

JCTLM – Looking to the Future

Organization and Governance Update

Gary L. Myers, PhD
Chair, JCTLM Executive Committee

Presented at the JCTLM Members' and Stakeholders' Meeting

98/79/EC of 27 October 1998 on in vitro diagnostic medical devices

"The traceability of values assigned to calibrators and/or control materials must be assured through available reference measurement procedures and/or available reference materials of a higher order.. "

**Annex I - Essential Requirements
Part A. General Requirements, Clause 3**

JCTLM Formation

The JCTLM was created in 2002 in response to the implementation of the European Community Directive 98/79/EC on *in vitro* medical devices.

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

JCTLM Formation

JCTLM: Sponsoring Organizations



Intergovernmental Treaty Organization for Measurement Standards (**JCTLM Secretariat**)



International NGO for National Associations in Laboratory Medicine



International NGO for Accreditation Bodies

What has JCTLM Provided?

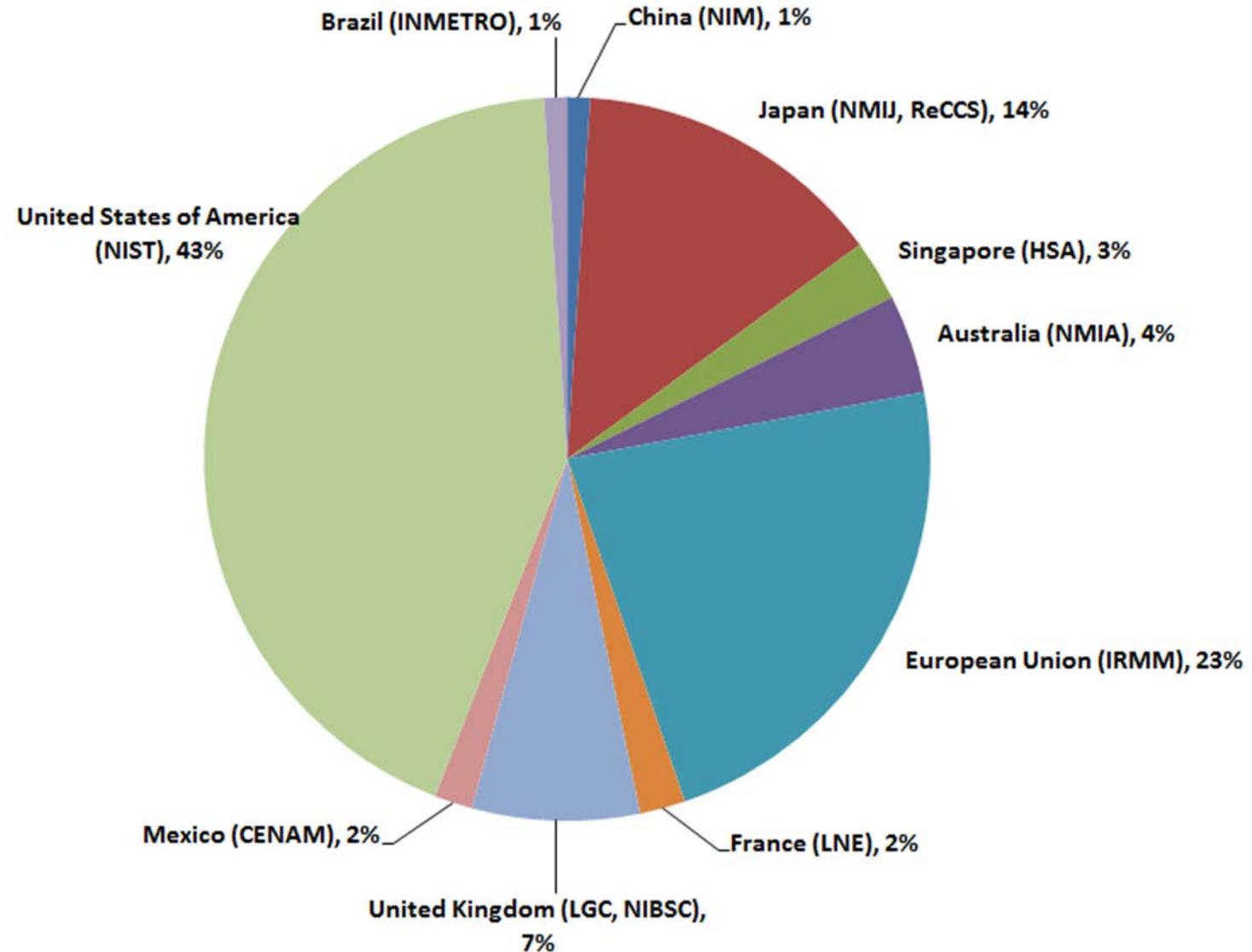
- **JCTLM** through **BIPM** developed and maintains a database of **Reference Measurement Systems** <http://www.bipm.org/jctlm/>
- Coordinates the nomination and review process for database entries

