1. Purpose

This policy and requirements described how to accept the metrological evaluation traceability and measurement uncertainty of tested results. It is intended for all BLQS's staffs, assessors, assessment report reviewer and accreditation committee for their decision making on the acceptance of metrological traceability and evaluation of measurement uncertainty for testing and calibration results.

2. Application

This policy is applied as acceptance criteria for metrological traceability and measurement uncertainty covers both of accredited laboratories and for those laboratories seeking accreditation to ISO 15189, ISO/IEC 17025 and ISO 17034. These requirements apply only to those tests and calibrations that are included in the scope (or proposed scope) of accreditation.

3. References

3.1	ILAC P10:07/2020	ILAC Policy on Metrological Traceability of Measurement Results.
3.2	ILAC P14:09/2020	ILAC Policy for Measurement Uncertainty in Calibration.
3.3	ILAC G17:01/2021	ILAC Guidelines for Measurement Uncertainty in Testing.
3.4	ILAC G24:2022	Guidelines for the determination of recalibration intervals of measuring equipment.
3.5	ISO 17034:2016	General requirement for the competence of reference material producer.
3.6	ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories.
3.7	ISO 15189:2022	Medical laboratories - Requirements for quality and competence.

3.8	Eurachem/CITA Guide	Metrological Traceability in Chemical Measurement. A guide to achieving comparable results in chemical measurement. 2nd Edition, 2019.
3.9	IUPAC Technical Report	Metrological Traceability of measurement results in Chemistry: Concepts and implementation. 15 June 2011.
3.10	JCGM 200:2012	International Vocabulary of Metrology - Basic and General Concepts and Associated Terms VIM, 3rd edition. (JCGM 200:2008 with minor corrections).
3.11	JCGM 100:2008	Evaluation of measurement data-Guide to expression of uncertainty in measurement. 1st edition, 2008.
3.12	JCGM GUM-1:2023	Guide to the expression of uncertainty in measurement – Part 1: Introduction.1st edition, 2023.
3.13	ISO 19036:2019	Microbiology of the food chain. Estimation of measurement uncertainty for quantitative determinations.
3.14	Eurachem Guide	Accreditation for Microbiological Laboratories. 3rd edition, 2023.
3.15	Eurachem Guide	Quantifying Uncertainty in Analytical Measurement. 3rd Edition, 2012.
3.16	ISO/TS 20914:2019	Medical laboratories – Practical guidance for the estimation of measurement uncertainty.
3.17	ISO 5725-2:2025	Accuracy (trueness and precision) of measurement methods and results Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method. 3rd edition, 2025.
3.18	Eurachem Guide	The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics. 3rd edition, 2025.

4. Definition and abbreviation

4.1 Metrological traceability (VIM 3 clause 2.41)

Property of a measurement result where by the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Note 1 For this definition, a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

Note 2 Metrological traceability requires an established calibration hierarchy.

Note 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

Note 4 For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

Note 5 Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

Note 6 A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

Note 7 the ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals.

Note 8 clause 2.41 stated that the abbreviated term “traceability” is sometimes used to mean ‘metrological traceability’ as well as other concepts, such as ‘sample traceability’ or ‘document traceability’ or ‘instrument traceability’ or ‘material traceability’, where the history (“trace”) of an item is meant. Therefore, the full term of “metrological traceability” is preferred if there is any risk of confusion

4.2 Metrological traceability chain, (VIM 3 clause 2.42)

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

Note 1 Metrological traceability chain is defined through a calibration hierarchy.

Note 2 Metrological traceability chain is used to establish metrological traceability of a measurement result.

Note 3 Comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

4.3 Metrological traceability to a measurement unit, (VIM 3 Clause 2.43)

Metrological traceability where the reference is the definition of a measurement unit through its practical realization.

Note 1 The expression “traceability to the SI” means metrological traceability to a measurement unit of the International System of Units.

4.4 Metrological comparability of measurement results, (VIM clause 2.46)

Comparability of measurement results, for quantities of a given kind, that are metrological traceable to the same reference. Note: Metrological comparability of measurement results does not necessitate that the measured quantity values and associated measurement uncertainties compared be of the same order of magnitude.

Note 1 Metrological comparability of measurement results does not necessitate that the measured quantity values and their associated measurement uncertainties being compared are equal in magnitude.

4.5 International measurement standard (VIM, clause 5.2)

Measurement standard recognized by signatories to an international agreement and intended to serve worldwide.

4.6 National Metrology Institute, NMI (VIM, clause 5.3)

Measurement standard recognized by national authority to serve in a state or economy as the basis for assigning quantity values to other measurement standards for the kind of quantity concerned.

4.7 Primary measurement standard (VIM clause 5.4)

Measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention as the followings;

- Primary measurement standard of amount-of-substance concentration prepared by dissolving a known amount of substance of a chemical component to a known volume of solution.
- Primary measurement standard for pressure based on separate measurements of force and area.
- Primary measurement standard for isotope amount-of-substance ratio measurements, prepared by mixing known amount-of-substances of specified isotopes.
- Triple-point-of-water cell as a primary measurement standard of thermodynamic temperature.

- The international prototype of the kilogram as an artifact, chosen by convention.

4.8 Secondary measurement standard (VIM clause 5.5)

Measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind.

Note 1 Calibration may be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a measurement result to the secondary measurement standard.

Note 2 A measurement standard having its quantity value assigned by a ratio primary reference measurement procedure is a secondary measurement standard.

4.9 Reference measurement standard (VIM, clause 5.6)

Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location.

