Bureau
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Acronyms definitions

1.1th edition

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Acronyms and definitions

Contents

1. Purpose

The purpose of this document is to provide a list of acronyms and definitions employed in the procedures of the Joint Committee for Traceability in Laboratory Medicine (JCTLM).

2. Scope

The scope of this document is all procedures that describe the activities of the JCTLM, notably those that are specified as the responsibility of the Database Working Group, the Secretariat or the Executive Committee.

3. Acronyms

BIPM	International Bureau of Weights and Measures, Website: https://www.bipm.org
CIPM	International Committee for Weights and Measures
CIPM MRA	The CIPM Mutual Recognition Arrangement
CRM	Certified Reference Material
DB WG	Database Working Group of the JCTLM, Website: https://www.bipm.org/en/committees/cc/wg/jctlm-dbwg.html
DB WG RT	Review Team of the Database Working Group
DB WG RTL	Review Team Leader of the Database Working Group
ICSH	International Council for standardization in Haematology Website: https://icsh.org/
IFCC	International Federation for Clinical Chemistry and Laboratory Medicine, Website: https://www.ifcc.org
ILAC	International Laboratory Accreditation Cooperation, Website: https://www.ilac.org/
ISO	International Organization for Standardization, Website : https://www.iso.org/
IVD	*In Vitro* Diagnostic
IVDD	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices
JCTLM	Joint Committee for Traceability in Laboratory Medicine, Website : https://www.bipm.org/en/committees/jc/jctlm/
KCDB	The BIPM key comparison database, Website : https://kcdb.bipm.org/
RELA	IFCC External Quality assessment scheme for Reference Laboratories in Laboratory Medicine, Website : https://www.dgkl-rfb.de:81/index.shtml

RM	Reference Material
RMM	Reference Measurement Method
RMP	Reference Measurement Procedure
RMM/P	The concatenation of RMM and RMP for brevity in the DB WG procedure documents
RML	Reference Measurement Laboratory
SI	The International System of Units
TEP WG	Working Group on Traceability: Education and Promotion, website: https://www.bipm.org/en/committees/cc/wg/jctlm-wg-tep.html
VIM	International Vocabulary of Metrology

4. Definitions

Certified Reference Material CRM	reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures, VIM 3rd Ed., 5.14 (2012).
Commutability of a reference material	Property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures, and the relation obtained among the measurement results for other specified materials, VIM 3rd Ed., 5.15 (2012). An example is provided in the Attachment 1 of this procedure, Chart JCTLM-0001.0. Demonstrating commutability among CRMs with any given measurement process does not assure commutability of any CRM across different measurement processes.
Consensus	Group solidarity in sentiment and belief (opinion); operationally, the absence of sustained opposition.
Extent of equivalence	An indication of the agreement among measured values of the same quantity assigned to two or more CRMs or ability of different measurement procedures to produce consistent values when used to measure the amount of substance in any given CRM. The extent of equivalence can be usefully communicated with Youden or Bland-Altman style graphics that include an indication of measurement uncertainty to identify and place differences among the measured values in perspective.
Higher order	The term “higher-order” was left undefined in the IVDD; however, ISO 15193:2009 and ISO 15194:2009 describe the essential requirements for higher-order reference materials and methods.
ISO Standards	Normative 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 a 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, ISO/IEC 17025:2005).
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).
JCTLM Database	Database of available higher order reference materials, reference measurement methods/procedures and of reference measurement services provided by reference laboratories that are compliant with the JCTLM criteria, website: https://www.bipm.org/jctlm/
JCTLM Database WG Chair	Leader of Database WG. The Chair position of the Database WG is held by the Chairman of JCTLM.
JCTLM Database WG vice-chair	Responsible for an Analyte Group comprising three or more review teams. The composition of each of the three Analyte Groups and their respective Database WG vice-chairs can be identified on the website at https://www.bipm.org/en/committees/cc/wg/jctlm-dbwg.html
JCTLM Executive Committee	The Executive Committee is the impartial final decision-making organ, only accountable to the Executive Committee Member Organizations. It comprises representatives of the Executive Committee Member Organizations that currently are the JCTLM Founding Organizations and the ICSH. Members of the Executive Committee can be identified on the website: https://www.bipm.org/en/committees/cc/wg/jctlm-exec.html

JCTLM Founding Organizations	The three organizations that by a Declaration of Cooperation formed the JCTLM; the BIPM, the IFCC and the ILAC.
JCTLM Executive Committee Member Organizations	Intergovernmental and international non-governmental organizations and bodies having technical competence in the field or a subspecialty, that: 1. are representative of the specialized field of interest in which they operate; 2. are concerned with matters covering a part or all of the Committee's activities; 3. have a permanent directing body, authorized representatives and systematic procedures for communicating with its membership.
JCTLM National and Regional Members	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.
JCTLM Stakeholder Members	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.
JCTLM Secretariat	Secretariat maintained on behalf of JCTLM by the BIPM, email address: jctlm@bipm.org
List I	Certified reference materials and reference measurement methods for well-defined chemical entities or internationally recognized reference method-defined measurands. Reference materials and measurement methods included in this category are those that provide values that are traceable to the SI units; e.g.,

	electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones, and some proteins.
List II	Reference materials for which values of the measurands are not SI-traceable but are assigned by or traceable to an internationally agreed upon protocol, e. g., reference materials for blood typing, coagulation factors, infectious diseases, nucleic acids, and some proteins and purified substances.. List II also contains a group of purified substances which, due to the absence of reference measurement procedures, should not be directly used for calibration of routine methods unless commutability is established and/or matrix effect independent internationally recognized standardized value transfer protocols to commutable samples are applied.
List III	Certified Reference Materials for nominal properties
Measurand	quantity intended to be measured, VIM 3rd Ed., 2.3 (2012).
Measurement principle	phenomenon serving as a basis of a measurement, VIM 3rd Ed., 2.4 (2012).
Measurement method	generic description of a logical organization of operations used in a measurement, VIM 3rd Ed., 2.5 (2012).
Reference measurement procedure	Measurement procedure accepted as providing measurement results fit for their intended use in assessing measurement trueness of measured quantity values obtained from other measurement procedures for quantities of the same kind, in calibration, or in characterizing reference materials, VIM 3rd Ed., 2.7 (2012)
Reference Measurement Laboratory	A laboratory that meets the requirements specified in ISO 15195 as a calibration laboratory. Reference measurement laboratories should implement reference measurement procedures and produce results of measurement that are accurate and traceable to national or international primary reference materials when such are

	available. Whenever possible, traceability should be established to a reference material which forms an embodiment of the SI unit (ISO 17511). This International Standard may form a basis for the accreditation of a reference measurement laboratory that applies for official recognition of the performance of a reference measurement procedure. Reference measurement laboratories are usually accredited by national accrediting bodies.
RELA Advisor	Qualified individual appointed by the Executive Committee to assist the Database WG to review the services nominated for assessment by JCTLM and/ or listed in the Database.

5. Revision History

Version number	Date of Issue/Review	Summary of change
0.1	10/05/2016	First draft
1.0	27/07/2017	Final version published
1.1	18/12/2019	Editorial modifications

Appendix 1. Operational Definition of Commutability

Chart

Example illustrating the distinguishing difference between a commutable and a non-commutable reference material in two measurement procedures:

Step 1

A series of patient samples, selected to cover the analytical range of the methods, are measured using both procedures. The results are plotted on a scatter-graph and the mathematical relationship between the patient sample results from the two procedures established along with a stated confidence interval on that relationship.

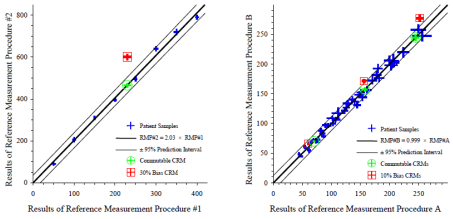
Step 2

The substance amount of the measurand in the certified reference material is measured using the same two procedures. Values from commutable CRMs will lie within the confidence interval found for the patient sample with approximately the

same stated confidence. Values from non-commutable materials will lie outside the confidence interval.

WG1-0001.0

Two Graphical Examples of Commutability Evaluations



Graphs are taken from the presentation given at the JCTLM symposium, Paris, June 2002, by Heinz Schimmel, Institute for Reference Materials and Measurements (Left side) and from Richard R. Miller, Dade Behring using data from Table A2, Clinical and Laboratory Standards Institute, EP9-A2. Confidence interval calculations and formatted graphs were provided by David L. Duewer, National Institute of Standards and Technology.

Related documents

[1] SI *The International System of Units* (SI), 8th Edition, Paris, France (2006). Website: https://www.bipm.org/en/publications/si-brochure/

[2] VIM *International Vocabulary of Metrology—Basic and General Concepts and Associated Terms*, (VIM 3rd edition), JCGM 200:2012 (JCGM 200:2008 with minor corrections) Website: https://www.bipm.org/en/publications/guides/#vim

[3] IVDD Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, Website.

[4] ISO 15193:2009 In vitro diagnostic medical devices—Measurement of quantities in samples of biological origin—Requirements for content and presentation of reference measurement procedures

[5] ISO 15194:2009 In vitro diagnostic medical devices—Measurement of quantities in samples of biological origin—Requirements for certified reference materials and content of supporting documentation.

[6] ISO 15195:2003 Laboratory medicine—Requirements for reference measurement laboratories.

[7] ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

[8] ISO 17511:2003 In vitro diagnostic medical devices—Measurement of quantities in biological samples—Metrological traceability of values assigned to calibrators and control materials.

[9] ISO 18153:2003 In vitro diagnostic medical devices—Measurement of quantities in biological samples—Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials.

[10] JCTLM ***Declaration of Cooperation*** between the BIPM, IFCC and ILAC, for the establishment of a Joint Committee for Traceability in Laboratory Medicine (JCTLM), revised in March 2016—available at: https://www.bipm.org/en/worldwide-metrology/jctlm-cooperation/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