

OUTLINE OF JCTLM EXECUTIVE COMMITTEE PROCEDURES				
Author: R.I. Wielgosz	Date : 27 Oct 09 Version : 1.0	Authorized : JCTLM-Executive	JCTLM EXE P-00	

OUTLINE OF JCTLM EXECUTIVE COMMITTEE PROCEDURES

PROCEDURE / DOCUMENT

JCTLM EXE-*P-00*

AUTHOR	AUTHORIZED
NAME ROBERT I. WIELGOSZ	NAME JCTLM EXECUTIVE COMMITTEE
FUNCTION JCTLM SECRETARIAT	FUNCTION
SIGNATURE	SIGNATURE

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2. Purpose

The purpose of this document is to describe the procedures of the Executive Committee of the Joint Committee for Traceability in Laboratory Medicine (JCTLM).

3. Scope

The scope of this document relates to the structures, operations and procedures employed by the JCTLM that are specified as the responsibility of the JCTLM Executive Committee.

4. Acronyms

All acronyms employed in JCTLM Executive Procedure Documents are given in the procedure document WG1-P-00 or WG2-P-00, *Quality Policy and Definitions*. Acronyms particularly relevant to the procedures of the Executive Committee are repeated below.

JCTLM.....	Joint Committee for Traceability in Laboratory Medicine
BIPM.....	International Bureau of Weights and Measures, website: http://www.bipm.org
IFCC.....	International Federation of Clinical Chemistry and Laboratory Medicine, website: http://www.ifcc.org
ILAC.....	International Laboratory Accreditation Cooperation, website: http://www.ilac.org/

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- WG1 Working Group 1 of the JCTLM, is responsible for identification, review and recommendation of reference materials and measurement methods/procedures for listing in the JCTLM Database
- WG2 Working Group 2 of the JCTLM, is responsible for identification, review and recommendation for listing in the JCTLM Database of reference laboratories that perform reference measurement (calibration) services.
- WGRT Working Group Review Team

5. Definitions

All definitions employed in JCTLM Procedure Documents are given in the procedure document JCTLM-WG1 and WG2 P-00, *Quality Policy and Definitions*. Definitions particularly relevant to this document are repeated below.

JCTLM Sponsors.... The three organizations that by a Declaration of Cooperation formed the JCTLM; the BIPM, the IFCC and the ILAC.

JCTLM Executive Committee

The leadership group for the JCTLM comprising representatives of the IFCC, BIPM and ILAC; the organizations that founded the JCTLM. Members of the Executive Committee are identified on the website: <http://www.bipm.org/en/committees/jc/jctlm/>

JCTLM Secretariat . Secretariat maintained on behalf of JCTLM by the BIPM, email address: jctlm@bipm.org

JCTLM Criteria Reviewing criteria derived from the applicable international standards for certified reference materials, reference measurement procedures and reference measurement services. Primary standards are from the International Organization for Standardization (ISO).

Consensus..... Group solidarity in sentiment and belief - the phrase consensus of opinion (which is not actually redundant) has been so often claimed to be a redundancy that many writers avoid it. You are safe in using consensus alone when it is clear you mean consensus of opinion, and most writers in fact do so. (From Miriam Webster – Online Dictionary)

WG Chair Leader of a WG. The Chair position of a working group may be held by more than a single individual to facilitate the WG activities.

JCTLM Database.... Database of available higher order reference materials, reference measurement methods/procedures that meet the criteria described in the JCTLM WG1 procedures and of reference measurement services provided by reference laboratories that are compliant with the criteria

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described in the JCTLM WG2 procedures; available at <http://www.bipm.org/jctlm/>

6. Related documents

- JCTLM ***Declaration of Cooperation*** between the CIPM, IFCC and ILAC, for the establishment of a Joint Committee for Traceability in Laboratory Medicine (JCTLM) - available at:
http://www.bipm.org/utills/en/pdf/establish_jctlm.pdf
- Appendix I: JCTLM Members
- Appendix II: JCTLM Working Groups
- 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. Available at: http://www.bipm.org/utills/en/pdf/jctlm_framework.pdf
- Appendix IV: Participation of Organizations in the JCTLM
- ***Mission Statement*** - available at:
http://www.bipm.org/en/committees/jc/jctlm/declaration_online.html
- ISO Standards..... Standards employed by JCTLM in reviewing and judging suitability for listing materials (ISO 15194), methods (ISO 15193) and procedure-defined measurands (ISO 18153) as being of higher metrological order (ISO 17511) as required in the European Community In Vitro Diagnostic Directive (EC IVDD) (98/79/EC, Annex1 (A) (3) 2nd paragraph) and reference measurement service laboratories (ISO 15195).