4.10 Reference material (RM), VIM clause 5.13)

Reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

4.11 Certified reference material (CRM), VIM clause 5.14)

Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures. Example is human serum with assigned quantity value for the concentration of cholesterol and associated measurement uncertainty stated in an accompanying certificate, used as a calibrator or measurement trueness control material.

Note 1 Certification of certified reference materials are given in ISO 17034.

Note 2 Procedure for the production and certification of CRM are given in ISO 17034 and ISO 33405.

Note 3 Uncertainty covers both “measurement uncertainty” and “uncertainty associated with the value of a nominal property” such as for identity

and sequence. “Traceability” covers both “metrological traceability of a quantity value” and “traceability of a nominal property value”.

Note 4 Specified quantity values of certified reference materials require metrological traceability with associated measurement uncertainty.

4.12 Commutability of a reference material, (VIM clause 5.15)

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

Note 1 The reference material in question is usually a calibrator and the other specified materials are usually routine samples.

Note 2 The measurement procedures referred to in the definition are the one preceding and the one following the reference material (calibrator) in question in a calibration hierarchy.

Note 3 The stability of commutable reference materials is monitored regularly.

4.13 Reference quantity value, (VIM clause 5.18)

Quantity value used as a basis for comparison with values of quantities of the same kind.

Note 1 A reference quantity value can be a true quantity value of a measurand, in which case it is unknown, or a conventional quantity value, in which case it is known.

Note 2 A reference quantity value with associated measurement uncertainty is usually provided with reference to;

a) a material, e.g. a certified reference material.
b) a device, e.g. a stabilized laser.
c) a reference measurement procedure.
d) a comparison of measurement standards.

4.14 National Metrology Institute, NMI National Metrology Institutes (NMI) and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term “NMI” is used to cover both National Metrology Institutes as well as Designated Institutes.

4.15 The Join Committee for Traceability in Laboratory Medicine (JCTLM) An internation consortium that promotes the global standardization of clinical laboratory test results and provides information on reference materials, reference measurement procedure, and services that are available from around the world. The committee members consist of the representative person from CIPM, IFCC and ILAC.

4.16 Measurand, (VIM 3, clause 2.3) Quantity intended to be measured.

Note 1 The specification of a measurand requires knowledge of the kind of quantity, description of the state of the phenomenon, body, or substance carrying the quantity, including and relevant component, and the chemical entities involved.

Note 2 In the second edition of the VIM and in IEC 60050-300:2001, the measurand is defined as the "particular quantity subject to measurement".

Note 3 The measurement, including the measuring system and the conditions under which the measurement is carried out, might change the phenomenon, body, or substance such that quantity being measured may differ from the measurand as defined. In this case, adequate correction is necessary.

Example 1. The potential difference between the terminals of a battery may decrease when using a voltmeter with a significant internal conductance to perform the measurement. The open-circuit potential difference can be calculated from the internal resistances of the battery and the voltmeter.

Example 2. The length of a steel rod in equilibrium with the ambient Celsius temperature of 23°C will be different from the length at the specified temperature of 20°C, which is the measurand. In this case, a correction is necessary.

Note 4 In chemistry, "analyte", or the name of a substance or compound, are terms used for 'measurand'. This usage is erroneous because these terms do not refer to quantities.

4.17 Measurement procedure (VIM 3, clause 2.6)

Detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result.

Note 1 A measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement.

Note 2 A measurement procedure can include a statement concerning a target measurement uncertainty.

Note 3 A measurement procedure is sometimes called a standard operating procedure, abbreviated SOP.

4.18 Reference measurement procedure (VIM 3, clause 2.7)

Measurement procedure accepted as providing measurement results fit for their intended use in assessing measurement trueness of measured quantity values obtained from the other measurement procedures for quantities of the same kind, in calibration, or in characterizing reference materials.

4.19 Measurement result

Result of measurement, set of quantity values being attributed to a measurand together with any other available relevant information.

Note 1 A measurement result generally contains “relevant information” about the set of quantity values, such that some may be more representative of the measurand than others. This may be expressed in the form of a probability density function (PDF).

Note 2 A measurement result is generally expressed as single measured quantity value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured quantity value. In many fields, this is the common way of expressing a measurement result.

Note 3 In the traditional literature and in the previous edition of the VIM, measurement result was defined as a value attributed to a measurand

and explained to mean an indication, or an uncorrected result, or a corrected result, according to the context.

4.20 Measurement uncertainty (VIM 3, clause 2.26)

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Note 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

Note 2 The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

Note 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

4.21 Calibration (VIM 3, clause 2.39)

Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in

a second step, uses this information to establish a relation for obtaining a measurement result form an indication.

Note 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

Note 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

Note 3 Often, the first step alone in the above definition is perceived as being calibration.

5. Associated Documents

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6. Procedures

Supplement Requirements

6.1 Policy

☞ 6.1.1 Metrological traceability of test or measurement results is a required property for all scopes applied for accreditation shall be in compliance with the policy specified in ILAC P10.

6.1.2 The degree of rigor or/and the need for reporting of uncertainty of measurement depends on the following:

1) the requirements of the customer;

2) the requirements of the test method;

3) the existence of narrow limits on which decisions on conformance to specification are based.

6.1.3 Risk factors included any consequences to validity of test results shall be analyzed and identified for qualitative test.

6.1.4 A testing laboratory performing its own calibrations shall have and shall apply a procedure to estimate the uncertainty of measurement.

6.2 Requirements

6.2.1 Measurement traceability (as given in both IUPAC and VIM) is characterized by:

1) an unbroken chain of comparisons going back to stated references acceptable to the parties, usually a national or international standard;

2) uncertainty of measurement; the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated;

3) documentation; each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be recorded;

4) competence; the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence (e.g., by demonstrating that they are accredited); 2) Pathologist,

5) reference to SI units; the chain of comparisons must, where possible, end at primary standards for the realization of the SI units;

6) Calibration intervals; calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables (e.g., uncertainty required, frequency of use, way of use, stability of the equipment).

