Demonstrating the extent-of-equivalence of reference measurement methods/procedures (RMM/Ps) for the same measurand

1. Purpose

This procedure describes the process employed by JCTLM for demonstrating and evaluating the extent-of-equivalence of Reference Measurement Method/Procedures (RMM/Ps) that are nominally fit for the identical purpose(s). The process is intended to ensure that extent-of-equivalence information is available for these RMM/Ps. When more than one RMM/P is listed by the JCTLM, potential users need this information to make an informed selection of the RMM/P best suited to their needs.

2. Contents

3. Scope

This procedure applies to all nominations of Reference Measurement Methods/Procedures (RMM/Ps) that are submitted for evaluation by JCTLM DB WG for inclusion in the JCTLM database where there are JCTLM listed RMM/Ps that are nominally fit for the same purpose.

4. Acronyms and definitions

All acronyms and definitions employed in the procedures of the JCTLM DB WG Quality Manual are given in the procedure document JCTLM EXE-G01, Glossary of terms and definitions.

5. Responsibilities and authorizations

5.1. The JCTLM Executive has the following responsibilities under this procedure.

5.1.1. To accept or reject DB WG's recommendations for listing in the JCTLM Database extent-of-equivalence reports of RMM/Ps evaluated for the same measurand.

5.1.2. To accept or reject DB WG's recommendation for corrective action to JCTLM listed methods where variability in measurement results is observed between evaluated RMM/Ps for the same measurand.

5.2. The JCTLM Secretariat has the following responsibilities under this procedure.

5.2.1. When requested by a review team leader, to request RMM/P nominators to provide supporting evidence required for appropriate assessment of measurement methods comparability.

5.2.2. To forward DB WG's recommendations to the JCTLM Executive and communicate the Executive's decisions to the RMM/P nominators.

5.2.3. To appropriately post approved RMM/Ps extent-of-equivalence reports on the JCTLM database website.

5.3. The DB WG vice-chair(s) have the following responsibilities under this procedure.

5.3.1. To review RT's recommendations.

5.3.2. To communicate DB WG's recommendations to the JCTLM Secretariat for EC approval.

5.4. The RT leaders have the following responsibilities under this procedure.

5.4.1. To ensure that representative comparison data for extent-of-equivalence demonstration are available for evaluation by the review team if necessary.

5.4.2. If necessary, to communicate with the JCTLM Secretariat regarding the procurement of supporting evidence for extent-of-equivalence studies.

5.5. The RTs have the following responsibilities under this procedure.

5.5.1. To review the extent-of-equivalence data as part of the evaluation of a method validation.

5.6. The RMM/P nominator has the following responsibilities under this procedure.

5.6.1. To initiate extent-of-equivalence evaluation when one or more JCTLM listed RMM/Ps are identified as being fit for the same purpose as the nominated RMM/P

5.6.2. To identify one or more qualified measurement laboratory(ies) willing to perform a comparison measurement study. In general, all involved RMM/P nominators are expected to participate.

5.6.3. In collaboration with the measurement laboratory(ies), to define an appropriate measurement protocol.

5.6.4. To prepare a report of analysis that suitably documents the results of the measurements and the measurement systems used.

5.6.5. In collaboration with the measurement laboratory and others who may be actively involved in the evaluation, to prepare a final report documenting the extent-of-equivalence determination of the evaluated RMM/Ps for review and publication by JCTLM.

5.7. The measurement laboratory owner of a RMM/P previously listed and fit for the same purpose has the following responsibilities under this procedure

5.7.1. To perform the necessary measurements.

5.7.2. In collaboration with other parties involved, to prepare a final report documenting the extent-of-equivalence determination of the evaluated RMM/Ps for review and publication by JCTLM.

5.7.3. To inform JCTLM of any existing discrepancies between the measurement results of the evaluated RMM/Ps.

6. Procedure

6.1. The process for demonstrating the extent-of-equivalence of RMM/Ps will be initiated by the RMM/P nominator which submits a method for inclusion in the Database whenever one or more RMM/Ps that are nominally fit for the same purpose are identified in the JCTLM database. The extent-of-equivalence demonstration process should be completed by the time the laboratory submits a RMM/P nomination for evaluation by DB WG RT.