JCTLM database was developed to help the IVD industry meet metrological traceability requirements of the EU IVD Directive

Database Contains:

- **295 Certified Reference Materials**
- **170 Reference Measurement Procedures**
- **130 Reference Measurement Services**

Source (country of origin) of CRMs in JCTLM Database



- Raise awareness of JCTLM Reference Measurement Systems Database and importance of traceability
 - Established a WG on Traceability: Education and Promotion
 - ✓ **Purpose:** To produce and promote educational materials to demonstrate the value of traceability in laboratory medicine as a means to reduce between method variability in the interests of improved clinical outcomes and patient safety.
 - ✓ Graham Beastall – WG Chair



- Raise awareness of JCTLM Reference Measurement Systems Database and importance of traceability
- Review and update JCTLM Governance
 - Established an ad-hoc WG to review and update JCTLM governance

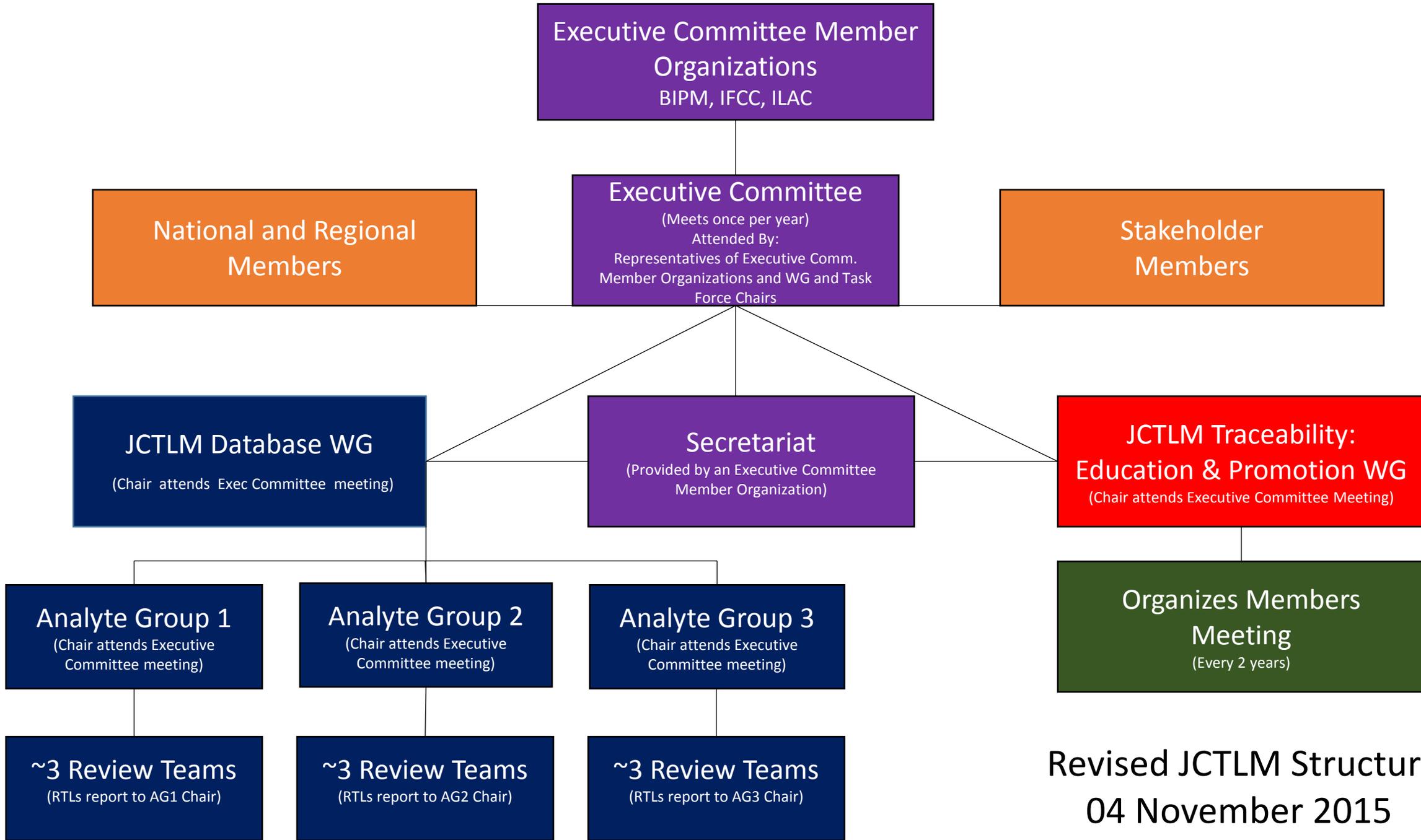


- Review and update JCTLM Governance
 - JCTLM Executive Committee Organizations
 - ✓ Expand EC to include other disciplines in lab medicine
 - JCTLM Member Organizations
 - ✓ Created new JCTLM Stakeholder Member category
 - ✓ Now three different member designations within JCTLM.
 - JCTLM Executive Committee Member Organizations
 - JCTLM National and Regional Members
 - JCTLM Stakeholder Members (New)



- JCTLM Member Organizations
 - ❖ JCTLM Executive Committee Member Organizations
 - ✓ International governmental and non-governmental organizations and bodies having technical competence in the field or a subspecialty
