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مركز الإمارات العالمي للاعتماد
Emirates International Accreditation Centre

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سياسة مركز الامارات العالمي في قياس الارتياب في مختبرات الفحص والمعايرة والمختبرات الطبية

EIAC Requirements on Measurement Uncertainty in Testing, Calibration and Clinical/Medical Laboratories

EIAC-RQ-LB-011

Signatories	
Approved:	Director, Laboratories Accreditation Department

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Contents

1 Objectives and Scope

- This document defines the policy for the evaluation and expression of measurement uncertainty by Testing, Calibration and Medical laboratories, and for the evaluation of the calibration and measurement capability (CMC) as per the requirements of ISO/IEC 17025: 2017, ISO 15189:2012, ILAC G8, ILAC G17 and requirements of ILAC-P14.
- Clinical/ Medical Laboratories comply with ISO 15189 shall also comply with ISO/TS 20914 Medical laboratories - Practical guidance for the estimation of measurement uncertainty

2 Terms and Definitions

For the purpose of this document, the relevant terms and definitions given in ISO /IEC 17025, ISO/IEC Guide 99 the "International Vocabulary of Metrology – Basic and General Concepts and Associated Terms" (VIM) apply.

2.1 Calibration and Measurement Capability (ILAC-P14 3.2)

In the context of the CIPM MRA and ILAC Arrangement, and in compliance with the CIPM-ILAC Common Statement, the following definition is agreed upon:

A CMC is a calibration and measurement capability available to customers under normal conditions:

a) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement; or

b) as published in the BIPM key comparison database (KCDB) of the CIPM MRA.

3 Measurement Uncertainty Categories for Testing Laboratories

3.1 Tests for which uncertainty does not apply:

3.1.1 Qualitative or semi-quantitative tests for which measurement uncertainty budgets will not be required, but laboratories must identify those components contributing to the uncertainty

Examples:

- Go-no- go tests.
- Tests that are exposure or environmental simulation only such as Salt Spray as per ASTM B117, etc..
- Tests where the result is numerically rated by judgment: such as Tape Adhesion ASTM D3359
- Tests where results are a comparison from a reference plaque such as, Microstructure ASTM A247).

3.1.2 Well-recognized test methods that test methods that specify limits to the values of the major sources of uncertainty of measurement and specify the form of presentation of calculated results. In such cases, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions

3.2 Tests for which uncertainty applies:

3.2.1 **Well-recognized test methods that specify limits to the values** of the major sources of uncertainty of measurement and specify the form of presentation of calculated results. In such cases, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (as defined in ISO/IEC 17025 Clause 7.6.3 Note 1).

3.2.2 **Test methods based on published regulatory or consensus methods** (examples: EPA, AOAC, ASTM, APHA/AWWA,..) for which the measurement uncertainty is not defined in the method. For these types of tests, uncertainty evaluation is required and can be evaluated using appropriate, published guidance documents such as the ISO Guide to the Expression of Uncertainty in Measurement, CITAC Guide 1, ISO 5725, etc. Also, there may be test methods that have no significant sources of uncertainty other than random error and when this is the case, determining the random error (usually per ISO/IEC 17025:2017 section 7.7) satisfies the requirement for uncertainty evaluation.

3.2.3 **Non-standard and laboratory-developed methods**, (including modified standard methods where the modification may affect the measurement uncertainty) that need identification of all components of uncertainty and detailed measurement uncertainty budgets calculated in accordance with published methods that are consistent with those described in JCGM 100:2008, Evaluation of measurement data — Guide to the expression of uncertainty in measurement

3.2.4 Uncertainty must be evaluated in order to determine **if the uncertainty affects compliance to a specification limit** (ISO/IEC 17025:2017, section 7.8.6),

4 Policy on Evaluation of Uncertainty of Measurement for Testing Laboratories

4.1 Applicant and accredited laboratories shall evaluate measurement uncertainty for all test methods categories described in 3.2 and shall be able to quantifiy all identified contributions to measurement uncertainty including those arising from sampling (if sampling is part of accreditation scope) using appropriate methods of analysis, Where a test measurement uncertainty evaluation is necessary for a test method proposed for accreditation it shall be available prior to the assessment

4.2 Laboratory-developed methods require validation per ISO/IEC 17025:2017, section 7.2. As part of this validation, the significance of the measurement components, or the significance of the modifications of the measurement components from the standard test method, must be considered so that the appropriate measurement uncertainty category for the laboratory- developed method can be identified among those specified in section 3.2.

4.3 Applicant and accredited laboratories shall check and update the measurement uncertainty of each test method on a regular basis using QC data e.g. data from participation in PT programs

4.4 The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percentage

4.5 EIAC has defined the following measurement uncertainty categories for the tests identified in the laboratory's proposed scope of accreditation:

4.6 Guidance on evaluation of measurement uncertainty for testing labs is given in EIAC Guidelines for evaluation and Expression of Uncertainty in Measurement in Testing Laboratories.

5 Policy on Evaluation of Uncertainty of Measurement for Calibration Laboratories

5.1 EIAC requires that all calibration laboratories and testing laboratories performing their own calibrations shall have and apply a procedure for the evaluation of the uncertainty of measurement for all calibrations.

5.2 Laboratories shall evaluate uncertainties of measurement in compliance with the “Guide to the Expression of Uncertainty in Measurement” (GUM), including its supplement documents and/or ISO Guide 35., The SI Brochure explains about traceability of measurement and its realization. The uncertainty of measurement resulting from credible traceability is paramount and shall be calculated according to the GUM.

5.3 The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percent. Usually, the inclusion of the relevant unit gives the necessary explanation.