6.1.1. To comply with the method validation requirements of ISO 15193, RMM/Ps nominators are required to provide extent-of-equivalence information as part of the nomination process. (See DBWG-P-03A). This equivalence data will be included in the JCTLM RMM/Ps Listing in order to adequately inform potential users.

6.1.2. In the case where no higher-order methods have been published by JCTLM to allow for such extent-of-equivalence studies to be performed, the RMM/P nominator is required to conduct a comparison study of its newly evaluated method with an existing method used by a routine measurement laboratory.

Alternatively, the RMM/P nominator must participate in an appropriate EQAS program that uses commutable materials for the measurand in question. In this case, this will be considered to constitute sufficient information for listing the method in the database until a new RMM/P becomes available for further comparability assessment.

It will be the responsibility of potential users of the RMM/P to interpret the significance of the comparability assessment.

6.1.2.1.The nominator-supplied comparison data obtained through the above studies will be included in the JCTLM RMM/Ps Listing in order to adequately inform potential users.

6.1.3. In the case where there is neither existing routine method nor published method of a particular measurand, the RMM/P nominator will provide as an attachment to its nomination a written statement indicating that he had sought for all possibilities to get comparability assessment, and recognize that the method will be subject to further comparability assessment when another published method becomes available, and to potential corrective action in case of results demonstrating between methods variability. See DBWG-P-03A.

6.2. The extent-of-equivalence of two or more RMM/Ps is best demonstrated by analyzing the same, representative suite of samples with each of the RMM/Ps. Where appropriate and available, the suite may include calibration and natural-matrix CRMs, multi-donor blended and spiked materials, as well as single-donor samples.

A extent-of-equivalence evaluation will be meaningful only if "identical" samples are presented to all RMM/Ps. Sufficient quantities of all materials must be available to provide suitable split-samples for all RMM/Ps involved. If the evaluation involves multiple measurement laboratories, the entire sample suite should be assembled and disseminated to the participating analysts at the same time using as similar shipping procedures as possible.

All measurements should be obtained under repeatability conditions by analysts skilled in the RMM/P, using fit-for-purpose materials and instrumentation.
The following apply separately to each measurand/matrix evaluated:

6.2.1. Measurement performance characteristics as functions of measurand level. The relative trueness and repeatability claims of an RMM/P can be verified through the analysis of a series of samples having measurand levels that span the expected analytical range. Since repeatability verification will involve the analysis of independently prepared aliquots, CRMs and/or multi-donor sample pools may be the sample materials of choice for this basic verification of measurement performance.

6.2.2. Commutability. The relative influence of variability in the physical and chemical composition expected in "routine" samples should be evaluated through analysis of a series of samples representative of the entire intended sample population(s) for the RMM/Ps. Where available, single-donor samples typical of the expected range of abnormal conditions should be included. Where such samples cannot be obtained in sufficient quantity for analysis by all of the RMM/Ps being evaluated, use of exogenously modified multi-donor pools may be necessary.

6.3. The RMM/P nominator identifies JCTLM listed RMM/Ps that are nominally fit for the same purpose, and contact the developers of these listed methods to verify of they are willing to participate in an inter-laboratory comparison for validation a newly developed method. The developers of the JCTLM listed RMM/Ps are expected to participate.

6.4. In consultation with the identified laboratory that agreed to participate in a comparison study, the RMM/P nominator develops an appropriate measurement protocol that has good potential for demonstrating the relative extent-of-equivalence of the RMM/Ps over a representative range of sample materials. The protocol should also provide for verifying the claimed measurement performance characteristics of the RMM/Ps. Example protocols are provided in the Attachments to this Procedure.

6.5. The participants in the comparison perform the measurements and prepare a report of analysis detailing their analysis of all samples in the evaluation suite.

6.6. A report of the extent-of-equivalence of the evaluated RMM/Ps will be prepared by the method owners and submitted as an attachment to the nomination of the RMM/P nominator for assessment by the DB WG RT. All parties actively involved in the study should co-author the report. Extent-of-equivalence can be evaluated and displayed using "Brand-Altman"-style plots of the differences in values as a function of measurand level, relative to the claimed RMM/P measurement performance characteristics.