7) When metrological traceability to the SI is not technically possible, a clearly defined measurand should be selected and consider to:

7.1) Using certified values of certified reference materials provided by a competent procedure e.g. the national institute of metrology and the accredited reference material producer in accordance with ISO 17034.

7.2) Using a reference measurement procedure, specified methods, or consensus standards the are clearly described and accepted as providing measurement results fit for their intended use. The comparison is established by ensuring the measurement procedures are properly validated or verified, that measuring equipment is

appropriately calibrated and that conditions of measurement are under sufficient control to provide a reliable result.

6.2.2 Evaluation of measurement uncertainty

The evaluation of measurement uncertainty is a fundamental element in demonstrating that an analytical method is fit for its intended purpose. Measurement uncertainty provides quantitative information on the reliability of measurement results and supports their appropriate interpretation, decision-making, and comparability.

Measurement uncertainty is a parameter associated with a measurement result that describes the dispersion of values that can reasonably be attributed to the measurand. The estimation of measurement uncertainty should take into account all recognized effects that influence the measurement result. The uncertainties arising from individual contributing factors are combined in accordance with established and internationally accepted procedures and guidelines.

In evaluating measurement uncertainty, the main significant sources of contributed uncertainty should be considered, including the following:

1) Long-term method precision, such as intermediate precision or reproducibility;

2) Bias and its associated uncertainty, including uncertainty in reference values and the statistical uncertainty involved in the estimation of bias;

3) Additional significant sources of uncertainty, such as environmental conditions, time-dependent effects, or method parameters that have not been fully investigated during method validation;

4) Sampling uncertainty, where sampling constitutes part of the measurement process and makes a significant contribution to the overall uncertainty of the measurement result.

The evaluation of measurement uncertainty may be classified and performed in accordance with applicable standards and relevant guidance documents, as follows:

6.2.2.1 Medical laboratory testing in accordance with ISO 15189

6.2.2.1.1 Quantitative examination

According to the requirements of ISO 15189, for examinations that report results as numerical values, the laboratory shall evaluate the measurement

uncertainty (Measurement Uncertainty: MU) using appropriate data that are consistent with the intended clinical use. In general, the estimation of measurement uncertainty should consider as follows:

1) Internal Quality Control
   - Internal quality control data are used to reflect the long-term precision of the method. As a general guideline, data covering at least six months or a minimum of 30 results should be used, particularly for newly introduced examinations.
   - The collected data are used to calculate the standard deviation (SD) or the coefficient of variation (CV). This information is commonly applied as the primary component of measurement uncertainty arising from imprecision, using a Type A evaluation or a top-down approach, as appropriate. Data derived from method validation studies or proficiency testing (PT/EQA) may also be used, where applicable.
2) Calibrator
   - Data related to the calibration uncertainty are used, which may be obtained from the calibrator certificate, information provided by the manufacturer, or data derived from reference materials. This component reflects the bias of the measurement system and the uncertainty associated with the bias.
3) In the case of examinations with a low-test volume and high cost
   - According to the Eurachem Guide: The Fitness for Purpose of Analytical Methods and Eurachem guidance on Measurement Uncertainty, laboratories may evaluate measurement uncertainty using a fit-for-purpose and risk-based approach for examinations with a low-test volume and high cost. This evaluation may be based on available internal quality control data, in combination with information obtained from

calibrators or other reliable reference sources, and assessed using appropriate statistical principles relevant to clinical application.

The practical approaches for such evaluations can be summarized as follows:

- It is not always necessary to rely on large datasets.

The evaluation of measurement uncertainty should follow a fit-for-purpose and risk-based approach. When extensive internal quality control (IQC) data are not available, the laboratory may use existing accumulated data, information derived from method validation, results from proficiency testing (PT/EQA), or data provided by the manufacturer, in combination with appropriate statistical evaluation.

- Use of the Top-Down Approach

Medical examinations shall evaluate the measurement uncertainty (MU) of quantitative medical test results using the Top-Down approach or the analytical methods approach, both of which are appropriate for application in medical laboratories.

In this regard, the note to Clause 7.3.4 of ISO 15189:2022 specifies that the evaluation of measurement uncertainty should follow the Top-Down approach, as described and exemplified in ISO/TS 20914: Medical laboratories — Practical guidance for the estimation of measurement uncertainty. A brief overview of this approach is presented in Appendix A.

- Appropriate statistical evaluation

When the amount of available data is limited, the laboratory shall provide a scientific justification demonstrating that the data are sufficient for the intended use. An appropriate time period, consistent with the testing frequency, should be

selected, and the results should be evaluated in conjunction with clinical allowable error or clinical decision limits, as applicable.

6.2.2.1.2 Qualitative examinations

For qualitative examinations, measurement uncertainty cannot be expressed as a single numerical value in the same manner as for quantitative examinations. Instead, it is necessary to demonstrate the performance specifications of the examination method in order to provide confidence in the reported results. Such performance specifications should be evaluated in a systematic manner and may include, but are not limited to, sensitivity, specificity, accuracy, precision or reproducibility, detection limit or cut-off value, and false positive and false negative rates. For qualitative examinations, measurement uncertainty is therefore expressed through documented evidence of method performance rather than as a numerical uncertainty value.

