

QUALITY POLICY AND DEFINITIONS			
Author: C. M. Jackson	Date : 2011/01/27 Version : 3.0	Authorized : JCTLM Executive	JCTLM WG1-P-00

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1. Contents

PARAGRAPH	TITLE	PAGE
1.	CONTENTS.....	2
2.	PURPOSE.....	2
3.	SCOPE.....	2
4.	ACRONYMS.....	2
5.	DEFINITIONS.....	3
6.	RELATED DOCUMENTS.....	5
7.	REVISION HISTORY.....	6
	ATTACHMENT 1 OPERATIONAL DEFINITION OF COMMUTABILITY.....	7

2. Purpose

The purpose of JCTLM Working Group 1 (WG1) is to implement the JCTLM Framework for the international recognition of reference measurement methods/procedures and reference materials of a higher metrological order. The JCTLM Framework facilitates the implementation of traceability to higher-order materials and reference measurement methods/procedures as required by the European IVDD. Nominated reference materials and reference methods/procedures are reviewed by WG1 for compliance with the normative standards, ISO 15194:2009(E) and ISO 15193:2009(E).

It is the policy of WG1 to make this evaluation by a transparent process using openly distributed procedure documents that are accessible to all interested parties.

The procedures provided in this Quality System document are those by which the evaluations are made.

3. Scope

The scope of this document is all procedures that describe the activities of JCTLM Working Group 1.

4. Acronyms

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

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- ISOInternational Organization for Standardization, website:
<http://www.iso.org/>
- IVD.....*In Vitro* Diagnostic
- IVDDDirective 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.
- SIInternational System of Units, the metric system.
- VIM *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms*, 3rd Edition, (2008), JCGM 200:2008 (E/F).
- WG1Working Group 1 of the JCTLM; is responsible for identifying and recommending for listing reference materials and reference measurement methods/procedures.
- WG1 Chair(s).....Leader(s) of WG1; during some time periods the Chair position may be held by more than a single individual to facilitate WG1 activities.
- WG1RTWorking Group 1 Review Team.
- WG1RTL.....Working Group 1 Review Team Leader.

5. Definitions

- Chart ID.....A unique number that identifies flowcharts and other diagrams independently of the QS Procedure document with which the chart is associated. Example: WG1-0001.0, WG1, Chart 1, Rev 0.
- Commutability Property of a given 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 measurement procedures, and the relation obtained among the measurement results for other specified materials ISO 15194:2009, 3.8.
- An example is provided in the Attachment 1 of this procedure, Chart WG1-0001.0.
- 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.
- CRM.....Certified Reference Material, a “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 (2008).

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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-OrderThe term “higher-order” was left undefined in the IVDD; however, ISO 15193:2009(E) and ISO 15194:2009(E) describe the essential requirements for higher-order reference materials and methods.

JCTLM ExecutiveCommittee of the JCTLM comprising representatives of the IFCC, BIPM and ILAC. See at website:
http://www.bipm.org/en/committees/jc/jctlm/jctlm_exec_committee.html

JCTLM SecretariatOffice of JCTLM maintained by the BIPM, email address:
jctlm@bipm.org

List ICertified 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.

This list of CRMs and RMPs evaluated by JCTLM WG1 and maintained by the JCTLM Secretariat, website:
<http://www.bipm.org/jctlm/>

List IIReference 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, microbial serology, 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.

This list of materials evaluated by JCTLM WG1 and maintained by the JCTLM Secretariat, website: <http://www.bipm.org/jctlm/>

List III.....Certified Reference Materials for nominal properties

This list of materials evaluated by JCTLM WG1 and maintained by the JCTLM Secretariat, website: <http://www.bipm.org/jctlm/>

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- Measurand “quantity intended to be measured”, *VIM* 3rd Ed., 2.3 (2008).
- MP Measurement principle, phenomenon serving as a basis of a measurement, *VIM* 3rd Ed., 2.4 (2008).
- Normative Standard.....A level of quality agreed upon as representing how or what ought to be, a prescriptive set of quality attributes against which particular realizations can be consistently compared. In the review and evaluation made by the JCTLM WG1, the normative standards are ISO standards, 15194, 15193 and 18153.
- RM.....Reference Material, “material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties *VIM* 3rd Ed., 5.13 (2008).
- RMMReference Measurement Method, a generically described procedure based on a particular principle of measurement. “generic description of a logical organization of operations used in a measurement”, *VIM* 3rd Ed., 2.5 (2008).
- RMPReference 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, 2008
- RMM/P.....The concatenation of RMM and RMP for brevity in the WG1 procedure documents.
- Stakeholder.....Any person holding membership in an organization belonging to or participating in activities of the JCTLM.