 - ❖ JCTLM National and Regional Members
 - ✓ National and international metrology institutes and organizations that are signatories to the CIPM-MRA
 - ✓ National Laboratory Medicine Societies affiliated with IFCC
 - ✓ Accreditation bodies that are signatories to the ILAC MRA for the relevant accreditation activities
 - ✓ Recognized Regional Cooperation bodies whose regional MRA/MLA have been successfully peer evaluated by ILAC.

- JCTLM Member Organizations
 - ❖ JCTLM Stakeholder Members (New)
 - ✓ Properly constituted “non-profit” and “for-profit” organizations, with interest, expertise and a demonstrated record of working to reduce the between method variability in laboratory medicine measurements and a commitment to promote the JCTLM database and activities.
 - ✓ Examples:
 - National and regional organizations active in laboratory medicine
 - EQAS providers
 - Standards writing bodies
 - In-vitro diagnostic instrument and reagent manufacturers
 - Private laboratory organizations
- Streamline Structure and Procedures of JCTLM



Revised JCTLM Structure
04 November 2015



- Raise awareness of JCTLM Reference Measurement Systems Database and importance of traceability
 - Establish a WG of Traceability Education and Promotion
- Review and update JCTLM Governance
 - Expand Executive Committee Organizations
 - JCTLM Member Organizations
 - Streamline Structure and Processes
- Member and Stakeholder meeting December 2015
- Focus on Gap analysis and where to expand Database

