation shall be subject to revision by agreement between the Parties.

This Declaration of Cooperation may be terminated by any of the Parties, with written notice given six (6) months in advance of the termination date.

IV. Entry into Force

The Declaration of Cooperation shall come into force upon its signature by all Parties. Previous versions of the Declaration of Cooperation, including previous appendixes, are hereby revoked.

Date and Signature

For the BIPM

Date

For the IFCC

Date

For the ILAC

Date

Appendix I: JCTLM Executive Committee Members (BIPM Website)

Appendix II: JCTLM Members (BIPM website)

Appendix III: JCTLM Working Groups (BIPM website)

Note: Updated versions of Appendices I, II and III are maintained on the JCTLM webpage of the BIPM website.

Appendix IV

The JCTLM Framework: A Framework for the international recognition of available higher-order reference materials, available higher-order reference measurement procedures and calibration (reference) 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 Committee oversees the JCTLM, and is the impartial final decision making organ. 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.

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 output 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 metrological traceability for in vitro diagnostic and laboratory medicine measurements.

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 metrological 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 JCTLM Database

The JCTLM 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 JCTLM Executive Committee Member.

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 JCTLM Executive Committee Member.

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

Appendix V: Participation of organizations in the JCTLM

Principles concerning participation of organizations in the JCTLM

I. Purpose of JCTLM participation

The purpose is to secure for the JCTLM 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 JCTLM, 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 metrological traceability to appropriate measurement standards.

II. Type of JCTLM participation

Organizations may apply for JCTLM membership as follows:

- JCTLM Executive Committee Member;
- 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. Representatives are accountable to the organization nominating them.

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.

The organizations eligible for JCTLM Executive Committee Member status are 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 JCTLM's activities;
- c) have a permanent directing body, authorized representatives and systematic procedures for communicating with its membership

The organizations that currently constitute the JCTLM Executive Committee are listed in Appendix I

Other organizations can be invited to join the JCTLM Executive Committee. The JCTLM Executive Committee shall establish the necessary procedures for accession to and exclusion from the JCTLM Executive Committee.

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 metrological traceability in laboratory medicine and demonstrate a willingness to provide experts for JCTLM Working Groups and Review Teams.

Eligible organizations may 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; or
- 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.

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.

III. Notification of the JCTLM Executive Committee

Organizations should inform the JCTLM Secretariat (jctlm@bipm.org) of their desire to participate in the work of the JCTLM, and supply the information outlined below:

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. Members (where applicable).
8. Structure (indicating the form of governing body).
9. Name, function and address of the person providing the information.

The JCTLM Secretariat shall transfer these to the JCTLM Executive 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.

IV. 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 meetings of JCTLM Members and Stakeholders
- Opportunities to run scientific or educational meetings under JCTLM auspices
- Access to all documents and discussion documents presented at meetings of JCTLM Members and Stakeholders
- 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 metrological traceability in laboratory medicine
- Freedom to submit written documents to the JCTLM Secretariat for consideration by the JCTLM Executive Committee or at meetings of JCTLM Members and Stakeholders
- Opportunity to comment on the JCTLM Executive Committee reports and plans presented to meetings of JCTLM Members and Stakeholders

V. Meetings and relationship of Members and Stakeholders with the JCTLM Executive Committee

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

VI. Organizational responsibilities as JCTLM National and Regional Member and JCTLM Stakeholder Member

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

- 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.

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VII. Financial commitments of membership

- There will be no membership fee for JCTLM Members
- JCTLM National and Regional Members and JCTLM Stakeholder Members will be responsible for all travel, accommodation and registration costs associated with attendance at the meeting of JCTLM Members and Stakeholders
- Where appropriate, JCTLM Members may make a financial contribution to support the work of the JCTLM

VIII. Review of JCTLM participation

The JCTLM Executive Committee shall establish the necessary procedures for accession to, and termination of, JCTLM participation.

- The JCTLM Executive Committee Member status may be terminated by a decision of the JCTLM Executive Committee taken by majority of its members if the organization:
 - no longer meets the criteria for membership;
 - activities are incompatible with the goals and mission of the JCTLM; or
 - does not participate in JCTLM activities.
- If an organization wishes to terminate its membership within the JCTLM Executive Committee it shall inform the JCTLM Secretariat in writing within six (6) months prior of the termination date.
- The JCTLM National and Regional Member or JCTLM Stakeholder Member status may be terminated by a decision of the JCTLM Executive Committee taken by the majority of its members if the organization:
 - no longer meets the criteria for membership;
 - activities are incompatible with the goals and mission of the JCTLM; or
 - does not participate in JCTLM activities.

The JCTLM Secretariat shall inform Parties to the Declaration of Cooperation, in writing, about any decision to terminate JCTLM participation.