6.2.2.1.3 Estimation of measurement uncertainty for quantitative examinations

The estimation of measurement uncertainty for quantitative examinations shall be performed under conditions in which bias and systematic error are controlled and minimized, and shall be based on the assumption that the entire measurement process is operating under controlled conditions, as described below.

1) Pre-examination procedures

- Sample collection, handling, transportation, and storage shall be performed in accordance with relevant reference documents and documented procedures as specified in the laboratory's operating manuals. Appropriate measures shall be implemented to minimize sources of variability related to the sample, thereby reducing sample-related uncertainty prior to examination.

2) Examination procedures

- Examinations shall be performed in accordance with documented examination procedures. Equipment

shall be appropriately calibrated, verified, and maintained in a condition suitable for use. Personnel performing the examinations shall be competent and have their competence formally assessed and authorized. The laboratory shall implement internal quality control (IQC) and participate in external quality assessment or proficiency testing (EQA/PT), as appropriate, to ensure ongoing monitoring and control of examination performance.

3) Post-examination procedures

- Calculation, review, validation, and reporting of examination results shall be performed in accordance with relevant reference documents and documented procedures. Measures shall be implemented to minimize errors related to data transcription, result transfer, and interpretation, thereby ensuring the accuracy and reliability of reported examination results.

4) In the case of examinations with a low-test volume and high cost.

The laboratory shall evaluate and control the uncertainty of test results based primarily on the fit-for-purpose concept and a risk-based approach. The management of uncertainty shall be appropriate to the intended clinical use, the nature of the examination, and the actual testing volume. It is not necessary to express measurement uncertainty (MU) as a numerical value in all cases.

Confidence in test results shall be demonstrated using evidence derived from method verification

and/or validation, manufacturer performance data, comparison with reference methods or reference laboratories (where appropriate), as well as internal quality control (IQC) and external quality assessment/proficiency testing (EQA/PT) results, or interlaboratory comparison as an alternative where EQA is not available. These measures are implemented to confirm the correctness of result classification and to reduce the risk of false-positive or false-negative results, particularly in the vicinity of the decision limit.

This approach is in accordance with the requirements of ISO 15189:2022 and the guidance provided by Eurachem and ISO/TS 20914:2019, as detailed below.

– Classification of qualitative examinations

Before selecting an approach for managing uncertainty, the laboratory shall classify qualitative examinations into two categories, as follows:

Case A: Examinations with a quantitative signal and qualitative interpretation (quantitative signal with qualitative interpretation)

For examinations that rely on a measurable signal or quantitative value and are interpreted as positive or negative based on a defined cut-off or threshold, the laboratory shall manage uncertainty by focusing on its impact on result interpretation, as follows:

1.Select representative samples of both positive and negative results, particularly samples with values close to the decision limit (cut-off/threshold).

2.Evaluate the variability of the signal or quantitative

value in the vicinity of the threshold, for example by assessing repeatability or within-laboratory precision at a level appropriate to the actual testing volume.

3.Describe the impact of such variability on result interpretation, such as the probability of result changes across the decision limit, and define appropriate risk management measures, including the establishment of a gray zone, repeat testing, or confirmation using a second or confirmatory method.

Case B: Nominal or true qualitative examinations

For examinations that report results directly in qualitative terms (e.g. detected/not detected, meets criteria/does not meet criteria) and do not rely on quantitative values for result reporting, the laboratory is not required to calculate measurement uncertainty (MU) as a numerical value. In such cases, uncertainty shall be managed in the form of a qualitative uncertainty statement, supported by appropriate performance indicators and objective evidence, as follows:

1.Evaluation of inter-operator or inter-observer agreement in test result interpretation.

2.Assessment of the robustness of the method against variations in significant factors, such as reagent or test kit lots, incubation time, temperature, environmental conditions, or sample matrix.

3.Evaluation of the ability to detect or not detect analytes near the method's limit, such as the limit of detection (LoD) or lowest detectable level, where defined.

4.Establishment and implementation of measures to reduce the risk of false-positive or false-negative results, such as the use of control samples, result interpretation by more than one operator (second reader), or confirmation using an appropriate alternative method.

6.2.2.1.4 Estimating of measurement uncertainty

1) Define source of uncertainty such as IQC, calibrator.
2) Evaluate standard uncertainty (SU) such as

IQC = Standard deviation (SD), Calibrator = Uncertainty ÷ Divisor

3) Define source of uncertainty such as IQC, calibrator.
4) Evaluate standard uncertainty (SU) such as

IQC = Standard deviation (SD), Calibrator = Uncertainty ÷ Divisor

5) Determine relative standard uncertainty (RSU)

RSU = Standard uncertainty (SU) ÷ Concentration

6) Determine combined relative standard uncertainty (UC)

$$U_C = \sqrt{(RSU_{IQC})^2 + (RSU_{Cal})^2}$$

7) Determine expanded uncertainty (U)

U = k x UC, Coverage factor (k) = 2

8) Determine expanded uncertainty of results (UR)

UR = Result x Expanded uncertainty (U)

9) Report = Result ± UR

Table 1 Estimating of measurement uncertainty.

	Factor	**Value (Concentration)**	**Value of the Uncertainty or Std. Deviation**	**Divisor**	**Std. Uncertainty (SU)**	**Relative Std. Uncertainty (RSU)**
U_{IQC}	Standard deviation inter-assay		Std. Deviation $\frac{\sqrt{\sum(x-\bar{x})^2}}{n-1}$	1	Std. Deviation	SU ÷ Concentration
U_{Cal}	Uncertainty of calibrator		Specified in certificate	Specified in certificate	Uncertainty ÷ Divisor	SU ÷ Concentration
U_C	Combined relative standard uncertainty	$U_C = \sqrt{(RSU_{IQC})^2 + (RSU_{Cal})^2}$				
U_X	Expand relative standard uncertainty	$U_X = k \times U_C$		Coverage factor (k) = 2		
U_R	Expanded uncertainty of result	U_R = Conc. x U			Report Result = Conc. ± U_R	

Table 2 Example for estimating of measurement uncertainty.