5.4 In the formulation of CMC, laboratories shall take notice of the performance of the “best existing device” which is available for a specific category of calibrations and Measurement uncertainties equal those covered by the CMC.

5.5 Guidance on evaluation of measurement uncertainty for calibration labs is given in EIAC Guidelines for evaluation and Expression of Uncertainty in Measurement in calibration labs'.

6 Policy on Statement of Uncertainty of Measurement on Calibration Certificates

6.1 Laboratories shall report the uncertainty of measurement in compliance with the GUM and the SI Brochure.

6.2 The measurement result shall normally include the measured quantity value y and the associated expanded uncertainty U. In calibration certificates the measurement result should be reported as $y \pm U$ associated with the units of y and U. Tabular presentation of the measurement result may be used and the relative expanded uncertainty $U/|y|$ may also be provided if appropriate. The coverage factor and the coverage probability shall be stated on the calibration certificate. To this an explanatory note shall be added, which may have the following content:

"The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %."

Note: For asymmetrical uncertainties other presentations than $y \pm U$ may be needed. This concerns also cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units

6.3 The numerical value of the expanded uncertainty shall be given to, at most, two significant figures. In the process of rounding, that rounding should be applied after the figure has been used for further calculation, not before; resultant values may then be rounded for presentation, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided i.e. in Section 7 of the GUM.

6.4 As the definition of CMC implies, accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

6.5 Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device. Where applicable the uncertainty shall cover the same contributions to the uncertainty that were included in the evaluation of the CMC uncertainty component, except the uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device. Therefore, reported uncertainties tend to be larger than the uncertainty covered by the CMC. Random contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties attributed by the laboratory, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

6.6 There are particular situations described in Annex A, 2.3 of ISO/IEC 17025 where a statement of conformity to a specification may provide metrological traceability. Certificates or reports, including these declarations of conformity may not overtly show the uncertainty of measurement.

7 Policy on Scopes of Accreditation of Calibration Laboratories

7.1 The scope of accreditation of an accredited calibration laboratory shall include the calibration and measurement capability (CMC) expressed in terms of:

a) measurand or reference material;
b) calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;
c) measurement range and additional parameters where applicable, e.g., frequency of applied voltage;
d) measurement uncertainty.

7.2 There shall be no ambiguity in the expression of the CMC on the scopes of accreditation and, consequently, on the smallest uncertainty of measurement that can be expected to be achieved by a laboratory during a calibration or a measurement. Where the measurand covers a value, or a range of values, one or more of the following methods for expression of the uncertainty shall be applied:

a) A single value, which is valid throughout the measurement range.
b) A range. In this case a calibration laboratory shall have a proper assumption for the interpolation to find the uncertainty at intermediate values.
c) An explicit function of the measurand or a parameter.
d) A matrix where the values of the uncertainty depend on the values of the measurand and additional parameters.
e) A graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the uncertainty.

Open intervals (e.g., $U < x$) are usually incorrect in the expression of CMCs.

7.3 The uncertainty covered by the CMC shall be expressed, unless explicitly agreed otherwise, as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percent, μV/V or part in 106. Usually, the inclusion of the relevant unit gives the necessary explanation.

The CMC quoted should include the contribution from a relative ideal or best available device to be calibrated such that the CMC claimed is demonstrably realizable.

7.4 Where laboratories provide services such as reference value provision, the uncertainty covered by the CMC shall include factors related to the measurement procedure as it will be carried out on a sample, i.e., typical matrix effects, interferences, etc. shall be considered. The uncertainty covered by the CMC will not generally include contributions arising from the instability or inhomogeneity of the material. The CMC shall be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

Note: The uncertainty covered by the CMC for the reference value measurement is not identical with the uncertainty associated with a reference material provided by a reference materials producer. The expanded uncertainty of a certified reference material will in general be higher than the uncertainty covered by the CMC of the reference measurement on the reference material.

8 References

8.1 ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

8.2 ISO/IEC 17011 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

8.3 ISO/IEC 17000 Conformity assessment - Vocabulary and general principles

8.4 ISO/IEC Guide 98-3 Uncertainty of measurement – Part 3, Guide to the expression of uncertainty in measurement (GUM:1995).

8.5 ISO/IEC GUIDE 99 International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

8.6 ISO/TS 20914 Medical laboratories - Practical guidance for the estimation of measurement uncertainty

8.7 ILAC G8 Guidelines on Decision Rules and Statements of Conformity

8.8 ILAC-P14 ILAC Policy for Uncertainty in Calibration. Freely available at https://ilac.org/publications-and-resources/ilac-policy-series/

8.9 ILAC P10 ILAC Policy on Metrological Traceability of Measurement Results. Freely available at https://ilac.org/publications-and-resources/ilac-policy-series/

8.10 JCGM 200 International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM). Freely available at https://www.bipm.org/en/publications/guides/vim.html. Also published as ISO/IEC Guide 99:2007.

8.11 JCGM 100 Guide to the expression of uncertainty in measurement (GUM). Freely available at https://www.bipm.org/en/publications/guides/gum.html. Also published as ISO/IEC Guide 98-3:2008

8.12 JCGM 106 The role of measurement uncertainty in conformity assessment. Freely available at https://www.bipm.org/en/publications/guides/. Also published as ISO/IEC Guide 98-4

8.13 EA 4/16 - EA guidelines on the expression of uncertainty in quantitative testing. Freely available at https://european-accreditation.org/wp-content/uploads/2018/10/ea-4-16-g-rev00-december-2003-rev.pdf

8.14 Calibration and Measurement Capabilities. A paper by the joint BIPM/ILAC working group. https://www.bipm.org/utils/common/documents/jcrb/CIPM_2007_11_CMC_BMC_accepted.pdf