6.7. If the results of an approved extent-of-equivalence study indicate discordance among the evaluated RMM/Ps relative to fit-for-purpose criteria, the DBWG will refer all RMM/Ps in the compared set to their nominators for further investigation to resolve the discrepant results. The review comment noting that the extent-of-equivalence of the RMM/Ps is under further review will be added to all of the listing of all of the RMM/Ps until resolution is achieved or one or more of the RMM/Ps is withdrawn by its nominator.

7. Related documents

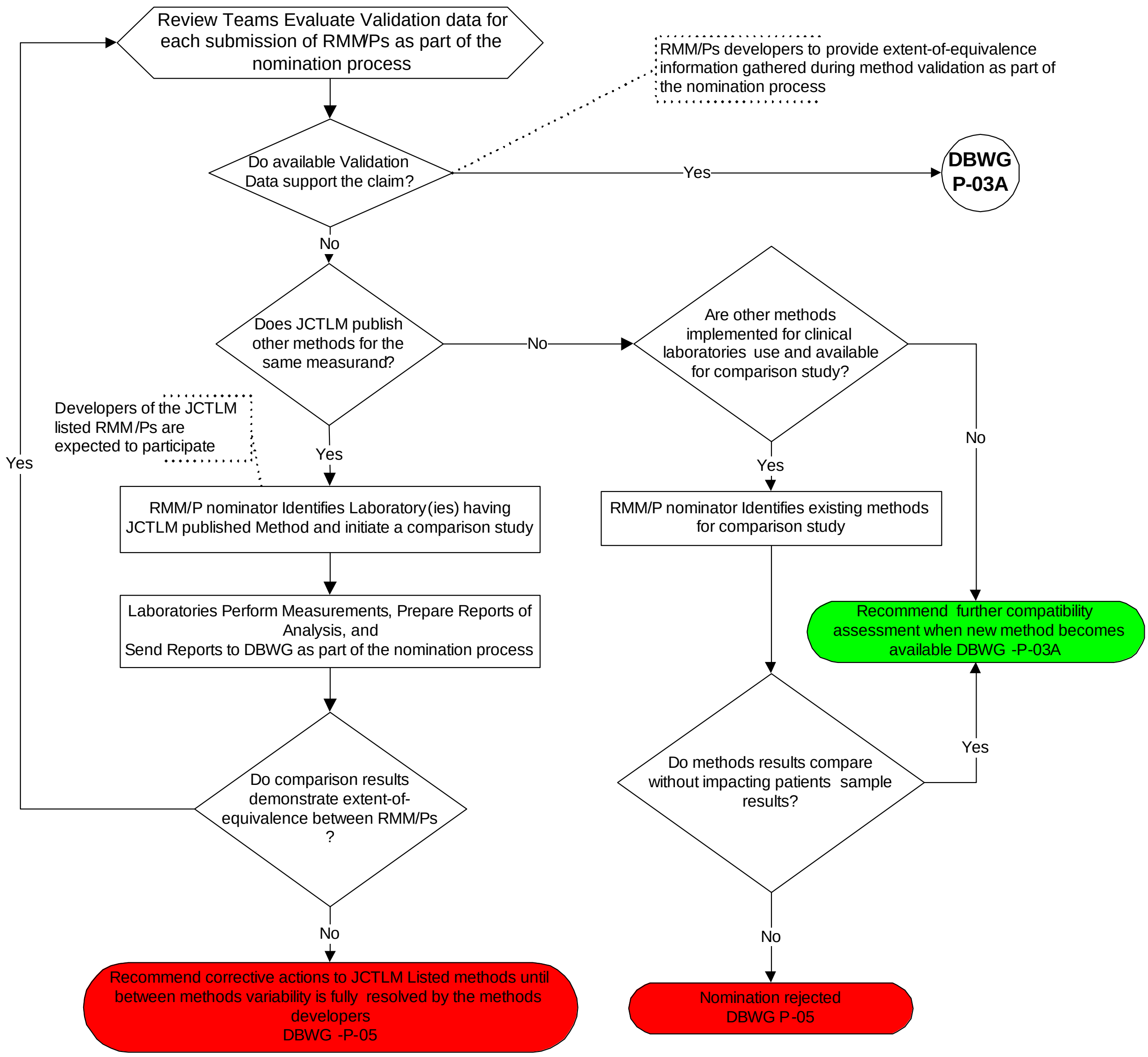
JCTLM Preamble	Available at - https://www.bipm.org/en/committees/jc/jctlm/wg/jctlm-dbwg/publications
JCTLM DBWG-P-00	Quality Policy of the JCTLM Database working group
	REVIEW PROCEDURES for Materials and Methods
JCTLM DBWG-P-01A	Outline of JCTLM DB WG process for evaluating and listing higher order materials and methods
JCTLM DBWG-P-02A	Requesting and accepting nominations for Certified Reference Materials and Reference Measurement Methods/Procedures
JCTLM DBWG-P-03A	Review of nominated Certified Reference Materials and Reference Measurement Methods/Procedures
JCTLM DBWG-P-05	Communicating Database WG recommendations