	Factor	Value (Concentration)	Value of the Standard Deviation or Uncertainty	Divisor	Std. Uncertainty (SU)	Relative Std. Uncertainty (RSU)
U_{IQC}	Standard deviation inter-assay	99 mg/dl	0.9 mg/dl	1	0.9 mg/dl	0.0091
U_{Cal}	Uncertainty of calibrator	167 mg/dl	2.17 mg/dl	2	1.085 mg/dl	0.0065
U_C	Combined relative standard uncertainty	$U_c = \sqrt{(0.0091)^2 + (0.0065)^2} = 0.0112$				
U_X	Expand relative standard uncertainty	Coverage factor(k) = 2 $U_X = 2 \times 0.0112 = 0.0224$				
U_R	Expand uncertainty x conc. analysis	If the glucose in sample is 90 mg/dl $U_R = 90 \times 0.0224 = 2.02$ mg/dl			Report Result = (90±2.02) mg/dl	

Note: Total Allowable Error for Medical laboratories refer to Desirable Specification for Total Error, Imprecision, and Bias, derived from intra-and inter-individual biologic variation from http://www.westgard.com/biodatabase1.htm

Table 3 Divisor a number associated with the assumed probability distribution.

Distribution	Divisor	Data
Normal (k=2)	2	The uncertainty in the confidence level of 95%.
Rectangular	$\sqrt{3}$	The certificate from the manufacturer, Specification of equipment.
Triangular	$\sqrt{6}$	Tolerance of glassware by volume.
U-shape	$\sqrt{2}$	The deviation of amount of environmental.

6.2.2.1.5 Examples of the evaluation of measurement uncertainty of quantitative medical examination results using the Top-Down approach (ISO/TS 20914:2019)

The evaluation of measurement uncertainty (MU) for quantitative medical examination results may be carried out using the following summarized steps:

1) Definition of the measurand
   Define the measurand for which the measurement uncertainty is to be estimated. For example, in the evaluation of measurement uncertainty for blood glucose results, the measurand is the concentration of glucose in blood, expressed in units of mg/dL.
2) Identify the main contributors to measurement uncertainty, such as internal quality control (IQC) data, calibrators, and other relevant components associated with the measurement process.
3) Calculation of the standard uncertainty (u(y)) of each component
   3.1) Standard uncertainty of IQC (u_Rw)
   Derived from repeated IQC precision data, where the standard deviation (SD) is considered the standard uncertainty under repeatability conditions (u(y)), as follows:
   1) Intra-assay precision data
   Use at least 30 intra-assay precision results, applicable for a newly introduced test. Calculate the SD from IQC measurements and divide by

√n, where n is the number of replicate measurements of the specimen. In the case of a single measurement, n = 1.

Note: The standard uncertainty of measurement obtained under short-term repeatability conditions does not include other sources of variability expected during routine operation. Therefore, it cannot be used to represent measurement uncertainty under long-term precision conditions.

2) Long-term imprecision data

Use data obtained under long-term precision (long-term imprecision) conditions. Calculate the SD from IQC measurements and divide by √n, where n is the number of replicate measurements of the specimen; for a single measurement, n = 1. Data pooling may include IQC results obtained from the same or different IQC lots, and from the same or different reagent and/or quality control material lots, as applicable.

3.2) Standard uncertainty of the calibrator (u_{cal})

The uncertainty of the calibrator as stated in the manufacturer's certificate, calculated as the calibrator expanded uncertainty divided by 2, corresponding to the coverage factor (k = 2).

3.3) Standard uncertainty of bias (u_{bias})

$$u_{bias} = \sqrt{\left(u_{ref}^2 + SD_{mean}^2\right)}$$

Derived from u_{ref} : uncertainty from reference value (for example as stated in the certificate of reference material)

$$SD_{mean} \ : \ SD/\sqrt{n}$$

4) Combination of sources of measurement uncertainty for medical examination results

The standard uncertainties from the relevant sources shall be combined as follows:

4.1) Case where bias data are not available, or the bias is not significant,

and there is no information on calibration uncertainty (calibration uncertainty):
Apply the following equation:

$$u(y) = \sqrt{(u_{Rw})^2}$$

4.2) Case where bias data are not available, or the bias is not significant, and information on calibration uncertainty is available:
Apply the following equation:

$$u(y) = \sqrt{(u_{Rw})^2 + (u_{cal})^2}$$

4.3) Case where significant bias data are available, together with information on the uncertainty of bias and the uncertainty of calibration:
Apply Equation 4.3.

$$u(y) = \sqrt{(u_{Rw})^2 + (u_{cal})^2 + (u_{bias})^2}$$

5) Calculation of the Expanded uncertainty (U) = k x UC, Coverage factor (k) = 2
6) Calculation of the Expanded uncertainty of results (UR) = test result x Expanded uncertainty (U)
7) Reporting of measurement uncertainty
Measurement uncertainty shall be reported with no more than two significant figures, as follows:
- Adjust the expanded uncertainty to no more than two significant figures, rounding upward to reduce the risk of underestimation, which could otherwise result in the true value of the measurement lying outside the calculated uncertainty interval.
- Round the reported value so that its decimal places are consistent with those of the measurement uncertainty.
- Report the metrological traceability of the measurement result by referencing the standards used for instrument calibration.