Annual publication of JCTLM Database Newsletter

(first released in April 2014)

- New entries in the database
- Content of the database
- Call for nomination announcement
- Call for experts nominations
- Quality Manual Modifications

jctlm@bipm.org

Reference Materials, Measurement Methods and Services for *In Vitro* Diagnostics



JCTLM Database Newsletter
<http://www.bipm.org/jctlm/> Issue 2 | March 2015

Meeting requirements for metrological traceability in laboratory medicine and clinical chemistry

The JCTLM database comprises lists of higher-order reference materials, measurement methods, and services that have been reviewed against appropriate metrological criteria and judged to be compliant with applicable ISO standards.

In this issue of the JCTLM Newsletter, we report on highlights from the last Executive meeting; the new entries in the database following the 2014 review cycle; a summary of current entries in the database; changes to JCTLM procedures; the announcement of the 2015 call for reference material, method and service nominations; and plans for the next JCTLM Members' and Stakeholders' meeting in 2015.

1 Highlights from the 13th Executive Committee meeting

The 13th meeting of the Executive Committee of the Joint Committee for Traceability in Laboratory Medicine (JCTLM)
The 13th meeting of the Executive Committee of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) took place at the BIPM on 4-5 December 2014. The [Executive Committee](#) convened for the last time under the Chairmanship of Prof. Mathias Müller whose term ended in December, and thanked him for his important contribution in support of the JCTLM.

Establishment of a new JCTLM Working Group on Education and Promotion on Traceability
The Executive decided to form a new JCTLM Working Group on Education and Promotion on Traceability in order to increase the level and recognition and acknowledgement of the JCTLM and the database that it produces.

Changes in the JCTLM Executive representatives
Prof. Linda Thienpont resigned from the Chairmanship of Working Group 2, and the Committee thanked her for her important contribution and great work in support of the JCTLM since it started. The JCTLM Executive approved the Chairmanship of Dr Gary Myers, and the BIPM's continued role as the Secretariat for the JCTLM.

Establishment of an *ad hoc* Working Group on JCTLM Governance
The Executive established an *ad hoc* Working Group on JCTLM Governance which would be tasked to revise JCTLM procedures, and propose the most appropriate structure and assignment of duties to the JCTLM Executive, Working Group Chairs and the Secretariat.

New JCTLM Member organization
The JCTLM Executive approved the JCTLM membership of China National Accreditation Service for Conformity Assessment (CNAS) from Beijing. As of 13 February 2015, there are 28 JCTLM Member organizations.

Traceability Statements – References to JCTLM – for IVD Manufacturers
The Executive finalized the guidance document on Traceability Statements, which provides advice to manufacturers and others on the appropriate manner to make reference to JCTLM-listing of reference materials, methods and services in any documentation in which information on metrological traceability is included.

See the full [list of JCTLM Member organizations](#).

The [Traceability Statement document](#) is available from the [JCTLM website](#).

See the full text of the [2014 JCTLM Executive Meeting report](#).

1

Thank You !



Bureau International des Poids et Mesures

Database of higher-order reference materials,
measurement methods/procedures and services



JCTLM Database
Laboratory medicine and *in vitro* diagnostics

> You are here : JCTLM-DB



JCTLM database: Laboratory medicine and *in vitro* diagnostics

JCTLM-DB

- [Search Form](#)
- [General information](#)
- [List of reference materials no longer listed](#)
- [Leaflet](#)
- [Contact us](#)

Highlights

- [Extension of the JCTLM-DB](#)
- [Publication of new data](#)

JCTLM

- [General information](#)

Analyte keyword search for reference materials, measurement methods/procedures and services

Type an analyte name in part or full, e.g. cholesterol

Refine search by analyte category

Refine search by matrix category

Please select your requirement :

- Higher-order reference materials
- Reference measurement methods/procedures
- Reference measurement services

Reset ×

Search →