8. Revision History

Version number	Date of Issue/Review	Summary of change
1.0	11/15/2005	Separated from JCTLM WG1-P-0 Version 2.0
1.1	24/01/2006	Correction to minor textual errors
2.0	27/01/2017	Document revised for implementing modifications requested by EC's at its 17th meeting
2.1	27/01/2018	Revision of the text of section 6.1.1 and 6.1.2 by EC at their 19th meeting
2.2	01/02/2019	Update of hyperlinks
2.3	01/02/2022	Editorial changes

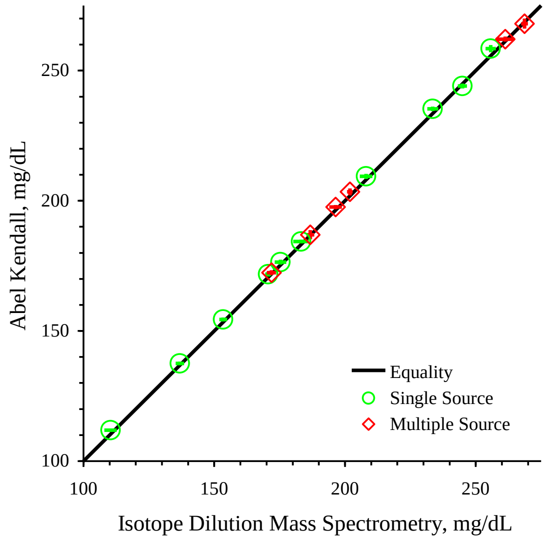
9. Flowchart

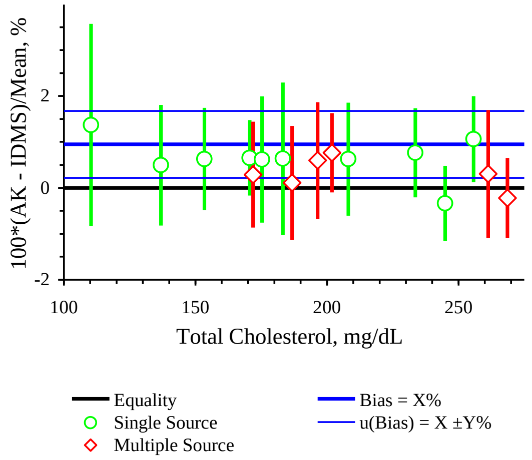
Process for demonstrating the extent-of-equivalence of Reference Measurement Methods/Procedures (RMM/Ps) for the same measurand DBWG-P-04B



10. Attachment:

Assessment of Extent of Equivalence of
IDMS and Abel-Kendall Cholesterol Measurements
in Liquid Frozen Serum





Private communication from David L. Duewer, Michael J. Welch, and Mary M. Kimberly. NIST provided the IDMS measurements, CDC provided the Abel-Kendall measurements. The “error bars” represent approximate 95% confidence intervals on the expected values.