Example: Blood cholesterol measurement

Measured blood cholesterol value: 180 mg/dL

Expanded uncertainty: 9.4 mg/dL

Accordingly, the expanded uncertainty is adjusted to 10 mg/dL (no decimal places).

Reported result:

(180 ± 10) mg/dL (approximately 95% confidence)

Example: Blood total protein measurement

Measured blood total protein value: 7.4 g/dL

Expanded uncertainty: 0.82 g/dL

Accordingly, the expanded uncertainty is rounded to one decimal place, resulting in 0.9 g/dL, to ensure consistency in decimal places.

Reported result:

(7.4 ±0.9) g/dL (approximately 95% confidence)

Table 4: Symbols and definitions according to the Top-Down approach (ISO/TS 20914:2019)

Symbol	Definition
k	Numerical factor (coverage factor) used to multiply the combined standard uncertainty to obtain the expanded uncertainty (U). Typical values range between 2 and 3, depending on the confidence level. For routine laboratory testing, a confidence level of approximately 95% is commonly achieved by multiplying the combined standard uncertainty by k.
SD_{mean}	Standard deviation of the mean of measured values obtained from repeatability studies.
u	Standard uncertainty, expressed as a standard deviation.
u_{bias}	Standard uncertainty of bias.
u_{cal}	Standard uncertainty of the value assigned to the calibrator used for end-user instrument calibration.
u_{ref}	Standard uncertainty of the value assigned to a reference material.
u_{Rw}	Standard uncertainty of long-term precision (within-laboratory reproducibility) of measured values under defined conditions within the same laboratory over a period sufficient to include all normal variations in measurement conditions.
$u(y)$	Standard uncertainty of the measurand y.
$u_{rel}\ (y)$	Relative standard uncertainty of the measurand *y*.
$\%u_{rel}\ (y)$	Percentage relative standard uncertainty of the measurand *y*.
$U(y)$	Expanded uncertainty of the measurand *y*.
$U_{rel}(y)$	Relative expanded uncertainty of the measurand *y*.
$\%\ U_{rel}\ (y)$	Percentage relative expanded uncertainty of the measurand *y*.
$u_r(y)$	Standard uncertainty of the mean of repeated measurements of the measurand *y* obtained under repeatability (r) conditions (e.g., within the same laboratory, IQC measured in the same analytical run).
$\bar{x}$	Mean value of the measurand *y*.

6.2.2.2 Public Health Laboratory Testing

The Laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference and complied with the requirements of ISO/IEC 17025 and ILAC P10 as follows;

1) Calibration provided by a competent laboratory,
2) Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI,
3) Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.
4) When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference e.g. through certified values or certified reference materials provided by a competent producer and results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.2.2.2.1 Physical testing

For physical testing, the measurement procedures and evaluation of measurement uncertainty of instrument or equipment used shall be applied. Physical measurements and obligated to be done with a calibrated reference instrument which by itself should be calibrated against the National Standard or other international Reference Standard issued by accredited party or a National Metrology Institute. The certificate issued by other calibration body shall contain estimation of uncertainty of measurement results.

6.2.2.2.2 Chemical testing

Chemical measurement, likewise, are obligated, where appropriate, to evaluate uncertainty of measurements. For quantitative chemical

testing, reasonable evaluation of uncertainty procedure shall be applied based on the international standard i.e., EURACHEM/CITAC Guild, UROLAB, UKAS, etc.

The method shall have specified reporting precision/accuracy and related values of their measurement to reference materials by the organization, traceable to international standards or traceable to a certified reference material (CRM) i.e., NIST, USP, LGC, Accredited RMP in accordance with ISO/IEC 10734. Available results from proficiency testing or inter-laboratory comparison may provide an appropriate reasonable to evaluate of the measurement uncertainty.

6.2.2.2.3 Microbiological testing

For quantitative test, the laboratory shall provide measurement uncertainty in accordance with international recognized procedures e.g. ISO 19036, EURACHEM guide, AOAC etc., the previous validation data can be a support. The standard strains or reference strains that using in testing shall be traceable to the national or international levels. Microbiological laboratories may not have report uncertainty unless required by customers or unless the interpretation of results may be compromised as appropriated.

Evaluation of measurement uncertainty is not possible in qualitative testing; laboratory shall at least attempt to analyzed and identified all the components of uncertainty that can be affected to the validity of test result.

6.2.3 Traceability for reference materials producer which is accredited according to ISO 17034 should be complied with ILAC policy as follows:

6.2.3.1 The assigned values to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO 17034, are considered to have established valid traceability.

6.2.3.2 The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

6.2.3.3 The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the reference material producer shall demonstrate that each RM or CRM is suitable for its intended use as required by ISO/IEC 17025 or ISO 15189.

6.3.2.4 Production or Preparation of Reference Materials in accordance with ISO 17034

The reference material producer shall establish and maintain systematic criteria for the evaluation, provision, and control of metrological traceability and measurement uncertainty associated with the production processes and the assignment of property values of reference materials (Reference Materials; RMs/CRMs), in order to comply with the requirements of ISO 17034 and the policy specified in ILAC P10. The details are as follows:

1. Metrological Traceability

The reference material producer shall establish and ensure that all measurement results used for the assignment of property values of reference materials (Reference Materials; RMs/CRMs) are metrologically traceable, in accordance with the definition provided in the International Vocabulary of Metrology (VIM), and in compliance with the requirements of ILAC P10. Metrological traceability shall be established, maintained, and demonstrably implemented in a systematic manner through an unbroken chain of calibrations or comparisons, linking the measurement results to appropriate reference standards. Such traceability shall be primarily related to the International System of Units (SI) or, where applicable, to other accepted references in accordance with the hierarchical order specified in ILAC P10. At each step of the traceability chain, documented evidence shall be available, and the associated measurement uncertainty shall be clearly identified and stated, as detailed below:

1) Evaluation of the Suitability of Sources of Metrological Traceability. Criteria shall be established for evaluating the suitability of sources of metrological traceability. This shall include verification of the accreditation status of calibration or testing service providers (e.g. accredited in accordance with ISO/IEC 17025 or ISO 17034), confirmation that such bodies operate under the ILAC Mutual Recognition

Arrangement (ILAC MRA) or an equivalent agreement, and consideration of the adequacy of the accreditation scope to ensure its consistency with the relevant measurand, measurement range, and measurement method.