6. Related documents

- SI*The International System of Units (SI)*, 8th Edition. Paris, France (2006). Website: http://www.bipm.org/en/si/si_brochure/
- VIMBIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML International vocabulary of metrology - basic and general terms in metrology, 3rd Edition, JCGM 200:2008 (E/F).
- IVDDDirective 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices Website: <http://www.fxtrans.com/medical/IVD98-79-EC.pdf>.
- ISO 15193:2009(E)In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for content and presentation of reference measurement procedures. ISO, Geneva, Switzerland (2009). Website: <http://www.iso.org>

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- ISO 15194:2009(E)In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for certified reference materials and content of supporting documentation. ISO, Geneva, Switzerland (2009). Website: <http://www.iso.org>
- ISO 15195Laboratory medicine – Requirements for reference measurement laboratories. ISO, Geneva, Switzerland (2003).
- ISO 17511In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials. ISO, Geneva, Switzerland (2003).
- ISO 18153In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials. ISO, Geneva, Switzerland (2003).
- JCTLMJoint Committee for Traceability in Laboratory Medicine. See: PREAMBLE (2005) and Declaration of Cooperation between the CIPM, IFCC and ILAC, for the Establishment of a Joint Committee for Traceability in Laboratory Medicine (JCTLM) See: Website: <http://www.bipm.org>

7. Revision History

Version number	Date of Issue/Review	Summary of change
1.0	23/02/2004	Initial issue of WG1 Quality System Procedures
2.0	11/15/2005	Corrected to accurately reflect changes in documents and forms used by WG1, revised definitions and minor textual errors
2.1	24/01/2006	Correction of minor textual errors
2.2	09/11/2009	Correction to reference current versions of ISO standards
3.0	27/01/2011	Corrections made in version 2.2 accepted

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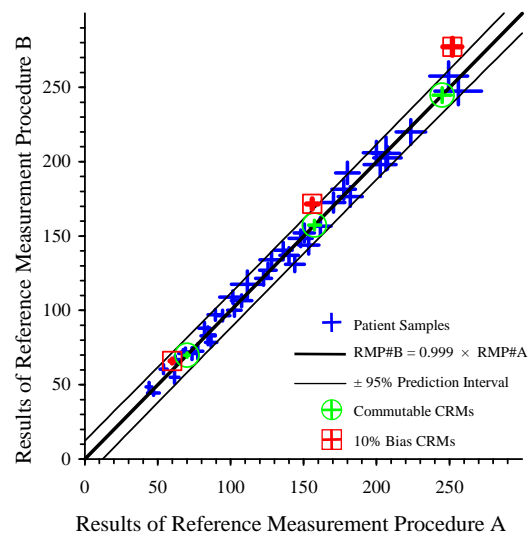
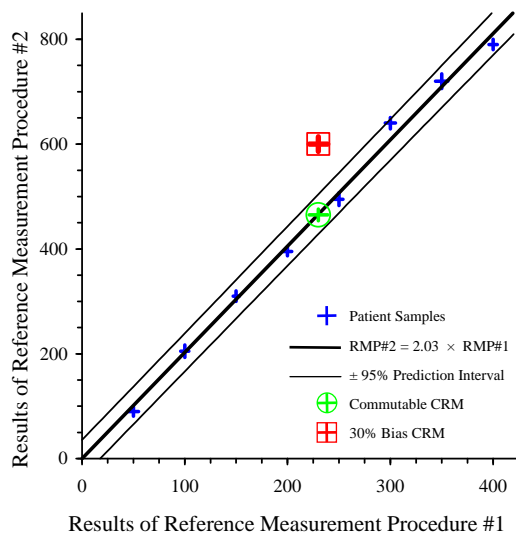
Attachment 1 Operational Definition of Commutability

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.