7. Organization and Operation

7.1. Organization of the JCTLM – See Organization Chart, Paragraph 10

- 7.1.1. The JCTLM is organized into six components
- 7.1.1.1. The Executive Committee – comprising representatives of the founding organizations, BIPM, IFCC and ILAC
- 7.1.1.2. A Secretariat – the operating entity that coordinates and manages the activities of the JCTLM
- 7.1.1.3. Two Working Groups
- 7.1.1.3.1. Working Group 1 – responsible for identification, review and recommendation of reference materials and measurement methods/procedures for listing in the JCTLM Database of Higher Order Reference Materials and Higher Order Reference Measurement Methods/Procedures

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7.1.1.3.1.1. A Quality System Procedure Team – responsible for the written procedures by which Working Group 1 operates

7.1.1.3.2. Working Group 2 – responsible for identification, review and recommendation of reference laboratories that perform reference measurement (calibration) services

7.1.1.3.2.1.A Quality System Procedure Team – responsible for the written procedures by which Working Group 2 operates

7.1.1.4. JCTLM Review Teams – groups of experts who review materials, methods and laboratory services on behalf of the two working groups

7.1.1.5. Members of the JCTLM – organizations with interests in traceability in laboratory medicine

7.2. Operation of the JCTLM - The operation of the JCTLM is overseen by its Executive Committee comprising representatives of the BIPM, IFCC and ILAC.

7.2.1. JCTLM is led by the Executive according to a set of procedures that govern the activities of the Executive Committee. These procedures are:

7.2.1.1. Outline of the JCTLM Executive Procedures (this document)

7.2.1.2. Process for Selection of Executive Committee Chair and Secretariat

7.2.1.3. Process for Selecting and Appointing Working Group Chairs

7.2.1.4. Process for the Appointment of WG Review Team Leaders and Review Team Members

7.2.1.5. Executive Committee Procedure for Initiation and Approval of Actions to be Taken by JCTLM Entities

7.2.1.6. Executive Committee Review of Recommendations from Working Groups

7.2.1.7. Executive Committee Review of Contested Recommendations

7.2.2. Notwithstanding the procedures described in 7.2.1, the Executive Committee has the authority to make decisions on any matter related to the activities of the JCTLM

7.2.3. The decision making process of the Executive Committee shall be by consensus. This may not imply complete agreement from every member organization of the Executive but allows for a single dissenting member organization.

8. Revision History

Version number	Date of Issue/Review	Summary of change
1.0	27/10/2009	1 st Published Version

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9. Attachments

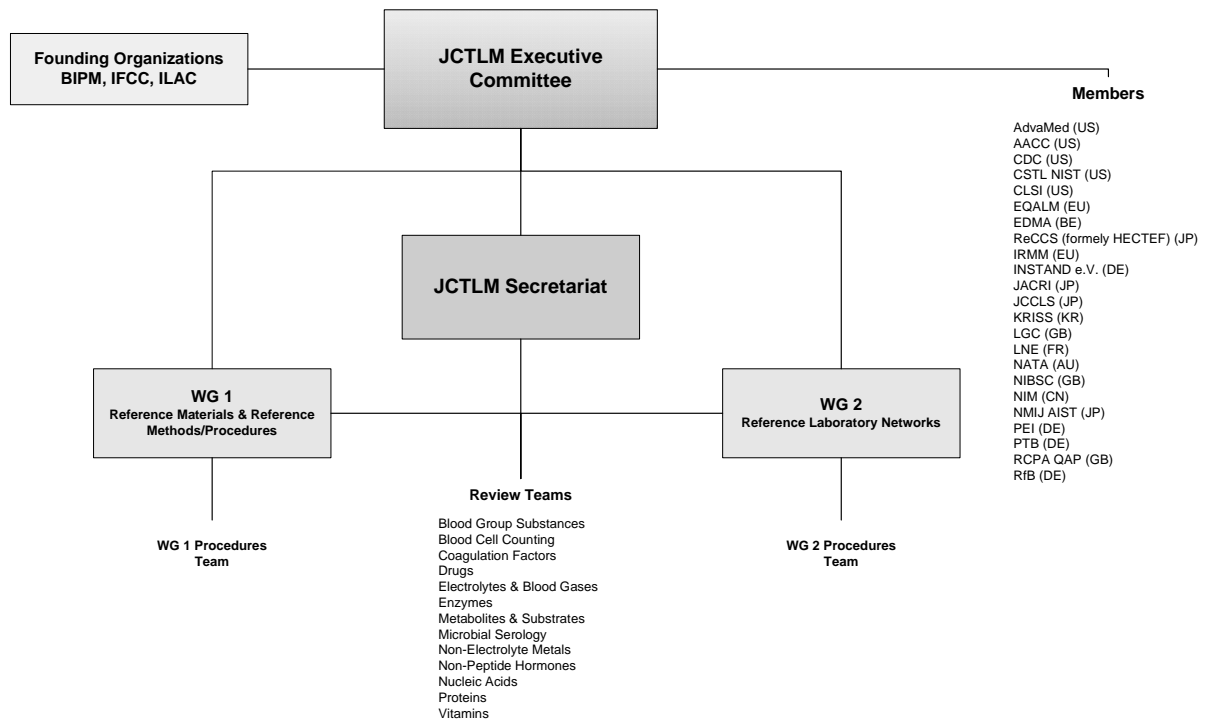
1. ***Declaration of Cooperation*** between the CIPM, IFCC and ILAC, for the establishment of a Joint Committee for Traceability in Laboratory Medicine (JCTLM) - available at http://www.bipm.org/utis/en/pdf/establish_jctlm.pdf

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10. JCTLM Organization Chart

Joint Committee for Traceability in Laboratory Medicine



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11. Outline of Executive Procedures – Flowchart Format

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Process Code