In addition, the reference material producer shall establish criteria for evaluating the adequacy of calibration certificates, reference material certificates, and test results obtained from external laboratories, in order to ensure that metrological traceability is correctly and appropriately implemented and remains in compliance with the requirements of ISO 17034 and the policy specified in ILAC P10.

2. Measurement Uncertainty

The reference material producer shall establish and implement procedures for the identification, evaluation, and control of measurement uncertainty associated with the assigned property values of reference materials (Reference Materials; RMs/CRMs), in accordance with the principles of the Guide to the Expression of Uncertainty in Measurement (GUM) and the requirements of ISO 17034, as well as the relevant guidance provided in the applicable ISO 334xx series. The evaluation of measurement uncertainty shall be carried out in a systematic manner and shall encompass all significant components that may influence the assigned property values. At a minimum, the following components shall be considered, as appropriate, and addressed in detail, as follows:

– Uncertainty arising from the characterization process (characterization uncertainty);

– Uncertainty arising from between-unit homogeneity (between-unit homogeneity uncertainty);

– Uncertainty arising from the stability of the material (stability uncertainty);

– Uncertainty associated with calibration, measuring instruments, measurement methods, or reference sources used.

In addition, each source of uncertainty shall be identified, analyzed, and quantified using appropriate statistical methods and mathematical models. An uncertainty budget shall be established and documented, clearly demonstrating the sources

of uncertainty, underlying assumptions, and calculation methods, in a manner that is transparent and traceable.

1) Definition of Metrological Traceability

Metrological traceability refers to the property of a measurement result whereby it can be related to a specified reference through an unbroken chain of calibrations or comparisons, each contributing to the measurement uncertainty. For reference material producers, metrological traceability is directly critical to the reliability of the assigned property values of reference materials, as such values shall be traceable to the International System of Units (SI) or to internationally accepted reference standards. Metrological traceability shall be demonstrable through documented evidence and shall be subject to verification and review, in accordance with the definition provided in the International Vocabulary of Metrology (VIM).

2) Hierarchy of Traceability Sources

According to ILAC P10:07/2020, reference material producers shall establish a hierarchy of sources of metrological traceability to ensure that the linkage of measurement results to reference standards is reliable and internationally recognized. The acceptable hierarchy of traceability sources is as follows:

2.1) National Metrology Institutes (NMIs).

National Metrology Institutes (NMIs) with Calibration and Measurement Capabilities (CMCs) published in the BIPM Key Comparison Database (KCDB) under the CIPM Mutual Recognition Arrangement (CIPM MRA); and calibration or testing laboratories accredited in accordance with ISO/IEC 17025 by an Accreditation Body (AB) that is a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA), with an accreditation scope covering the relevant measurands and measurement ranges.

2.2) Certified Reference Materials (CRMs)

Certified Reference Materials (CRMs) produced by organizations accredited in accordance with ISO 17034 under an Accreditation Body (AB) that is a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA).

3) Criteria for Evaluation of Traceability.

The reference material producer shall establish criteria for evaluating the adequacy and suitability of metrological traceability. At a minimum, the following aspects shall be considered:

– Validity of the accreditation status of calibration or testing service providers;

– Adequacy of the accreditation scope to ensure consistency with the relevant measurands, measurement methods, and measurement ranges;

– Availability of a statement of traceability in the relevant certificates;

– Identification and documentation of measurement uncertainty at each step of the traceability chain;

– Suitability of the stated measurement uncertainty with respect to fitness for the intended use.

The results of such evaluations shall be systematically documented and shall be reviewed by authorized technical personnel prior to the use of measurement results for the assignment of property values of reference materials. Where it is not feasible to use sources within the above hierarchy, appropriate technical justification and risk assessment shall be documented and shall be subject to approval by authorized technical personnel.

4. Requirements for Measurement Uncertainty Evaluation

The reference material producer shall perform the evaluation of measurement uncertainty in accordance with the principles of the Guide to the Expression of Uncertainty in Measurement (GUM) and the requirements of ISO 17034. The evaluation shall include the following:

– Identification of all significant sources of measurement uncertainty;

– Quantification of each uncertainty component using appropriate statistical data or data derived from reliable sources;

– Establishment of an appropriate calculation model;

– Combination of the relevant uncertainty components to determine the combined standard uncertainty;

– Reporting of the expanded uncertainty, with the coverage factor (k) and the associated level of confidence clearly stated.

For Certified Reference Materials (CRMs), the uncertainty evaluation shall include, as a minimum, the following principal components:

– Uncertainty arising from characterization;

– Uncertainty arising from between-unit homogeneity;

– Uncertainty arising from stability.

The uncertainty evaluation shall be supported by a documented and traceable uncertainty budget and shall be subject to review prior to the issuance of the reference material certificate.

5. Responsibilities.

To ensure that metrological traceability and measurement uncertainty evaluation are correctly implemented, the organization shall clearly define responsibilities as follows:

– Technical Manager: Responsible for the review and approval of the traceability chain and the measurement uncertainty evaluation prior to the issuance of reference material certificates;

– Quality Manager: Responsible for document control, monitoring compliance with ISO 17034 and ILAC P10, and the maintenance and retention of records;

– Analyst / Technical Staff: Responsible for performing uncertainty calculations, preparing the uncertainty budget, and compiling supporting evidence related to metrological traceability.

6. Documentation Requirements.

The organization shall establish, maintain, and control documentation related to the following:

– Calibration certificates;

– Certificates of reference materials used as reference sources;

– Evidence of the accreditation status of external service providers;

– Records of traceability evaluations;

– Uncertainty budgets;

– Records of review and approval.

All documents listed above shall be traceable and shall be retained for a period specified within the quality management system.

7. Data record and Used document

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8. Supplementary notes

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9. History of change

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
00	Initial Document	Miss Natamol Tienmanee	
07	- Page 1/7 Edited the reference to current APLAC TC 005 Issue No. 4, 09/10 : Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing - Page 1/7 Add Clause 5.2.2.2.3 Microbiological testing	Miss Natamol Tienmanee	22 September 2014
08	- Page 1/10 Edited the reference to current APLAC TC 010 Issue No. 2, 09/10 : General Information on Uncertainty of Measurement - Page 1/10 Edited the reference to current ISO 15189: 2012 Medical laboratories - Requirements for quality and competence.	Miss Sirimas Khamsai	28 October 2016

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
09	-Page 1/10 Edited the reference to current ISO 17034 : 2016 : General requirement for the competence of reference material producer.	Miss Sirimas Khamsai	19 February 2018
10	-Page 1/12 Edited the reference to current ISO/IEC17025: 2017 General requirements for the competence of testing and calibration laboratories -Page 1/10 added the reference - IUPAC Technical Report (2011) – Metrological Traceability of measurement results in Chemistry: Concepts and implementation - ILAC G17: 2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 – under revision, - ILAC G24: 2007 Guidelines for the determination of calibration intervals of measuring instruments – under revision - JCGM 100: 2008: Evaluation of measurement data-Guide to expression of uncertainty in measurement - Page 2/12 added the reference - ISO/IEC GUIDE 98-4:2012 [JCGM 106] Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment -ISO/TS 19036:2006(en) Microbiology of	Miss Sirimas Khamsai	21 October 2020

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
	food and animal feeding stuffs — Guidelines for the estimation of measurement uncertainty for quantitative determinations - Appendix J: AOAC International Methods Committee Guidelines for Validation of Microbiological Methods for food and Environmental surfaces, 2016 - Page 3/12 - clause 5.2.1 **Traceability** (as given in both ILAC G2 and VIM) edited to **Traceability** (as given in both IUPAC and VIM) - Page 7/12 edited - clause 5.2.2.2 ISO/IEC 17025: 2017 clause 5.6.2.2.1 and 5.6.2.2.2 edited to ISO/IEC 17025: 2017 clause 7.6 - clause 5.2.2.2.2 Chemical testing edited NATA and added EURACHEM/CITAC Guild, UROLAB, UKAS -added Accredited RMP in accordance with ISO/IEC 10734 - Page 8/12 edited - based on APLAC TC 005: Interpretation and Guidance on the Estimation of Uncertainty of Measurement and added based on AOAC (2016) Appendixes - clause 5.2.3 ISO guide 34 edited to ISO 17034		

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
11	- Changed document format complied with document control procedure of BLQS, current version. - Changed document title complied with related standard. - Revised on the objective covered the assessor, assessment report reviewer and accreditation committee. - Revised the related reference documents to the current version. - Edited definition and abbreviation aligned to current version related reference documents. - Added policy covered every test that applied for accreditation and qualitative testing. - Added detail of metrological traceability in requirements of ISO/IEC 17025 in clause 6.2.2.2. - Edited details of clause 6.2.2.2.3, microbiological testing complied with the current version of international standard ISO 19036:2019 and EURACHME Guide.	Mr. Awiruth Khejonnit and Miss Sirimas Khamsai	12 March 2024
12	- Add Reference in clause 3.15, 3.16 3.17 and 3.18 - Add detail in clause 4 Definition and Abbreviation and sub-clause 4.1, 4.2, 4.3, 4.4, 4.8, 4.11, 4.12, 4.13 all of clause add note.	Mr. Awiruth Khejonnit and Miss Sirimas Khamsai	26 January 2026

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
	- Add detail in clause 4.16, 4.17, 4.18, 4.19, 4.20, 4.21 - Add detail in clause 7 In cases where measurement results are not traceable to the International System of Units (SI units). - Edite detail in clause 6.2.2 Evaluation of Measurement Uncertainty - Edite detail in clause 6.2.2.1.1. Quantitative examination - Edite detail in clause 6.2.2.1.2. Quantitative Examination - Edite detail in clause 6.2.2.1.3 sub clause 4) In the case of examinations with a low-test volume and high cost - Add detail in clause 6.2.2.1.5 Examples of the evaluation of measurement uncertainty of quantitative medical examination results using the Top-Down approach (ISO/TS 20914:2019) - Add detail in Table 4: Symbols and definitions according to the Top-Down approach (ISO/TS 20914:2019) - Edite detail in clause 6.2.3.1 add reference standard CIPM MRA and verification through the BIPM and the Key Comparison Database (KCDB).		

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
13	- Revise the content of Clause 6.1.1 to ensure compliance with the policy specified in ILAC P10. - Add content to Clause 6.2.3.4 on the production or preparation of reference materials in accordance with ISO 17034.	Mr. Awiruth Khejonnit and Miss Sirimas Khamsai	